AUGUST 1982

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Pediatrics

AMERICAN ACADEMY OF PEDIATRICS EVANSTON ILLINOIS 60204

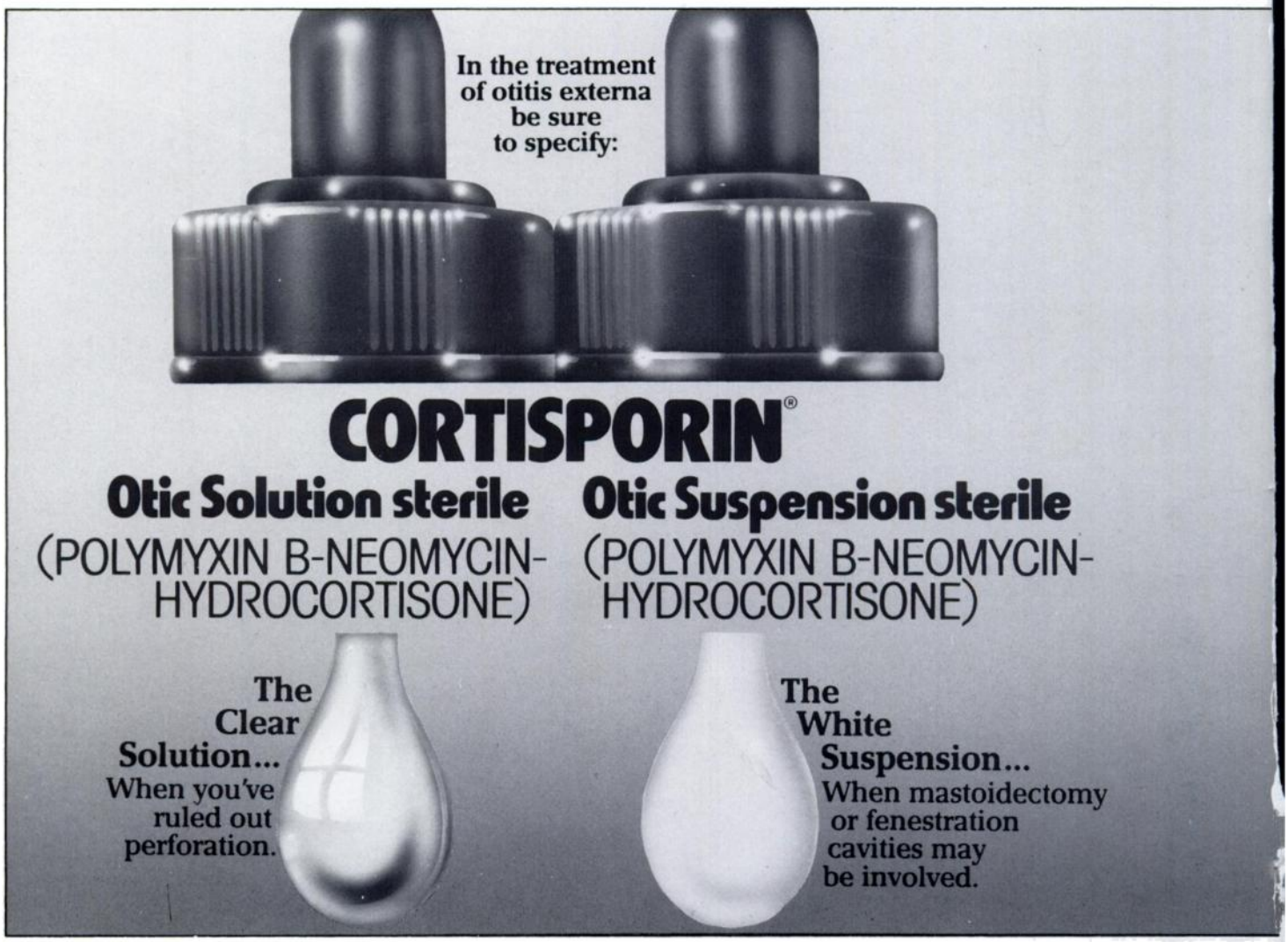
ARTICLES

EXPERIENCE AND REASON

AMERICAN ACADEMY OF PEDIATRICS

PEDIAU 70(2) pp. 165–331 (1982)

Vive la Différence!



Economical broad-spectrum bactericidal

CORTISPORIN® OTIC SUSPENSION Sterile (Polymyxin B-Neomycin-Hydrocortisone)

DESCRIPTION Each cc contains:

Aerosporin® (Polymyxin B Sulfate)	10,000 units
Neomycin sulfate (equivalent to 3.5 mg neomycin base)	5 mg
Hydrocortisone	10 mg (1%)

The vehicle contains the inactive ingredients cetyl alcohol, propylene glycol, polysorbate 80, water for injection and thimerosal (preservative) 0.01%.

INDICATIONS: For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics, and for the treatment of infections of mastoidectomy and fenestration cavities caused by organisms susceptible to the antibiotics.

PRECAUTIONS: This drug should be used with care in cases of perforated eardrum and in long-standing cases of chronic otitis media because of the possibility of ototoxicity caused by neomycin.

CORTISPORIN® OTIC SOLUTION Sterile (Polymyxin B-Neomycin-Hydrocortisone)

DESCRIPTION: Each cc contains:

Aerosporin® (Polymyxin B Sulfate)	10,000 units
Neomycin sulfate (equivalent to 3.5 mg neomycin base)	5 mg
Hydrocortisone	10 mg (1%)

The vehicle contains the inactive ingredients cupric sulfate, glycerin, hydrochloric acid, propylene glycol, water for injection and potassium metabisulfite (preservative) 0.1%.

INDICATIONS: For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics.

PRECAUTIONS: This drug should be used with care when the integrity of the tympanic membrane is in question because of the possibility of ototoxicity caused by neomycin.

ADVERSE REACTIONS: Stinging and burning have been reported when this drug has gained access to the middle ear.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS COMMON TO BOTH PRODUCTS

CONTRAINDICATIONS: These products are contraindicated in those individuals who have shown hypersensitivity to any of the components, and in herpes simplex, vaccinia and varicella.

WARNINGS: As with other antibiotic preparations, prolonged treatment may result in overgrowth of nonsusceptible organisms and fungi. If the infection is not improved after one week, cultures and susceptibility tests should be repeated to verify the identity of the organism and to determine whether therapy should be changed.

When using neomycin-containing products to control secondary infection in the chronic dermatoses, such as chronic otitis externa, it should be borne in mind that the skin in these conditions is more liable than is normal skin to become sensitized to many substances, including neomycin. The manifestation of sensitization to neomycin is usually a low grade reddening with swelling, dry scaling and itching; it may be manifest simply as a failure to heal. During long-term use of neomycin-containing products, periodic examination for such signs is advisable and the patient should be told to discontinue the product if they are observed. These symptoms regress quickly on withdrawing the medication. Neomycin-containing applications should be avoided for that patient thereafter.

PRECAUTIONS: If sensitization or irritation occurs, medication should be discontinued promptly. Patients who prefer to warm the medication before using should be cautioned against heating the solution above body temperature, in order to avoid loss of potency.

Treatment should not be continued for longer than ten days. Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin.

ADVERSE REACTIONS: Neomycin is a not uncommon cutaneous sensitizer. There are articles in the current literature that indicate an increase in the prevalence of persons sensitive to neomycin.

Wellcome

Burroughs Wellcome Co.
Research Triangle Park
North Carolina 27709

Your diagnosis may take just 5 minutes. She may have to live with the therapy for 10 years.

Voluntary hyperventilation producing brief, clinical seizure of 5-30 second duration[1]... EEG showing 3-per-second spike-wave forms... confirming your diagnosis: *absence seizures* (petit mal).

For effective management of absence seizures, sometimes spanning a decade or more of continued drug therapy, consider ZARONTIN® (ethosuximide).

Why ZARONTIN? Because crucial factors concerning its long-term use are a matter of extensive record:

- Well-known specificity—does not mask developing tonic-clonic activity in susceptible patients.
- Well-known efficacy against absence seizures.
- Well-known safety.
- Predictably compatible with barbiturates.
- Low daily cost to patients.

ZARONTIN... the drug of choice in absence epilepsy.[2] Its last 20 years of experience may make her next ten easier to live with.

1/Livingston S, Pruce I: Petit mal epilepsy. *Am Fam Physician* 17 (1):107-114, January 1978.

2/Livingston S, Pruce I, Pauli LL: Initiation of drug therapy. *Pediatr Ann* 8 (4):213-229, 1979.

ZARONTIN®
(ethosuximide, USP)

Capsules/Syrup
250 mg 250 mg/5 ml

the drug of choice in absence epilepsy

PARKE-DAVIS

Please see brief summary of prescribing information on following page.

ZARONTIN® (Ethosuximide Capsules, USP)

Before prescribing, please consult full prescribing information. A brief summary follows.

Indication: Zarontin is indicated for the control of absence (petit mal) epilepsy.

Contraindication: Ethosuximide should not be used in patients with a history of hypersensitivity to succinimides.

Warnings: Blood dyscrasias, including some with fatal outcome, have been reported to be associated with the use of ethosuximide; therefore, periodic blood counts should be performed.

Ethosuximide is capable of producing morphological and functional changes in the animal liver. In humans, abnormal liver and renal function studies have been reported.

Ethosuximide should be administered with extreme caution to patients with known liver or renal disease. Periodic urinalysis and liver function studies are advised for all patients receiving the drug.

Cases of systemic lupus erythematosus have been reported with the use of ethosuximide. The physician should be alert to this possibility.

Usage in Pregnancy: The effects of Zarontin in human pregnancy and nursing infants are unknown.

Recent reports suggest an association between the use of anticonvulsant drugs by women with epilepsy and an elevated incidence of birth defects in children born to these women. Data are more extensive with respect to phenytoin and phenobarbital, but these are also the most commonly prescribed anticonvulsants; less systematic or anecdotal reports suggest a possible similar association with the use of all known anticonvulsant drugs.

The reports suggesting an elevated incidence of birth defects in children of drug-treated epileptic women cannot be regarded as adequate to prove a definite cause-and-effect relationship. There are intrinsic methodologic problems in obtaining adequate data on drug teratogenicity in humans; the possibility also exists that other factors, eg, genetic factors or the epileptic condition itself, may be more important than drug therapy in leading to birth defects. The great majority of mothers on anticonvulsant medication deliver normal infants. It is important to note that anticonvulsant drugs should not be discontinued in patients in whom the drug is administered to prevent major seizures because of the strong possibility of precipitating status epilepticus with attendant hypoxia and threat to life. In individual cases where the severity and frequency of the seizure disorder are such that the removal of medication does not pose a serious threat to the patient, discontinuation of the drug may be considered prior to and during pregnancy, although it cannot be said with any confidence that even minor seizures do not pose some hazard to the developing embryo or fetus.

The prescribing physician will wish to weigh these considerations in treating or counseling epileptic women of childbearing potential.

Hazardous Activities: Ethosuximide may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a motor vehicle or other such activity requiring alertness; therefore, the patient should be cautioned accordingly.

Precautions: Ethosuximide, when used alone in mixed types of epilepsy, may increase the frequency of grand mal seizures in some patients.

As with other anticonvulsants, it is important to proceed slowly when increasing or decreasing dosage, as well as when adding or eliminating other medication. Abrupt withdrawal of anticonvulsant medication may precipitate absence (petit mal) status.

Adverse Reactions

Gastrointestinal System: Gastrointestinal symptoms occur frequently and include anorexia, vague gastric upset, nausea and vomiting, cramps, epigastric and abdominal pain, weight loss, and diarrhea.

Hemopoietic System: Hemopoietic complications associated with the administration of ethosuximide have included leukopenia, agranulocytosis, pancytopenia, aplastic anemia, and eosinophilia.

Nervous System: Neurologic and sensory reactions reported during therapy with ethosuximide have included drowsiness, headache, dizziness, euphoria, hiccups, irritability, hyperactivity, lethargy, fatigue, and ataxia. Psychiatric or psychological aberrations associated with ethosuximide administration have included disturbances of sleep, night terrors, inability to concentrate, and aggressiveness. These effects may be noted particularly in patients who have previously exhibited psychological abnormalities. There have been rare reports of paranoid psychosis, increased libido, and increased state of depression with overt suicidal intentions.

Integumentary System: Dermatologic manifestations which have occurred with the administration of ethosuximide have included urticaria, Stevens-Johnson syndrome, systemic lupus erythematosus, and pruritic erythematous rashes.

Miscellaneous: Other reactions reported have included myopia, vaginal bleeding, swelling of the tongue, gum hypertrophy, and hirsutism.

YC

PARKE-DAVIS
Div of Warner-Lambert Co
Morris Plains, NJ 07950 USA

PD-JA-0209-1-P (2-80)

MANUSCRIPT PREPARATION

Send all manuscripts to:
Jerold F. Lucey, MD
Editor
Pediatrics Editorial Office
Mary Fletcher Hospital
Colchester Avenue
Burlington, VT 05401

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Manuscripts should be prepared in the manner described in *Manual for Authors & Editors* © 1981 by the American Medical Association. See also "Uniform Requirements for Manuscripts Submitted to Biomedical Journals." A current issue of PEDIATRICS should be consulted for general style.

Three complete copies of the manuscript including tables and illustrations must be supplied. All material should be typed on white bond paper, 21.6 × 27.9 cm (8½ × 11 in). Use double spacing throughout, including title page, abstract, text, acknowledgments, references, tables, and legends for illustrations.

The author's style will be respected; however, writing should conform to acceptable English usage and syntax, and American Medical Association style preferences will be observed. Titles should be concise and clear, subtitles avoided. Terminology should follow *Standard Nomenclature of Diseases and Operations*. Give authors' full names and professional degrees, principal author's address, and name of institution(s) where work was done; omit departmental appointments unless necessary for special reasons. Slang, medical jargon, obscure abbreviations, and abbreviated phrasing should be avoided. Mathematical terms, formulas, abbreviations, and units of measurement must conform to usage in PEDIATRICS, based on standards in *Science* 120:1078, 1954. The metric system will be used; equivalent measurement in the English system may be included in parentheses. Name of chemical compounds—not formulas—should be given. Proprietary names, if unavoidable, will be indicated by capitalization of the first letter. Conversions to accepted standards and terms should be made before the manuscript is submitted.

Authors are requested to furnish (in addition to the full title) a condensed title for the cover, not exceeding 60 spaces, and a running foot of not more than 35 spaces. Original articles should be accompanied by an abstract of 200 words or less, as well as up to five key words under which the paper should be indexed. Authors should also supply an alphabetical list of any unusual abbreviations used and their definitions.

Manuscripts should include a clear introductory statement of purpose; a historical review when desirable; a description of the technique and the scope of the experiments or observations (previously published procedures require only references to the original); a full presentation of the *Results* obtained; a brief *Comment or Discussion* on the significance of the findings and any correlation with those of other workers; a paragraph headed *Speculation and Relevance*, or *Implications*; and a *Summary*, in brief, logical résumé which may include conclusions.

References must be numbered consecutively according to their citation in the text. Abbreviations for journals should be those listed in *Index Medicus*. The following reference style (a modified form of that shown in "Uniform Requirements for Manuscripts Submitted to Biomedical Journals") will appear in the journal effective with volume 71 (January 1983 issue):

Journal (list first three authors then et al):

1. Starzl TE, Klintmalm GBG, Porter KA, et al: Liver transplantation with use of cyclosporin A and prednisone. *N Engl J Med* 1981;305: 266–269

Book

1. Kavet J: Trends in the utilization of influenza vaccine: An examination of the implementation of public policy in the United States, in Selby P (ed): *Influenza: Virus, Vaccines, and Strategy*. New York, Academic Press Inc, 1976, pp 297–308

Tables must be comprehensible to the reader without reference to the text and typed (double-spaced) rather than photographed. Each table should be typed on a separate sheet, be numbered consecutively, and have a brief title. Care should be taken to make tables as concise and brief as possible.

Illustrations—Photographs of line drawings and any other figures that are not composed simply of letters, numerals, and routine symbols must be furnished. Do not send original artwork or printed forms. A reasonable number of black-and-white illustrations will be printed from black-and-white glossies or film without charge.

Each illustration should be identified on its back, indicating the number, author's name, and "top." They should be keyed in the text. If unessential, their omission may be requested. The prints should not be stapled, clipped together, mounted, or trimmed. Details to be emphasized or crop marks should be indicated on a tissue overlay, not on the illustration itself. Illustrations of poor quality may be returned for improvement. Photographs of patients should be submitted *only* when written parental permission has been obtained. It is the responsibility of the authors to obtain this permission and to keep it in their files. If a figure has been published, acknowledge the original source and obtain written permission for its use from the coyright holder. Use cardboard inserts to protect illustrations in the mail. Legends for figures are to be on a separate sheet.

Color illustrations and other special processing involve extra costs that are usually borne by the author. Manuscripts containing such materials will not be processed until arrangements for payment, on the basis of estimated prices, are made. Color work requires one month longer for production.

Revised, March 1982

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The Impetigo Handoff

• Effective adjunctive therapy to systemic antibacterial • Handy applicator tip • Reliable

DESCRIPTION: Each gram contains: Aerosporin* (Polymyxin B Sulfate) 5,000 units, bacitracin zinc 400 units, neomycin sulfate 5 mg (equivalent to 3.5 mg neomycin base); special white petrolatum qs; in tubes of 1 oz and ½ oz and 1/32 oz (approx.) foil packets.

INDICATIONS: *Therapeutically* (as an adjunct to systemic therapy when indicated), for topical infections, primary or secondary, due to susceptible organisms, as in: • infected burns, skin grafts, surgical incisions, otitis externa • primary pyodermas (impetigo, ecthyma, sycosis vulgaris, paronychia) • secondarily infected dermatoses (eczema, herpes, and seborrheic dermatitis) • traumatic lesions, inflamed or suppurating as a result of bacterial infection. *Prophylactically*, the ointment may be used to prevent bacterial contamination in burns, skin grafts, incisions, and other clean lesions. For abrasions, minor cuts and wounds accidentally incurred, its use may prevent the development of infection and permit wound healing.

CONTRAINDICATIONS: Not for use in the eyes or in the external ear canal if the eardrum is perforated. This product is contraindicated in those individuals who have shown hypersensitivity to any of its components.

WARNING: Because of the potential hazard of nephrotoxicity and ototoxicity due to neomycin, care should be exercised when using this product in treating extensive burns, trophic ulceration and other extensive conditions where absorption of neomycin is possible. In burns where more than 20 percent of the body surface is affected, especially if the patient has impaired renal function or is receiving other aminoglycoside antibiotics concurrently, not more than one application a day is recommended.

When using neomycin-containing products to control secondary infection in the chronic dermatoses, it should be borne in mind that the skin is more liable to become sensitized to many substances, including neomycin. The manifestation of sensitization to neomycin is usually a low grade reddening with swelling, dry scaling and itching; it may be manifest simply as a failure to heal. During long-term use of neomycin-containing products, periodic examination for such signs is advisable and the patient should be told to discontinue the product if they are observed. These symptoms regress quickly on withdrawing the medication. Neomycin-containing applications should be avoided for that patient thereafter.

PRECAUTIONS: As with other antibacterial preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

ADVERSE REACTIONS: Neomycin is a not uncommon cutaneous sensitizer. Articles in the current literature indicate an increase in the prevalence of persons allergic to neomycin. Ototoxicity and nephrotoxicity have been reported (see Warning section).

Complete literature available on request from Professional Services Dept. PML.

Wellcome

Burroughs Wellcome Co.
Research Triangle Park
North Carolina 27709

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Pediatrics

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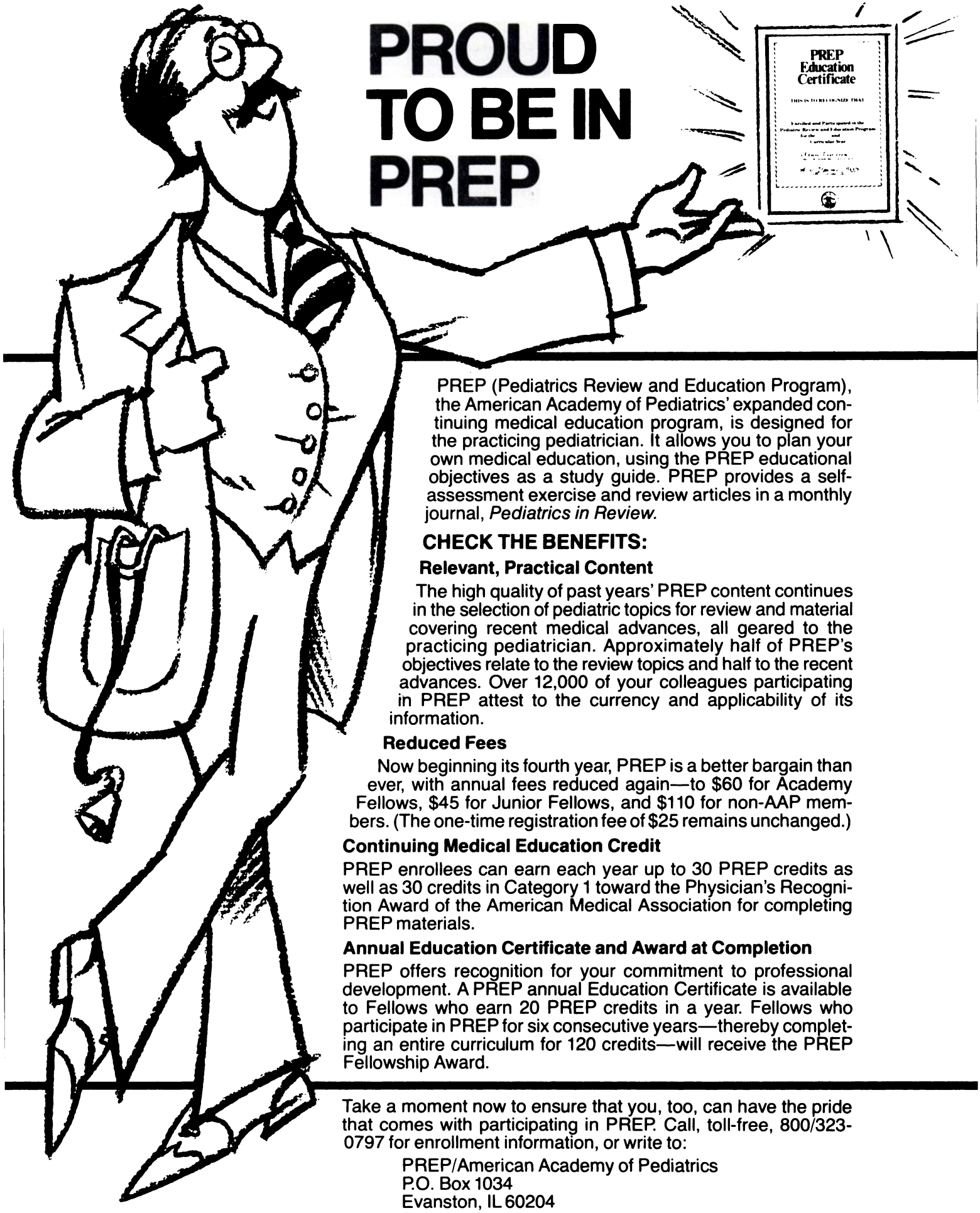
ARTICLES

PROUD TO BE IN PREP



PREP (Pediatrics Review and Education Program), the American Academy of Pediatrics' expanded continuing medical education program, is designed for the practicing pediatrician. It allows you to plan your own medical education, using the PREP educational objectives as a study guide. PREP provides a self-assessment exercise and review articles in a monthly journal, *Pediatrics in Review.*

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New USDA survey reveals:

Up to 55% of preschoolers may be at nutritional risk.

Problem 1: **55% of 1-5 year olds receive less than 70% of the 1980 RDA for one or more key vitamins and minerals.**

Preliminary results from the USDA Nationwide Food Consumption Survey[1] of preschoolers' daily diets show:

	Percent of 1-5 year olds receiving:			
No. participants	less than 100% RDA[2]		less than 70% RDA	
	One or more key vitamins	Iron	One or more key vitamins	Iron
2,750	53%	87%	25%	55%

Problem 2: **These children come from all income, ethnic and geographic groups—They cannot be identified easily...**

...and dietary counseling often may not be feasible for the concerned physician on a daily basis.

Problem 3: **Inadequate fluoride. Increased caries risk.**

Recent research[3] indicates that 65% of children 2-8 who live in non-fluoridated water areas receive no daily systemic fluoride supplementation. It is generally recognized that 50%-80% caries reduction is possible through optimal fluoride supplementation.

Your solution: **Routine vitamin supplementation to help assure your pediatric patients' optimal growth and development.**

Help guard your patients against nutritional risk with routine vitamin specification.

Vi-Sol®/Vi-Flor™ products are the nation's most prescribed children's vitamin and fluoridated vitamin supplements.

For information on pediatric vitamin supplementation, write the Medical Affairs Department, Mead Johnson Nutritional Division, Evansville, Indiana 47721.

Products shown include Poly-Vi-Flor multivitamins and fluoride supplements.

[1]Source: Preliminary three-day dietary reports data from USDA Nationwide Food Consumption Survey conducted 4/77-3/78 using Food and Nutrition Board 1980 Recommended Dietary Allowances. Data exclude nutrient contribution from vitamin and mineral supplements.

[2]1980 Recommended Dietary Allowances.

[3]Data on file, Mead Johnson Nutritional Division.

Mead Johnson
NUTRITIONAL DIVISION

AMERICAN ACADEMY
OF PEDIATRICS

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SCHEDULE OF MEETINGS

ANNUAL MEETINGS

1982
New York Hilton
Sheraton Centre
New York City
October 23-28

1983
San Francisco
October 22-27

1984
Chicago
September 15-20

1985
San Antonio, Texas
October 19-24

1986
Washington, DC
November 1-6

1987
New Orleans
October 17-22

1988
San Francisco
October 22-27

Note: All Annual Meetings start on Saturday


When gentle cleaning really counts.
IVORY
Whenever your patients need a soap that's gentle to the skin, that's Ivory. Because Ivory is a basic, natural soap that cleans without a lot of extra ingredients. Doctors have trusted Ivory's gentle cleaning for years. You can trust Ivory. And you can recommend it with confidence.
More doctors recommend Ivory than any other soap.

SIMILAC®, SIMILAC® WITH IRON and *new*...

Infant Formula Infant Formula

SIMILAC® WITH WHEY

Infant Formula

Ross Laboratories has now extended the range of infant feeding alternatives.

NEW Similac With Whey offers...

- **15.5 g of heat-denatured protein/L with a 60:40 whey-casein ratio *plus***
- **12 mg of iron/L to help prevent iron deficiency *plus***
- **the nutritional advantages of other Similac Infant Formulas.**

Now there's a Similac® Infant Formula for every preference.

B433/2870

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COLUMBUS, OHIO 43216
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OF PEDIATRICS

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SCHEDULE OF MEETINGS

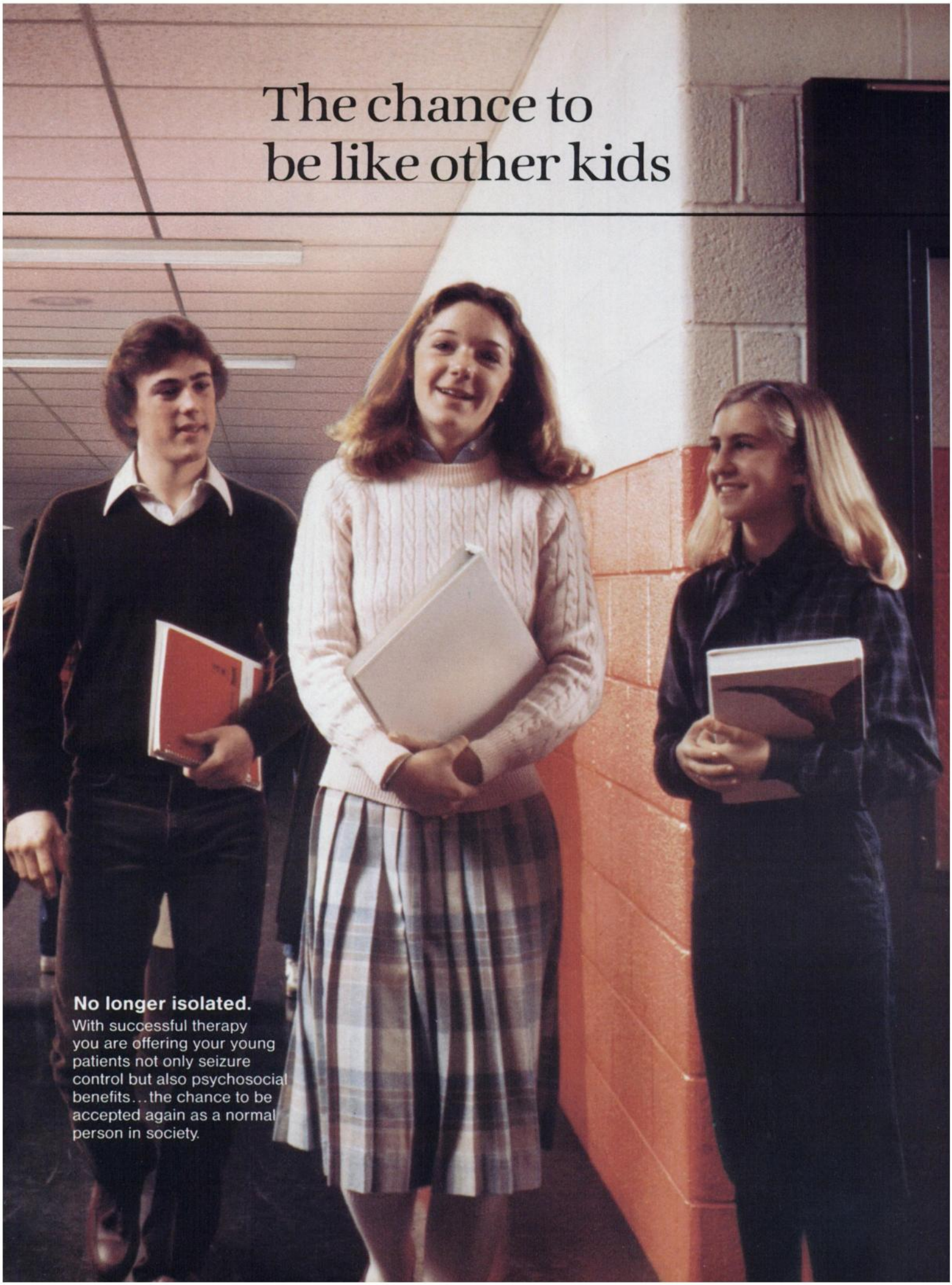
SPRING SESSIONS

1983
Philadelphia
April 16-21

1984
Phoenix, Arizona
March 24-29

1985
Atlanta
April 13-18

Note: All Spring Sessions start on Saturday


The chance to
be like other kids
No longer isolated.
With successful therapy
you are offering your young
patients not only seizure
control but also psychosocial
benefits...the chance to be
accepted again as a normal
person in society.

Seizure-free

with Depakene® Valproic Acid

The Broad Spectrum Antiepileptic

Impressive efficacy is seen with Depakene as a major adjunct in a broad spectrum of seizure disorders. These include absence (petit mal) when associated with many other generalized seizure conditions (e.g., tonic-clonic or grand mal, myoclonic, atonic), as well as in selected cases of absence with partial (focal and psychomotor) seizure types.

In tonic-clonic seizures mixed with absence, impressive results have been attained. Thus in six groups of those seizure patients, 71% were improved, and the majority of these gained 75% to 100% reduction in their seizure frequency.[1]

Before starting Depakene and frequently thereafter, test CBC, bleeding time, and liver profile in view of occasional reports of hepatic reactions, including fatalities.

1. Pinder, R.M., et al., *Drugs* 13:81, 1977

250 mg capsules, 250 mg/5 ml syrup. See an adjacent page for prescribing information. 2013434

The chance to be like other kids

with Depakene®
Valproic Acid

PRESCRIBING INFORMATION

WARNING: HEPATIC FAILURE RESULTING IN FATALITIES HAS OCCURRED IN PATIENTS RECEIVING DEPAKENE. THESE INCIDENTS USUALLY HAVE OCCURRED DURING THE FIRST SIX MONTHS OF TREATMENT WITH DEPAKENE. SERIOUS OR FATAL HEPATOTOXICITY MAY BE PRECEDED BY NON SPECIFIC SYMPTOMS SUCH AS LOSS OF SEIZURE CONTROL, MALAISE, WEAKNESS, LETHARGY, ANOREXIA AND VOMITING. LIVER FUNCTION TESTS SHOULD BE PERFORMED PRIOR TO THERAPY AND AT FREQUENT INTERVALS THEREAFTER, ESPECIALLY DURING THE FIRST SIX MONTHS.

DESCRIPTION: DEPAKENE (valproic acid) is a carboxylic acid designated as 2 propylpentanoic acid. It is also known as dipropylacetic acid.

Valproic acid (pKa 4.8) has a molecular weight of 144 and occurs as a colorless liquid with a characteristic odor. It is slightly soluble in water (1.3 mg/ml) and very soluble in organic solvents.

DEPAKENE is supplied as soft elastic capsules and syrup for oral administration. Each capsule contains 250 mg valproic acid. The syrup contains the equivalent of 250 mg valproic acid per 5 ml as the sodium salt.

CLINICAL PHARMACOLOGY: DEPAKENE is an antiepileptic agent which is chemically unrelated to other drugs used to treat seizure disorders. It has no nitrogen or aromatic moiety characteristic of other antiepileptic drugs. The mechanism by which DEPAKENE exerts its antiepileptic effects has not been established. It has been suggested that its activity is related to increased brain levels of gamma aminobutyric acid (GABA). The effect on the neuronal membrane is unknown.

DEPAKENE is rapidly absorbed after oral administration. Peak serum levels of valproic acid occur approximately one to four hours after a single oral dose of DEPAKENE. The serum half life ($t_{0.5,s}$) of the parent compound is approximately eight to twelve hours. A slight delay in absorption occurs when the drug is administered with meals but this does not affect the total absorption.

Valproic acid is rapidly distributed and at therapeutic drug concentrations drug is highly bound (90%) to human plasma proteins. Increases in dose may result in decreases in the extent of protein binding and variable changes in valproate clearance and elimination.

Elimination of DEPAKENE and its metabolites occurs principally in the urine, with minor amounts in the feces and expired air. Very little unmetabolized parent drug is excreted in the urine. The drug is primarily metabolized in the liver and is excreted as the glucuronide conjugate. Other metabolites in the urine are products of beta and omega oxidation (C 3 and C 5 position). The three major oxidative metabolites are 2 propyl 3 keto pentanoic acid, 2 propyl 5 hydroxypentanoic acid, and 2 propyl glutaric acid.

INDICATIONS: DEPAKENE (valproic acid) is indicated for use as sole and adjunctive therapy in the treatment of simple (petit mal) and complex absence seizures. DEPAKENE may also be used adjunctively in patients with multiple seizure types which include absence seizures.

In accordance with the International Classification of Seizures, simple absence is defined as very brief clouding of the sensorium or loss of consciousness (lasting usually 2-15 seconds), accompanied by certain generalized epileptic discharges without other detectable clinical signs. Complex absence is the term used when other signs are also present.

SEE "WARNINGS" SECTION FOR STATEMENT REGARDING FATAL HEPATIC DYSFUNCTION.

CONTRAINDICATIONS: DEPAKENE (VALPROIC ACID) SHOULD NOT BE ADMINISTERED TO PATIENTS WITH HEPATIC DISEASE OR SIGNIFICANT DYSFUNCTION.

DEPAKENE is contraindicated in patients with known hypersensitivity to the drug.

WARNINGS: Hepatic failure resulting in fatalities has occurred in patients receiving DEPAKENE. These incidents usually have occurred during the first six months of treatment with DEPAKENE. Serious or fatal hepatotoxicity may be preceded by non-specific symptoms such as loss of seizure control, malaise, weakness, lethargy, anorexia and vomiting. Liver function tests should be performed prior to therapy and at frequent intervals thereafter, especially during the first six months. However, physicians should not rely totally on serum biochemistry since these tests may not be abnormal in all instances, but should also consider the results of careful interim medical history and physical examination. Caution should be observed when administering DEPAKENE to patients with a prior history of hepatic disease. Patients with various unusual congenital disorders, those with severe seizure disorders accompanied by mental retardation, and those with organic brain disease may be at particular risk.

The drug should be discontinued immediately in the presence of significant hepatic dysfunction, suspected or apparent. In some cases, hepatic dysfunction has progressed in spite of discontinuation of drug. The frequency of adverse effects (particularly elevated liver enzymes) may be dose related. The benefit of improved seizure control which may accompany the higher doses should therefore be weighed against the possibility of a greater incidence of adverse effects.

Usage in Pregnancy. THE EFFECTS OF DEPAKENE IN HUMAN PREGNANCY ARE UNKNOWN. ANIMAL STUDIES HAVE DEMONSTRATED TERATOGENICITY.

Studies in rats and human females demonstrated placental transfer of the drug. Doses greater than 65 mg/kg/day given to pregnant rats and mice produced skeletal abnormalities in the offspring, primarily involving ribs and vertebrae; doses greater than 150 mg/kg/day given to pregnant rabbits produced fetal resorptions and (primarily) soft tissue abnormalities in the offspring. In rats a dose related delay in the onset of parturition was noted. Postnatal growth and survival of the progeny were adversely affected, particularly when drug administration spanned the entire gestation and early lactation period.

THERE ARE MULTIPLE REPORTS IN THE CLINICAL LITERATURE WHICH INDICATE THAT THE USE OF ANTIEPILEPTIC DRUGS DURING PREGNANCY RESULTS IN AN INCREASED INCIDENCE OF BIRTH DEFECTS IN THE OFFSPRING. ALTHOUGH DATA ARE MORE EXTENSIVE WITH RESPECT TO TRIMETHADIONE, PARAMETHADIONE, PHENYTOIN, AND PHENOBARBITAL, REPORTS INDICATE A POSSIBLE SIMILAR ASSOCIATION WITH THE USE OF OTHER ANTIEPILEPTIC DRUGS. THEREFORE, ANTIEPILEPTIC DRUGS SHOULD BE ADMINISTERED TO WOMEN OF CHILDBEARING POTENTIAL ONLY IF THEY ARE CLEARLY SHOWN TO BE ESSENTIAL IN THE MANAGEMENT OF THEIR SEIZURES.

Antiepileptic drugs should not be discontinued in patients in whom the drug is administered to prevent major seizures because of the strong possibility of precipitating status epilepticus with attendant hypoxia and threat to life. In individual cases where the severity and frequency of the seizure disorder are such that the removal of medication does not pose a serious threat to the patient, discontinuation of the drug may be considered prior to and during pregnancy, although it cannot be said with any confidence that even minor seizures do not pose some hazard to the developing embryo or fetus.

The prescribing physician will wish to weigh these considerations in treating or counseling epileptic women of childbearing potential.

PRECAUTIONS: *Hepatic Dysfunction.* See "Contraindications" and "Warnings" sections.

General. Because of reports of thrombocytopenia and platelet aggregation dysfunction, platelet counts and bleeding time determination are recommended before initiating therapy and at periodic intervals. It is recommended that patients receiving DEPAKENE be monitored for platelet count prior to planned surgery. Clinical evidence of hemorrhage, bruising or a disorder of hemostasis/coagulation is an indication for reduction of DEPAKENE dosage or withdrawal of therapy pending investigation.

Hyperammonemia with or without lethargy or coma has been reported and may be present in the absence of abnormal liver function tests. If elevation occurs, DEPAKENE should be discontinued.

Since DEPAKENE (valproic acid) may interact with concurrently administered antiepileptic drugs, periodic serum level determinations of concomitant antiepileptic drugs are recommended during the early course of therapy. (See "Drug Interactions" section).

DEPAKENE is partially eliminated in the urine as a keto metabolite which may lead to a false interpretation of the urine ketone test.

Information for Patients. Since DEPAKENE may produce CNS depression, especially when combined with another CNS depressant (e.g., alcohol), patients should be advised not to engage in hazardous occupations, such as driving an automobile or operating dangerous machinery, until it is known that they do not become drowsy from the drug.

Drug Interactions. DEPAKENE may potentiate the CNS depressant activity of alcohol.

THERE IS EVIDENCE THAT DEPAKENE CAN CAUSE AN INCREASE IN SERUM PHENOBARBITAL LEVELS BY IMPAIRMENT OF NON RENAL CLEARANCE. THIS PHENOMENON CAN RESULT IN SEVERE CNS DEPRESSION. THE COMBINATION OF DEPAKENE AND PHENOBARBITAL HAS ALSO BEEN REPORTED TO PRODUCE CNS DEPRESSION WITHOUT SIGNIFICANT ELEVATIONS OF BARBITURATE OR VALPROATE SERUM LEVELS. ALL PATIENTS RECEIVING CONCOMITANT BARBITURATE THERAPY SHOULD BE CLOSELY MONITORED FOR NEUROLOGICAL TOXICITY. SERUM BARBITURATE LEVELS SHOULD BE OBTAINED, IF POSSIBLE, AND THE BARBITURATE DOSAGE DECREASED, IF APPROPRIATE.

Primidone is metabolized into a barbiturate and, therefore, may also be involved in a similar or identical interaction.

THERE HAVE BEEN REPORTS OF BREAKTHROUGH SEIZURES OCCURRING WITH THE COMBINATION OF DEPAKENE AND PHENYTOIN. MOST REPORTS HAVE NOTED A DECREASE IN TOTAL PLASMA PHENYTOIN CONCENTRATION. HOWEVER, INCREASES IN TOTAL PHENYTOIN SERUM CONCENTRATION HAVE BEEN REPORTED. AN INITIAL FALL IN TOTAL PHENYTOIN LEVELS WITH SUBSEQUENT INCREASE IN PHENYTOIN LEVELS HAS ALSO BEEN REPORTED. IN ADDITION, A DECREASE IN TOTAL SERUM PHENYTOIN WITH AN INCREASE IN THE FREE VS. PROTEIN BOUND PHENYTOIN LEVELS HAS BEEN REPORTED. THE DOSAGE OF PHENYTOIN SHOULD BE ADJUSTED AS REQUIRED BY THE CLINICAL SITUATION.

THE CONCOMITANT USE OF VALPROIC ACID AND CLONAZEPAM MAY PRODUCE ABSENCE STATUS.

Caution is recommended when DEPAKENE (valproic acid) is administered with drugs affecting coagulation, e.g., aspirin and warfarin. (See "Adverse Reactions" section).

There have been reports of altered thyroid function tests associated with DEPAKENE. The clinical significance of these is unknown.

Carcinogenesis, Mutagenesis. There has been insufficient study of the drug in animals to determine whether it has carcinogenic potential. Carcinogenicity studies in rats and mice are currently in progress.

Mutagenesis studies on DEPAKENE have been performed using bacterial and mammalian systems. These studies have provided no evidence of a mutagenic potential for DEPAKENE.

Pregnancy. See "Warnings" section.

Nursing Mothers. DEPAKENE is excreted in breast milk. Concentrations in breast milk have been reported to be 1-10% of serum concentrations. It is not known what effect this would have on a nursing infant. As a general rule, nursing should not be undertaken while a patient is receiving DEPAKENE.

Fertility. Chronic toxicity studies in juvenile and adult rats and dogs demonstrated reduced spermatogenesis and testicular atrophy at doses greater than 200 mg/kg/day in rats and greater than 90 mg/kg/day in dogs. Segment I fertility studies in rats have shown doses up to 350 mg/kg/day for 60 days to have no effect on fertility. THE EFFECT OF DEPAKENE (VALPROIC ACID) ON THE DEVELOPMENT OF THE TESTES AND ON SPERM PRODUCTION AND FERTILITY IN HUMANS IS UNKNOWN.

ADVERSE REACTIONS: Since DEPAKENE (valproic acid) has usually been used with other antiepileptic drugs, it is not possible, in most cases, to determine whether the following adverse reactions can be ascribed to DEPAKENE alone, or the combination of drugs.

Gastrointestinal. The most commonly reported side effects at the initiation of therapy are nausea, vomiting and indigestion. These effects are usually transient and rarely require discontinuation of therapy. Diarrhea, abdominal cramps and constipation have been reported. Both anorexia with some weight loss and increased appetite with weight gain have also been reported.

CNS Effects. Sedative effects have been noted in patients receiving valproic acid alone but are found most often in patients receiving combination therapy. Sedation usually disappears upon reduction of other antiepileptic medication. Ataxia, headache, nystagmus, diplopia, asterixis, "spots before eyes", tremor, dysarthria, dizziness, and incoordination have rarely been noted. Rare cases of coma have been noted in patients receiving valproic acid alone or in conjunction with phenobarbital.

Dermatologic. Transient increases in hair loss have been observed. Skin rash and petechiae have rarely been noted.

Psychiatric. Emotional upset, depression, psychosis, aggression, hyperactivity and behavioral deterioration have been reported.

Musculoskeletal. Weakness has been reported.

Hematopoietic. Thrombocytopenia has been reported. Valproic acid inhibits the secondary phase of platelet aggregation. (See "Drug Interactions" section). This may be reflected in altered bleeding time. Bruising, hematoma formation and frank hemorrhage have been reported. Relative lymphocytosis and hypofibrinogenemia have been noted. Leukopenia and eosinophilia have also been reported. Anemia and bone marrow suppression have been reported.

Hepatic. Minor elevations of transaminases (e.g., SGOT and SGPT) and LDH are frequent and appear to be dose related. Occasionally, laboratory test results include, as well, increases in serum bilirubin and abnormal changes in other liver function tests. These results may reflect potentially serious hepatotoxicity. (See "Warnings" section).

Endocrine. There have been reports of irregular menses and secondary amenorrhea occurring in patients receiving DEPAKENE.

Abnormal thyroid function tests have been reported. (See "Precautions" section).

Pancreatic. There have been reports of acute pancreatitis occurring in patients receiving DEPAKENE.

Metabolic. Hyperammonemia. (See "Precautions" section).

Hyperglycinemia has been reported and has been associated with a fatal outcome in a patient with preexistent nonketotic hyperglycinemia.

OVERDOSAGE: Overdosage with valproic acid may result in deep coma.

Since DEPAKENE is absorbed very rapidly, the value of gastric evacuation will vary with the time since ingestion. General supportive measures should be applied with particular attention being given to the maintenance of adequate urinary output.

Naloxone has been reported to reverse the CNS depressant effects of DEPAKENE overdosage. Because naloxone could theoretically also reverse the antiepileptic effects of DEPAKENE it should be used with caution.

DOSAGE AND ADMINISTRATION: DEPAKENE (valproic acid) is administered orally. The recommended initial dose is 15 mg/kg/day, increasing at one week intervals by 5 to 10 mg/kg/day, until seizures are controlled or side effects preclude further increases. The maximum recommended dosage is 60 mg/kg/day. If the total daily dose exceeds 250 mg, it should be given in a divided regimen.

The following table is a guide for the initial daily dose of DEPAKENE (valproic acid) (15 mg/kg/day).

Weight (kg)	Weight (lb)	Total Daily Dose (mg)	Number of Capsules or Teaspoonfuls of Syrup Dose 1	Dose 2	Dose 3
10-24.9	22-54.9	250	0	0	1
25-39.9	55-87.9	500	1	0	1
40-59.9	88-131.9	750	1	1	1
60-74.9	132-164.9	1,000	1	1	2
75-89.9	165-197.9	1,250	2	1	2

The frequency of adverse effects (particularly elevated liver enzymes) may be dose related. The benefit of improved seizure control which may accompany the higher doses should therefore be weighed against the possibility of a greater incidence of adverse reactions.

A good correlation has not been established between daily dose, serum level and therapeutic effect; however, therapeutic serum levels for most patients will range from 50 to 100 mcg/ml. Occasional patients may be controlled with serum levels lower or higher than this range.

As the DEPAKENE dosage is titrated upward, blood levels of phenobarbital and/or phenytoin may be affected. (See "Precautions" section).

Patients who experience GI irritation may benefit from administration of the drug with food or by slowly building up the dose from an initial low level.

THE CAPSULES SHOULD BE SWALLOWED WITHOUT CHEWING TO AVOID LOCAL IRRITATION OF THE MOUTH AND THROAT.

HOW SUPPLIED: DEPAKENE (valproic acid) is available as orange colored soft gelatin capsules of 250 mg valproic acid in bottles of 100 capsules (**NDC** 0074-5681-13), in ABBO-PAC® unit dose packages of 100 capsules (**NDC** 0074-5681-11), and as a red syrup containing the equivalent of 250 mg valproic acid per 5 ml as the sodium salt in bottles of 16 ounces (**NDC** 0074-5682-16).

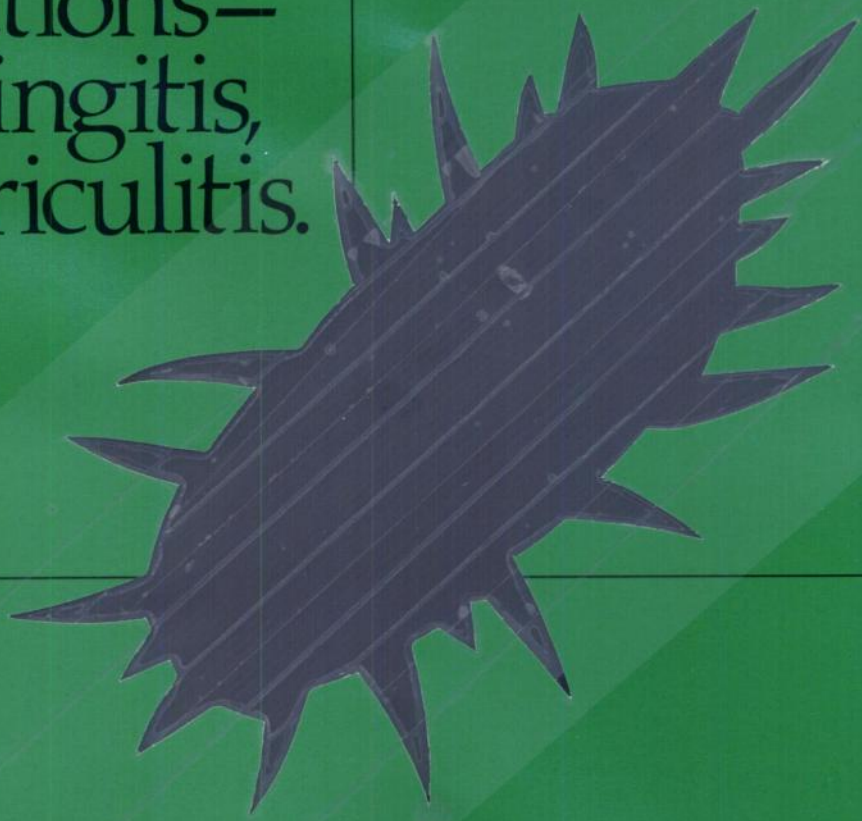
2013434

Claforan®
(cefotaxime sodium)
Sterile IM/IV

...now two new indications:

For central nervous system infections—meningitis, ventriculitis.

For neonates, infants and children.



For central nervous system infections—meningitis, ventriculitis.

Claforan® achieves bactericidal concentrations in cerebrospinal fluid greater than those reported for previously available cephalosporins.[1] In 75 cases of meningitis, a clinical success rate of 88.0% was reported—95.2% for adults, 85.2% for pediatric patients.[2] Claforan® effectively eradicated 98.2% of the following causative pathogens: *Neisseria meningitidis, Klebsiella pneumoniae, Streptococcus pneumoniae, Haemophilus influenzae* and *Escherichia coli*.

For neonates, infants and children.

In studies of infant and pediatric patients with lower respiratory tract, urinary tract, skin and skin structure, bone and joint, CNS and other infections, as well as in bacteremia and septicemia, Claforan® achieved a clinical response rate of 98.2%.[2] Side effects were reported in only 2.6% of patients, and most of these were rashes and pruritus.[2]

1. Landesman SH, et al: Past and Current Roles for Cephalosporin Antibiotics in Treatment of Meningitis. Emphasis on Use in Gram-Negative Bacillary Meningitis. *Am J Med* 71:693-703, October 1981.
2. Data on file, Hoechst-Roussel Pharmaceuticals Inc.

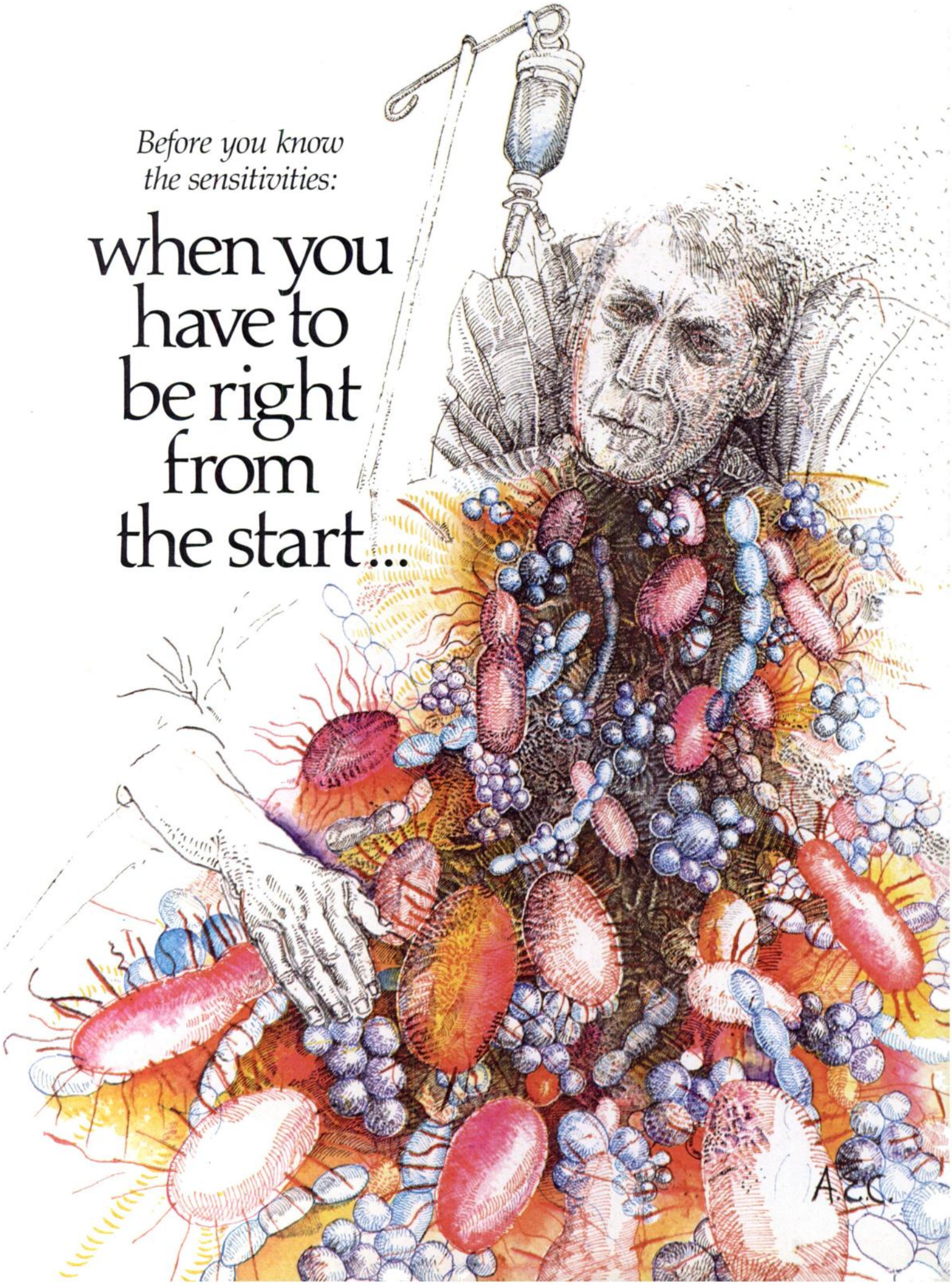
*U.S. Patent No. 4,152,432

Please see brief summary of full prescribing information.

Claforan®
(cefotaxime sodium)
Sterile IM/IV

Before you know the sensitivities:

when you have to be right from the start...



Start with

Greater in vitro‡‡ antibiotic spectrum than previous cephalosporins:

gram-positive, gram-negative ...aerobic, anaerobic.

Pathogens	Cephalothin* (1st Generation Cephalosporin)	Cefamandole* (2nd Generation Cephalosporin)	Claforan (3rd Generation Cephalosporin)
Gram-positive			
Staphylococcus aureus	●	●	●
Staphylococcus epidermidis	●	●	●
Streptococcus pyogenes (Group A beta-hemol.)	●	●	●
Streptococcus agalactiae (Group B)	●	●	●
Streptococcus pneumoniae	●	●	●
Clostridium species (An) (Excluding C. difficile)		●	●
Peptococcus species (An)		●	●
Peptostreptococcus species (An)		●	●
Gram-negative			
Citrobacter species			●
Bacteroides species (An)		●	●
Enterobacter species		●	●
Escherichia coli	●	●	●
Haemophilus influenzae	●	●	●
Klebsiella species	●	●	●
Klebsiella pneumoniae	●	●	●
Neisseria gonorrhoeae (including penicillinase-producing strains)			●
Neisseria meningitidis			●
Proteus mirabilis	●	●	●
Morganella morganii†		●	●
Proteus rettgeri		●	●
Proteus vulgaris		●	●
Providencia species			●
Salmonella species	●		●
Salmonella typhi	●		●
Serratia species			●
Shigella species	●		●
Pseudomonas aeruginosa (some strains)			●

Comparison of spectra from published literature shows range of Claforan activity in vitro‡‡ substantially greater than available cephalosporins.

*Data based on PDR®, 35th Edition, 1981.

†Formerly called Proteus morganii.

‡‡Although a useful guide, in vitro activity does not necessarily imply in vivo effectiveness.

Claforan®
(cefotaxime sodium)*
Sterile IM/IV

Its spectrum is broader, it's more active and it's just as safe as previous cephalosporins.

Greater beta-lactamase stability than penicillins and earlier cephalosporins–

For greater in vitro activity against problem organisms frequently encountered in the hospital.

Outstanding range of indications.

For lower respiratory infections:
Highly effective in treating pneumonia—even in the presence of serious underlying lung disease (carcinoma, cystic fibrosis, COPD).[1] Bacteriologic success of 92.2% and clinical success of 95.2% in all lower respiratory tract infections evaluated in one 415-patient trial[2] confirm the usefulness of Claforan® for this important indication.

For intraabdominal infections:
With its excellent antimicrobial activity and tissue penetration, Claforan® has proven to be the bacteriologic and clinical equal of the classic gentamicin-clindamycin combination for treating intraabdominal infections caused by *Escherichia coli*, *Klebsiella* sp., *Bacteroides* sp., and anaerobic gram-positive cocci.[4]

For bacteremia and septicemia:
Bacteriologic and clinical success rates of 100% against *S. marcescens* and *Klebsiella* sp., and 92/91%, respectively, against *Escherichia coli*[2] make Claforan® a valuable agent for controlling most episodes of bacteremia and septicemia.
High serum levels are readily attainable: 214.4 mcg/ml five minutes after a 2-g I.V. injection.[2]

For skin and skin structure infections:
A wide variety of potential pathogens in these infections falls within the antimicrobial spectrum of Claforan®—as demonstrated by 93.6% clinical success rate in one trial involving 328 patients.[2]

For urinary tract infections:
Highly effective against such common urinary tract pathogens as *Escherichia coli*, *Klebsiella* sp. and *Proteus* sp. (both indole-positive and indole-negative), Claforan® is 96.8% successful, clinically, and 80.4%, bacteriologically, in urinary tract infections.[2]

For uncomplicated gonorrhea:
So resistant is Claforan® to β-lactamase, a single treatment with this drug eradicated 100% of penicillinase-producing *N. gonorrhoeae* (compared to 19% for aqueous procaine penicillin G and probenecid) in one clinical comparison.[3]

The safety you expect from a cephalosporin.

No nephrotoxicity or ototoxicity has been reported for Claforan®/No need to reduce dosage except in the presence of severe renal impairment†/No reports of disulfiram-like reactions after ingesting ethanol/Not shown to cause hypoprothrombinemia or hemorrhagic complications/Side effects are generally mild, usually consisting of local reactions at the injection site, and seldom warrant discontinuation of Claforan®.

Please see brief summary of full prescribing information on last page of this advertisement.

*U.S. Patent No. 4,152,432
Claforan® Registered trademark of ROUSSEL UCLAF.
†Claforan® has not been shown to be nephrotoxic; however, it is suggested that the dose be halved in patients with estimated creatinine clearances of less than 20 ml/min/ 1.73 m^2.

In most serious hospital infections

Claforan®
(cefotaxime sodium)
Sterile IM/IV

The right one from the start.

References:
1. Berman TM, Kronenberg RS: Cefotaxime treatment of lower respiratory tract infections in patients with underlying lung diseases. *Drug Therapy* :35-39, January 1981.
2. Data on file, Hoechst-Roussel Pharmaceuticals Inc.
3. Lancaster DJ, Berg SW, Harrison WO, et al: Treatment of penicillin-resistant gonorrhea with cefotaxime. *Drug Therapy* :87-91, January 1981.
4. Stone HH, Geheber CE, Kolb LD, et al: Clinical comparison of cefotaxime versus the combination of gentamicin plus clindamycin in the treatment of peritonitis and similar polymicrobial soft-tissue surgical sepsis. *Clin Ther* 4:67-80, 1981.

Claforan®
(cefotaxime sodium)* Sterile IM/IV

Brief Summary

CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.

INDICATIONS AND USAGE

Treatment

Claforan is indicated for the treatment of patients with serious infections caused by susceptible strains of the designated microorganisms in the diseases listed below.

(1) Lower respiratory tract infections, including pneumonia, caused by *Streptococcus pneumoniae* (formerly *Diplococcus pneumoniae*), *Streptococcus pyogenes* (Group A streptococci) and other streptococci (excluding enterococci, e.g., *Streptococcus faecalis*), *Staphylococcus aureus* (penicillinase- and nonpenicillinase-producing), *Escherichia coli*, *Klebsiella* species, *Haemophilus influenzae* (including ampicillin-resistant strains), *Proteus mirabilis*, *Serratia marcescens*, and *Enterobacter* species.

(2) Genitourinary infections. Urinary tract infections caused by *Enterococcus* species, *Staphylococcus epidermidis*, *Staphylococcus aureus* (penicillinase- and nonpenicillinase-producing), *Citrobacter* species, *Enterobacter* species, *Escherichia coli*, *Klebsiella* species, *Proteus mirabilis*, indole-positive *Proteus* (i.e., *Proteus morganii*, *Proteus rettgeri*, and *Proteus vulgaris*), and *Serratia marcescens*. Also, uncomplicated gonorrhea of single or multiple sites caused by *Neisseria gonorrhoeae*, including penicillinase-producing strains.

(3) Gynecologic infections, including pelvic inflammatory disease, endometritis and pelvic cellulitis caused by *Staphylococcus epidermidis*, *Streptococcus* species, *Enterococcus* species, *Escherichia coli*, *Proteus mirabilis*, *Bacteroides* species (including *B. fragilis*), *Clostridium* species, and anaerobic cocci (including *Peptostreptococcus* species and *Peptococcus* species).

(4) Bacteremia/Septicemia caused by *Escherichia coli*, *Klebsiella* species, and *Serratia marcescens*.

(5) Skin and skin structure infections caused by *Staphylococcus aureus* (penicillinase- and nonpenicillinase-producing), *Staphylococcus epidermidis*, *Streptococcus pyogenes* (Group A streptococci) and other streptococci, *Enterococcus* species, *Escherichia coli*, *Enterobacter* species, *Klebsiella* species, *Proteus mirabilis*, and indole-positive *Proteus* (i.e., *Proteus morganii*, *Proteus rettgeri*, and *Proteus vulgaris*), *Pseudomonas* species, *Serratia marcescens*, *Bacteroides* species, and anaerobic cocci (including *Peptostreptococcus* species and *Peptococcus* species).

(6) Intraabdominal infections including peritonitis caused by *Escherichia coli*, *Klebsiella* species, *Bacteroides* species, and anaerobic cocci (including *Peptostreptococcus* species and *Peptococcus* species).

(7) Bone and/or joint infections caused by *Staphylococcus aureus* (penicillinase- and nonpenicillinase-producing strains).

(8) Central nervous system infections, e.g., meningitis and ventriculitis, caused by *Neisseria meningitidis*, *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Klebsiella pneumoniae*, and *Escherichia coli*.

Although many strains of enterococci (e.g., *S. faecalis*) and *Pseudomonas* species are resistant to cefotaxime sodium *in vitro*, Claforan has been used successfully in treating patients with infections caused by susceptible organisms.

Specimens for bacteriologic culture should be obtained prior to therapy in order to isolate and identify causative organisms and to determine their susceptibilities to Claforan. Therapy may be instituted before results of susceptibility studies are known; however, once these results become available, the antibiotic treatment should be adjusted accordingly.

In certain cases of confirmed or suspected gram-positive or gram-negative sepsis or in patients with other serious infections in which the causative organism has not been identified, Claforan may be used concomitantly with an aminoglycoside. The dosage recommended in the labeling of both antibiotics may be given and depends on the severity of the infection and the patient's condition. Renal function should be carefully monitored, especially if higher dosages of the aminoglycosides are to be administered or if therapy is prolonged, because of the potential nephrotoxicity and ototoxicity of aminoglycoside antibiotics. Some β-lactam antibiotics also have a certain degree of nephrotoxicity. Although, to date, this has not been noted when Claforan was given alone, it is possible that nephrotoxicity may be potentiated if Claforan is used concomitantly with an aminoglycoside.

Prevention

The administration of Claforan perioperatively (preoperatively, intraoperatively, and postoperatively) may reduce the incidence of certain postoperative infections in patients undergoing surgical procedures (e.g., vaginal hysterectomy, genitourinary surgery) that are classified as contaminated or potentially contaminated.

In patients undergoing cesarean section, intraoperative (after clamping the umbilical cord) and postoperative use of Claforan may reduce the incidence of certain postoperative infections.

Effective perioperative use depends on the time of administration. Claforan usually should be given ½ to 1½ hours before surgery, which is sufficient time to achieve effective tissue levels. Administration should usually be stopped within 24 hours, since continuing use of any antibiotic increases the possibility of adverse reactions but, in the majority of surgical procedures, does not reduce the incidence of subsequent infection.

If there are signs of infection, specimens for culture should be obtained for identification of the causative organism so that appropriate therapy may be instituted.

CONTRAINDICATIONS

Claforan is contraindicated in patients who have shown hypersensitivity to cefotaxime sodium or the cephalosporin group of antibiotics.

WARNINGS

BEFORE THERAPY WITH CLAFORAN IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEFOTAXIME SODIUM, CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN WITH CAUTION TO PATIENTS WITH TYPE I HYPERSENSITIVITY REACTIONS TO PENICILLIN. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY, PARTICULARLY TO DRUGS. IF AN ALLERGIC REACTION TO CLAFORAN OCCURS, DISCONTINUE TREATMENT WITH THE DRUG. SERIOUS HYPERSENSITIVITY REACTIONS MAY REQUIRE EPINEPHRINE AND OTHER EMERGENCY MEASURES.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

Treatment with broad spectrum antibiotics alters normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind the toxin *in vitro*.

Mild cases of colitis may respond to drug discontinuance alone.

Moderate to severe cases should be managed with fluid, electrolyte, and protein supplementation as indicated.

When the colitis is not relieved by drug discontinuance or when it is severe, oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should also be considered.

PRECAUTIONS

Claforan should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Claforan has not been shown to be nephrotoxic; however, because high and prolonged serum antibiotic concentrations can occur from usual doses in patients with transient or persistent reduction of urinary output because of renal insufficiency, the total daily dosage should be reduced when Claforan is administered to such patients. Continued dosage should be determined by degree of renal impairment, severity of infection, and susceptibility of the causative organism.

Although there is no clinical evidence supporting the necessity of changing the dosage of cefotaxime sodium in patients with even profound renal dysfunction, it is suggested that, until further data are obtained, the dose of cefotaxime sodium be halved in patients with estimated creatinine clearances of less than 20 ml/min/1.73 m^2.

When only serum creatinine is available, the following formula (based on sex, weight, and age of the patient) may be used to convert this value into creatinine clearance. The serum creatinine should represent a steady state of renal function.

Males: $$\frac{\text{Weight (kg)} \times (140 - \text{age})}{72 \times \text{serum creatinine}}$$

Females: 0.85 x above value

As with other antibiotics, prolonged use of Claforan may result in overgrowth of nonsusceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Drug Interactions: Increased nephrotoxicity has been reported following concomitant administration of cephalosporins and aminoglycoside antibiotics.

Carcinogenesis, Mutagenesis: Long-term studies in animals have not been performed to evaluate carcinogenic potential. Mutagenic tests included a micronucleus and an Ames test. Both tests were negative for mutagenic effects.

Pregnancy Category B: Reproduction studies have been performed in mice and rats at doses up to 30 times the usual human dose and have revealed no evidence of impaired fertility or harm to the fetus because of Claforan (cefotaxime sodium). However, there are no well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nonteratogenic Effects: Use of the drug in women of childbearing potential requires that the anticipated benefit be weighed against the possible risks.

In perinatal and postnatal studies with rats, the pups in the group given 1200 mg/kg of Claforan were significantly lighter in weight at birth and remained smaller than pups in the control group during the 21 days of nursing.

Nursing Mothers: Claforan is excreted in human milk in low concentrations. Caution should be exercised when Claforan is administered to a nursing woman.

ADVERSE REACTIONS

Claforan is generally well tolerated. The most common adverse reactions have been local reactions following IV or IM injection. Other adverse reactions have been encountered infrequently.

The most frequent adverse reactions (greater than 1%) are:

Local (4.7%)—Injection site inflammation with IV administration. Pain, induration, and tenderness after IM injection.

Hypersensitivity (1.8%)—Rash, pruritus, fever.

Gastrointestinal (1.7%)—Colitis, diarrhea, nausea, and vomiting.

Symptoms of pseudomembranous colitis can appear during or after antibiotic treatment.

Nausea and vomiting have been reported rarely.

Less frequent adverse reactions (less than 1%) are:

Hemic and Lymphatic System—Granulocytopenia, transient leukopenia, eosinophilia, and neutropenia have been reported. Some individuals have developed positive direct Coombs Tests during treatment with the cephalosporin antibiotics.

Genitourinary System—Moniliasis, vaginitis.

Central Nervous System—Headache.

Liver—Transient elevations in SGOT, SGPT, serum LDH, and serum alkaline phosphatase levels have been reported.

Kidney—As with some other cephalosporins, transient elevations of BUN have been occasionally observed with Claforan.

NOTE: As with antibiotic therapy in general, administration of Claforan should be continued for a minimum of 48 to 72 hours after the patient defervesces or after evidence of bacterial eradication has been obtained; a minimum of 10 days of treatment is recommended for infections caused by Group A beta-hemolytic streptococci in order to guard against the risk of rheumatic fever or glomerulonephritis; frequent bacteriologic and clinical appraisal is necessary during therapy of chronic urinary tract infection and may be required for several months after therapy has been completed; persistent infections may require treatment of several weeks, and doses smaller than those indicated above should not be used.

71789

*U.S. Patent 4,152,432 CLAFORAN® REG TM ROUSSEL-UCLAF Edition 7/82

Hoechst-Roussel
Pharmaceuticals Incorporated
Somerville, New Jersey 08876 **Hoechst**

Now age is no barrier to successful asthma therapy...

NEW INTAL® cromolyn sodium NEBULIZER SOLUTION

Up till now, the benefits of long-term Intal® therapy were only available to patients able to use the Spinhaler® turbo-inhaler correctly. Now the introduction of the new Intal Nebulizer Solution guarantees that even your younger patients can benefit from the proven efficacy of Intal.

Clinical studies have demonstrated that Intal dramatically reduces coughing, wheezing and dyspnea when administered via power-driven nebulizer.[1] And unlike bronchodilators, which merely relieve the symptoms of asthma, Intal acts on one of its fundamental causes, an excess sensitivity to various pharmacologic, physical and chemical stimuli. In fact, Intal is the only medication that reduces the overall severity of asthma by reducing the level of hyperreactivity.[2,3,4]

Intal acts directly on the bronchial airways. Little drug is absorbed systemically and side effects are rare[5]—an important consideration in managing younger children with asthma. And Intal therapy is rarely associated with the nausea, irritability and headaches that may occur with bronchodilator therapy.

Please see next page for prescribing information.

NEW INTAL® (cromolyn sodium, USP) NEBULIZER SOLUTION

FOR INHALATION USE ONLY — NOT FOR INJECTION

Simplifies asthma management in younger patients

Brief Summary

INDICATIONS AND USAGE: Intal Nebulizer Solution is indicated in the management of patients with bronchial asthma in whom the frequency, intensity and predictability of episodes indicate the use of a continuing program of symptomatic medication. Such patients must have a significant bronchodilator-reversible component to their airway obstruction as demonstrated by a generally accepted pulmonary function test of airway mechanics.

If improvement occurs, it will ordinarily occur within the first 4 weeks of administration as manifested by a decrease in the severity of clinical symptoms of asthma, or in the need for concomitant therapy, or both.

A decision to continue the administration of Intal Nebulizer Solution on a long term basis is justified if introduction of the drug into the patient's regime:

produces a significant reduction in the severity of the symptoms of asthma, or

permits a significant reduction in or elimination of steroids, or

permits better management of patients who have intolerable side effects to sympathomimetic agents or methylxanthines.

CONTRAINDICATIONS: Intal Nebulizer Solution is contraindicated in those patients who have shown hypersensitivity to cromolyn sodium.

WARNINGS: Intal (cromolyn sodium, USP) Nebulizer Solution has no role in the treatment of an acute attack of asthma, especially status asthmaticus.

The prophylactic effect of cromolyn sodium is usually evident after several weeks of treatment, although some patients show an almost immediate response.

In some animal toxicity studies, a previously unreported proliferative arterial lesion found predominantly in the kidneys occurred in both treated and untreated macaque monkeys. The possibility that the increased incidence of the lesion in the treated monkeys is due to the administration of cromolyn sodium can neither be affirmed nor refuted. (For additional details, see Animal Toxicology in the package insert.) The relevance of these data to man is unknown. In considering the long term administration of Intal Nebulizer Solution to a patient, the physician should take into consideration the possible risk as well as the degree of efficacy achieved in the individual patient.

PRECAUTIONS:

General: In view of the biliary and renal routes of excretion for cromolyn sodium, consideration should be given to decreasing the dosage or discontinuing the administration of the drug in patients with impaired renal or hepatic function.

If eosinophilic pneumonia (pulmonary infiltrates with eosinophilia) occurs during the course of Intal Nebulizer Solution therapy, the drug should be discontinued.

Occasionally patients may experience cough and/or bronchospasm following cromolyn sodium inhalation. At times, patients with cromolyn sodium induced bronchospasm may not be able to continue its administration despite prior bronchodilator administration. Rarely very severe bronchospasm has been encountered.

Symptoms of asthma may recur if Intal Nebulizer Solution is reduced below the recommended dosage, or discontinued.

Carcinogenicity: Long term studies have been conducted in mice (12 months and 18 months) and in hamsters (24 months) using cromolyn sodium injected intraperitoneally. There was no effect of the treatment on the incidence of neoplasia.

Pregnancy: Pregnancy Category B.

Reproduction studies performed in rabbits, rats, and mice at doses up to 600 times the human dose have revealed no evidence of impaired fertility or harm to the fetus due to cromolyn sodium. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Reproduction studies with parenterally administered cromolyn sodium have been performed in rabbits, rats, and mice. Adverse fetal effects (increased resorptions and decreased fetal weight) were noticed only at very high parenteral doses that produced maternal toxicity. The relevance to the human is not known.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Intal Nebulizer Solution is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children below the age of 2 years have not been established.

ADVERSE REACTIONS: The adverse reactions which have been observed in clinical trials with Intal Nebulizer Solution are noted as follows:

Cough, Nasal congestion, Nausea, Sneezing, Wheezing

Other reactions have been reported in clinical trials; however, a causal relationship could not be established:

Drowsiness, Nasal itching, Nose bleed, Nose burning, Serum sickness, Stomach ache

In addition, adverse reactions have been reported with Intal (cromolyn sodium) 20 mg Capsules. The most frequently reported adverse reactions attributed to Intal capsules (on the basis of reoccurrence following readministration) involve the respiratory tract and include:

Bronchospasm, Cough, Laryngeal edema (rare), Nasal congestion, Pharyngeal irritation, Wheezing

Other adverse reactions which have also been attributed to Intal® capsules (on the basis of reoccurrence following readministration) are:

Angioedema, Dizziness, Dysuria and urinary frequency, Joint swelling and pain, Lacrimation, Nausea and headache, Rash, Swollen parotid gland, Urticaria

In addition, the following adverse reactions have been reported as rare events and it is unclear whether these are attributable to Intal capsules:

Anaphylaxis, Anemia, Exfoliative dermatitis, Hemoptysis, Hoarseness, Myalgia, Nephrosis, Periarteritic vasculitis, Pericarditis, Peripheral neuritis, Photodermatitis, Polymyositis, Pulmonary infiltrates with eosinophilia, Vertigo

DOSAGE AND ADMINISTRATION: The usual starting dosage for adults and children 2 years of age and over is the contents of one ampule administered by nebulization four times a day. One ampule contains 20 mg cromolyn sodium. Intal Nebulizer Solution should be administered from a power-operated nebulizer having an adequate flow rate, equipped with a suitable face mask. Hand operated nebulizers are not suitable for the administration of Intal Nebulizer Solution. Patients should be advised that the effect of Intal Nebulizer Solution therapy is dependent upon its administration at regular intervals, as directed. Intal Nebulizer Solution should be introduced into the patient's therapeutic regimen when the acute episode has been controlled, the airway cleared and the patient is able to inhale adequately.

Once a patient is stabilized on Intal Nebulizer Solution, if there is no need for steroids, the frequency of administration may be titrated downward to the least frequent level consistent with the desired effect. The usual decrease is from four to three Intal Nebulizer Solution ampules per day. It is important that the dosage be reduced slowly, maintaining close supervision of the patient, to avoid exacerbation of asthma. It should be emphasized that in patients who have been titrated to less than four ampules per day, an increase in dosage may be needed if the patient's clinical condition worsens.

CORTICOSTEROID TREATMENT AND ITS RELATION TO INTAL NEBULIZER SOLUTION USE: An attempt to decrease corticosteroid administration and particularly to institute an alternate day regimen should be made in asthmatic patients receiving corticosteroids. Concomitant corticosteroids, as well as bronchodilators, should be continued following the introduction of Intal Nebulizer Solution. If the patient improves, an attempt to decrease corticosteroids should be made. Even if the steroid-dependent patient fails to improve following Intal Nebulizer Solution administration, gradual tapering of steroid dosage may nonetheless be attempted. It is important that the dose be reduced slowly, maintaining close supervision of the patient to avoid an exacerbation of asthma. It should be borne in mind that prolonged corticosteroid therapy frequently causes a reduction in the activity and size of the adrenal cortex. Relative adrenocortical insufficiency upon discontinuation of therapy may be avoided by gradual reduction of dosage.

However, a potentially critical degree of insufficiency may persist asymptomatically for some time even after gradual discontinuation of adrenocortical steroids. Therefore, if a patient is subjected to significant stress, such as a severe asthmatic attack, surgery, trauma or severe illness while being treated or within one year (occasionally up to two years) after corticosteroid treatment has been terminated, consideration should be given to reinstituting corticosteroid therapy. When the inhalation of Intal Nebulizer Solution is impaired, as may occur in severe exacerbation of asthma, a temporary increase in the amount of corticosteroids and/or other medications may be required.

It is particularly important that great care be exercised if for any reason Intal Nebulizer Solution is withdrawn in cases where its use has permitted a reduction in the maintenance dose of steroids. In such cases, continued close supervision of the patient is essential since there may be sudden reappearance of severe manifestations of asthma which will require immediate therapy and possible reintroduction of corticosteroids.

HOW SUPPLIED: Intal (cromolyn sodium, USP) Nebulizer Solution is supplied in a double ended glass ampule containing 20 mg cromolyn sodium in 2 ml purified water.

NDC 0585-0673-01 — 48 ampules × 2 ml

Intal Nebulizer Solution should be stored below 30°C (86°F) and protected from direct light.

CAUTION: Federal law prohibits dispensing without prescription.

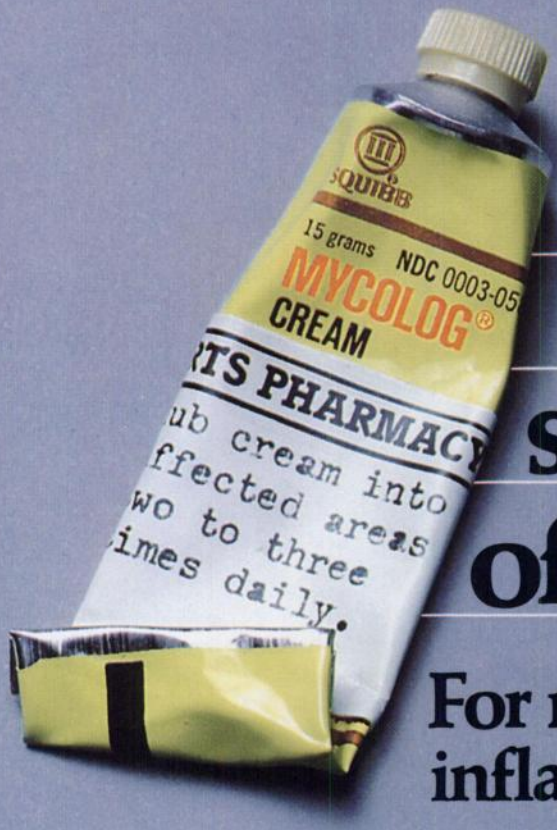
Manufactured for: Fisons Corporation, Bedford, MA 01730 By: Fisons plc, Boulevard Industriel, 76 580 Le Trait, France

*Registered Trademarks

References: 1. Hilman B, Hyte MK, Vekovius A, et al: Safety and efficacy of nebulized cromolyn sodium in asthmatic children, abstracted. *Ann Allergy* 47:118, Aug 1981. **2.** Altounyan REC: Review of the clinical activity and modes of action of sodium cromoglycate, in Pepys J, Edwards AM (eds): *The Mast Cell: Its Role in Health and Disease.* Kent, England, Pitman Medical, 1979, pp 199-216. **3.** Dickson W, Cole M: Severe asthma in children — A 10-year follow-up, in Pepys J, Edwards AM (eds): *The Mast Cell: Its Role in Health and Disease.* Kent, England, Pitman Medical, 1979, pp 343-352. **4.** Easton JG: Effect of an inhaled corticosteroid on methacholine airway reactivity. *J Allergy Clin Immunol* 67:388-390, 1981. **5.** NIAID Task Force Report: Asthma and Other Allergic Diseases. U.S. Department of Health, Education, and Welfare (Public Health Service — National Institutes of Health). NIH Publications No. 79-387, May 1979, p 35.

FISONS

FISONS CORPORATION
Bedford, Massachusetts 01730



A lot of relief has been squeezed out of this tube

For rapid relief of itch,* inflammation,* infection*

There's only one

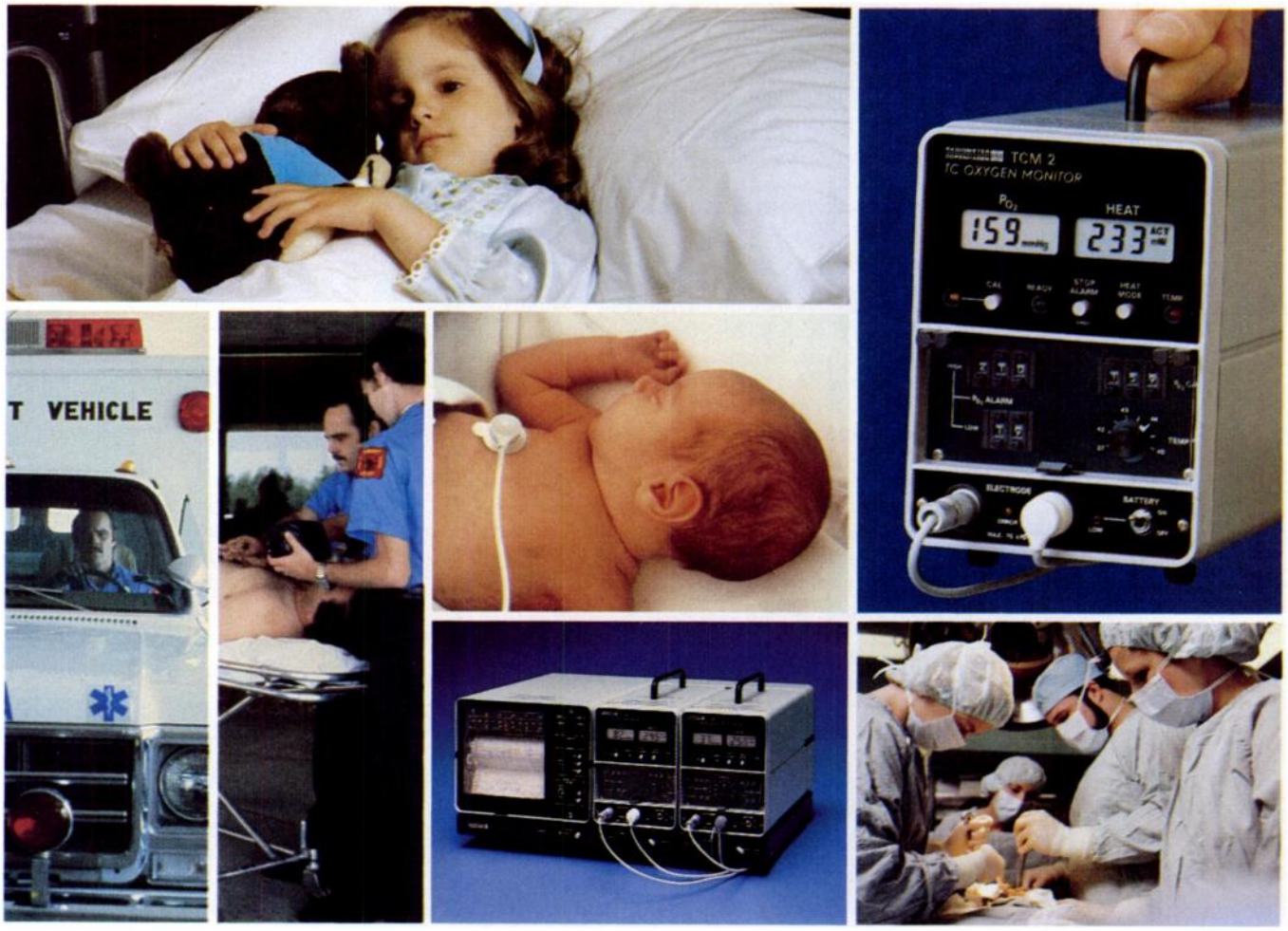
Mycolog® Cream

Nystatin–Neomycin Sulfate–Gramicidin–Triamcinolone Acetonide Cream

*This drug has been evaluated as possibly effective for all indications.
See brief summary on next page.

SQUIBB®

The new Radiometer non-invasive blood gas system is as flexible as your needs are.



Bedside, transport, operating room, emergency, intensive care; now there is a non-invasive oxygen and carbon dioxide system that can do it all. The new Radiometer TCM System with detachable TCM2, $tcP0_2$ and TCM20 $tcPC0_2$ Monitors and a recharger database that features a 2 pen, 2 speed recorder with 3 sensitivity ranges.

The rechargeable battery powered $tcP0_2$ and $tcPC0_2$ Monitors are microprocessor controlled and feature the convenience of automated push button calibration and built-in programs that monitor and control electrode temperature and performance characteristics. Other features include electrode temperature selectors, adjustable high and low visual and acoustic alarms, temperature out-of-range and low battery indicators and both analog and digital (RS232) outputs. Monitors may be used separately from the database for a typical six hours per charge or used in pairs in the database for two site or two patient monitoring.

The new small Radiometer electrodes for the TCM System feature new simple snap-on membranes and soft rimmed fixation rings that easily bend to the curvature of the body.

The Radiometer TCM transcutaneous blood gas system, flexible, convenient and easy to use. And, of traditional Radiometer quality. For a free descriptive brochure contact Radiometer America, Inc., 811 Sharon Drive, Westlake, Ohio 44145. Or call, toll free, (800) 321-9484. In Ohio, call (216) 871-8900.

CAUTION
The TCM20 $tcPCO_2$ Monitor is limited to use with neonates and infants.

RADIOMETER COPENHAGEN

BOOKS RECEIVED

Cortical Dysfunctioning in Children with Specific Reading Disability. 1982, W. S. Sobotowicz and J. R. Evans. Springfield, IL, Charles C Thomas, 1982, $19.75, 130 pp.

National Boards Examination Review, For Part II, Clinical Sciences. R. E. Pieroni. Garden City, NY, Medical Examination Publishing Co, 1982, $24.75, 362 pp.

This Is How My Body Works. E. Heuser (illustrated by D. Metteldirgrn). Woodbury, NY, Barron's Education Series, Inc, 1982, $3.95, 75 pp.

Child & Adolescent Psychiatry, Continuing Education Review, ed 2. Edited by G. P. Sholevar. Garden City, NY, Medical Examination Publishing Co, 1982, $28, 311 pp.

Euthanasia and Clinical Practice: Trends, Principles and Alternatives. The Report of a Working Party: The Linacre Centre. Liverpool, England, The Linacre Centre, 1982, £ 2.75, 88 pp.

Handbook of Audiological Rehabilitation. G. D. Chermak. Springfield, IL, Charles C Thomas, 1982, $34.75, 452 pp.

Reports of the Ross Conferences on Pediatric Research Nos 71-80, 1977-1981, by Ross Labs. Columbus, OH, Ross Laboratories, 1982.

Milk-Free Diet, Cookbook: Cooking for the Lactose Intolerant. E. A. Gelzayd. New York, Sterling Publishing Co, 1982, $12.95 ($6.95 paperback), 155 pp.

The Limb Deficient Child. Y. Setoguchi and R. Rosenfelder. Springfield, IL, Charles C Thomas, 1982, $32.50, 322 pp.

Premature Babies: A Handbook for Parents. Sherri Nance and Premature, Inc. New York, Arbor House Publishing Co, 1982, $15.95, 316 pp.

The Practice of Pediatric Neurology, Volumes 1 and 2, ed 2. K. F. Swaiman and F. S. Wright. St Louis, CV Mosby Co, 1982, $169.50 (set), 1322 pp.

What Shall We Tell the Kids? B. Olshaker. New York, Arbor House Publishing Co, 1982, $6.95, 256 pp.

Neurorehabilitation: A Multisensory Approach. S. D. Farber. Philadelphia, WB Saunders, 1982, $17.95 ($21.55 Canada), 282 pp.

The Role of Vision in The Multidisciplinary Approach to Children with Learning Disabilities: Proceedings from Learning Disabilities Institute II. Edited by M. Davis and J. C. Whitener. Springfield, IL, Charles C Thomas, 1982, $24.50, 307 pp.

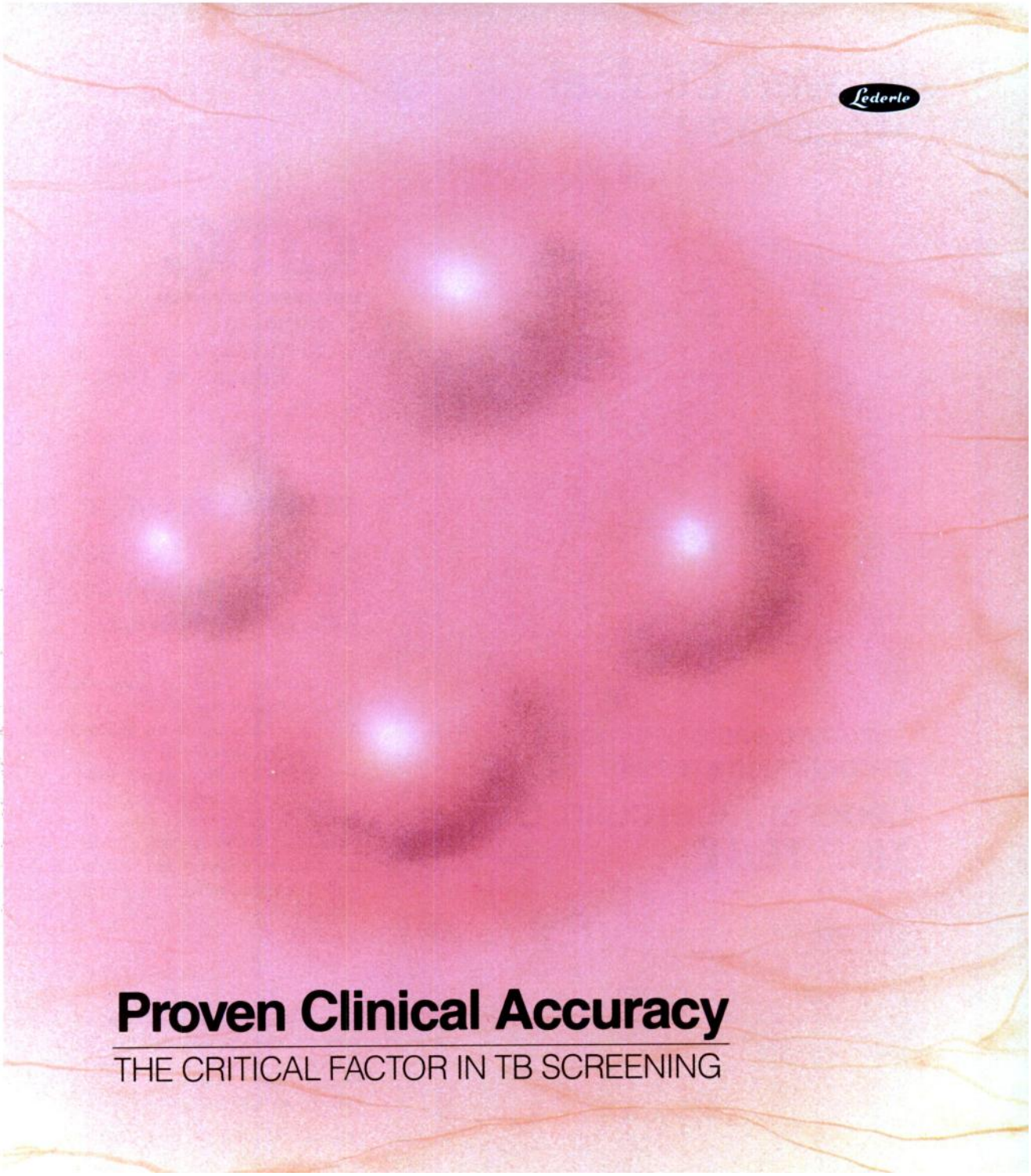
Failure to Thrive in Infancy and Early Childhood: A Multidisciplinary Team Approach. P. J. Accardo, Baltimore, University Park Press, 1982, $27.95, 410 pp.

Health Care of Women: Labor & Delivery. B. Gorvine, J. W. Hawkins, N. Fazekas, et al. Belmont, CA, Wadsworth, Health Sciences Division, 1982, $15.95, 117 pp.

Essential Trauma and Emergency Care. F. Wilson, New York, Appleton-Century-Crofts, Div of Prentice-Hall, Inc, 1982, $29, 308 pp.

Identifying the Developmentally Delayed Child. N. J. Anastasiow, W. K. Frankenburg, and A. W. Fandal, Baltimore, University Park Press, 1982, $29.95, 175 pp.

Artist's rendition of TB-positive induration



Lederle Tuberculin, Old, TINE TEST®

95.8% agreement with Mantoux

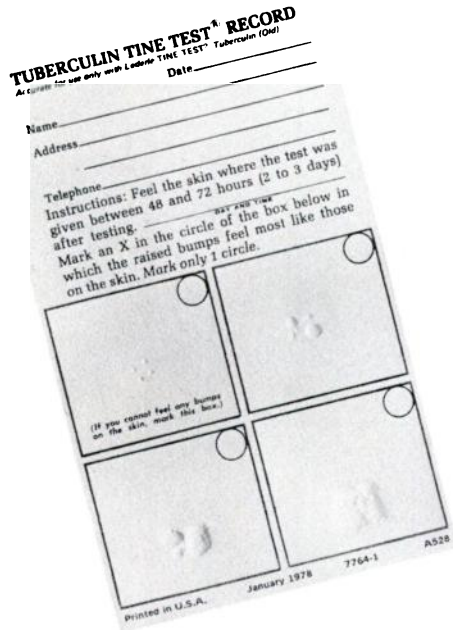
ACCURACY* demonstrated in over 31,000 clinical comparisons
BENEFITS confirmed in over 150,000,000 office uses

*Data on file – Lederle Laboratories, Pearl River, N.Y.

Please see following page for Brief Summary of Prescribing Information.

Proven Clinical Accuracy

THE CRITICAL FACTOR IN TB SCREENING



...and no easier method to confirm the results.

Lederle Tuberculin, Old, TINE TEST®

Indications: For screening for tuberculosis.

Precautions: Use with caution in persons with acute tuberculosis (activation of quiescent lesions is rare); and in patients with known allergy to acacia. Reactivity to the test may be suppressed in those receiving corticosteroids or immunosuppressive agents, or those who have recently been vaccinated with live virus vaccine such as measles, mumps, rubella, polio, etc. With a positive reaction, further diagnostic procedures must be considered, i.e., chest x-ray, microbiologic examinations of sputum and other specimens, confirmation of positive tine test (except vesiculation reactions) by Mantoux method. When vesiculation occurs, the reaction is to be interpreted as strongly positive and a repeat test by the Mantoux method must not be attempted. If a patient has a history of occurrence of vesiculation and necrosis with a previous tuberculin test by any method, tuberculin testing should be avoided. Similar or more severe vesiculation with or without necrosis is likely to occur.

Pregnancy Category C. Animal reproduction studies have not been conducted; whether Tuberculin, Old, TINE TEST® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity is unknown. Tuberculin, Old, TINE TEST should be given to a pregnant woman only if clearly needed. During pregnancy, known positive reactors may demonstrate a negative response.

Adverse Reactions: Vesiculation, ulceration, or necrosis may appear at test site in highly sensitive persons. Pain, pruritus and discomfort at test site may be relieved by cold packs or by topical glucocorticoid ointment or cream. Any transient bleeding at puncture site is not significant.

Lederle

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A Division of American Cyanamid Company
Wayne, New Jersey 07470

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American Academy of Pediatrics

CME

Continuing Medical Education 1982-83

PLAN NOW TO JOIN US FOR CME COURSE #2 . . . .

GENERAL PEDIATRICS

October 15-17, 1982
Del Webb's Sahara
Las Vegas, Nevada

This course has been designed to increase the pediatrician's knowledge in four subspecialty areas of pediatrics. The areas to be focused upon are: Allergy, Dermatology, Infectious Disease, and School Health. The School Health area will feature discussion of the pediatrician's management of the school-aged child, as well as his/her role as consultant to the schools. In all subject areas, lecture and workshop topics have been carefully selected to provide a review and update in the practical management of specific pediatric problems.

GUEST FACULTY

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William L. Weston, M.D., FAAP—*Dermatology*
Gregg F. Wright, M.D. and Lance A. Chilton, M.D., FAAP—*School Health*

George D. Comerci, M.D., FAAP—*Course Monitor*

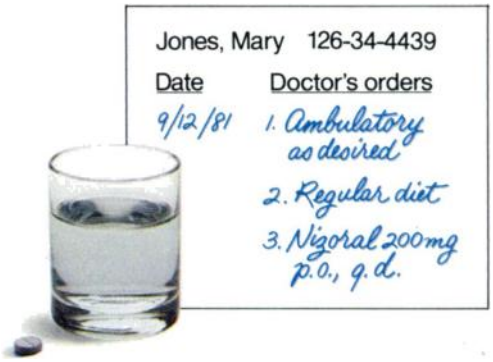
- Detailed information about this course, along with a course registration form, will be forwarded to you upon request.
- For further information, please contact:

Jean Dow
Department of Education
American Academy of Pediatrics
P.O. Box 1034
Evanston, IL 60204

Or phone toll-free (800) 323-0797

An important first:

NIZORAL® TABLETS (ketoconazole)



Safe and effective and offers a number of distinct advantages over nystatin in treating severe oral thrush

Saves time and trouble for patients and staff

- Simple one-tablet-a-day regimen fosters compliance, facilitates ambulatory and outpatient therapy
- No need for patients to suck on suppositories or swish around nystatin preparations several times a day
- Cost of therapy significantly less than nystatin treatment

Systemic action can reach remote Candida lesions

- In contrast to the topical action of nystatin, NIZORAL® (ketoconazole) can reach asymptomatic lesions in the esophagus or GI tract
- Excellent overall effectiveness...one week clinical cures seen in over 50 percent of patients
- SAFE: Can be administered for prolonged periods; well tolerated. Since possible idiosyncratic hepatocellular dysfunction has been reported, it is desirable to perform appropriate liver function tests before and during treatment, particularly in patients on long-term therapy.

Please see revised brief summary of Prescribing Information on next page.

Top: Severe oral thrush before therapy.
Bottom: After 7 days, 200 mg per day oral NIZORAL.

world leader in antimycotic research

JANSSEN PHARMACEUTICA

Janssen Pharmaceutica Inc., 501 George St., New Brunswick, N.J. 08903

JPI-312R

NIZORAL® TABLETS
(ketoconazole)

Before prescribing, please consult complete prescribing information, of which the following is a brief summary

INDICATIONS AND USAGE
NIZORAL® is indicated for the treatment of the following systemic fungal infections: candidiasis, chronic mucocutaneous candidiasis, oral thrush, candiduria, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis. NIZORAL® should not be used for fungal meningitis because it penetrates poorly into the cerebral-spinal fluid.

For the initial diagnosis, the infective organism should be identified; however, therapy may be initiated prior to obtaining laboratory results.

CONTRAINDICATIONS
NIZORAL® is contraindicated in patients who have shown hypersensitivity to the drug.

WARNINGS
Several cases of possible idiosyncratic hepatocellular dysfunction have been reported during NIZORAL® treatment. It is important to recognize that liver disorders may occur with NIZORAL® therapy. The rare occurrences of liver disorders could be potentially fatal unless properly recognized and managed.

It is desirable to perform liver function tests, such as SGGT, alkaline-phosphatase, SGPT, SGOT and bilirubin, before treatment and at periodic intervals during treatment (monthly or more frequent), particularly in patients who will be on prolonged therapy or who have a history of liver disease. Instances of minor elevations of liver enzyme levels in patients on NIZORAL® have been shown to normalize during therapy and may not necessitate discontinuation of treatment. However, if liver function tests are significantly elevated or other signs and symptoms are suggestive of hepatocellular dysfunction, ketoconazole should be discontinued.

In female rats treated three to six months with ketoconazole at dose levels of 80 mg/kg and higher, increased fragility of long bones, in some cases leading to fracture, was seen. The maximum "no-effect" dose level in these studies was 20 mg/kg (2.5 times the maximum recommended human dose). The mechanism responsible for this phenomenon is obscure. Limited studies in dogs failed to demonstrate such an effect on the metacarpals and ribs.

PRECAUTIONS
General: In four subjects with drug-induced achlorhydria, a marked reduction in NIZORAL® absorption was observed. NIZORAL® requires acidity for dissolution. If concomitant antacids, anticholinergics, and H_2-blockers are needed, they should be given at least two hours after NIZORAL® administration. In cases of achlorhydria, the patients should be instructed to dissolve each tablet in 4 ml aqueous solution of 0.2 N HCl. For ingesting the resulting mixture, they should use a glass or plastic straw so as to avoid contact with the teeth. This administration should be followed with a cup of tap water.

Information for Patient: Patient should be instructed to report any signs and symptoms which may suggest liver dysfunction so that appropriate biochemical testing can be done. Such signs and symptoms may include unusual fatigue, nausea or vomiting, jaundice, dark urine or pale stools (see WARNINGS).

Drug Interactions: There is no evidence for clinically significant interaction with oral anticoagulant or oral hypoglycemic agents.

Carcinogenesis, Mutagenesis, Impairment of Fertility: The dominant lethal mutation test in male and female mice revealed that single oral doses of NIZORAL® as high as 80 mg/kg produced no mutation in any stage of germ cell development. The Ames' *Salmonella* microsomal activator assay was also negative.

Pregnancy: Teratogenic effects. *Pregnancy Category C.* NIZORAL® has been shown to be teratogenic (syndactylia and oligodactylia) in the rat when given in the diet at 80 mg/kg/day, (10 times the maximum recommended human dose). However, these effects may be related to maternal toxicity, evidence of which also was seen at this and higher dose levels.

There are no adequate and well controlled studies in pregnant women. NIZORAL® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic effects. NIZORAL® has also been found to be embryotoxic in the rat when given in the diet at doses higher than 80 mg/kg during the first trimester of gestation.

In addition, dystocia (difficult labor) was noted in rats administered NIZORAL® during the third trimester of gestation. This occurred when NIZORAL® was administered at doses higher than 10 mg/kg (higher than 1.25 times the maximum human dose).

It is likely that both the malformations and the embryotoxicity resulting from the administration of NIZORAL® during gestation are a reflection of the particular sensitivity of the female rat to this drug. For example, the oral LD_{50} of NIZORAL® given by gavage to the female rat is 166 mg/kg, whereas in the male rat the oral LD_{50} is 287 mg/kg.

Nursing Mothers: Since NIZORAL® is probably excreted in the milk, mothers who are under NIZORAL® treatment should not breast-feed the child.

Pediatric Use: Safety in children under two years of age has been documented in a limited number of cases.

ADVERSE REACTIONS
NIZORAL® is usually well tolerated. Most adverse reactions reported have been mild and transient and have only rarely required withdrawal of therapy.

The most frequent adverse reactions were nausea and/or vomiting, which occurred in approximately 3% of patients. Abdominal pain was reported in approximately 1.2% of patients, pruritus in approximately 1.5% of patients. The following have been reported in less than 1% of patients: headache, dizziness, somnolence, fever and chills, photophobia, diarrhea, jaundice and gynecomastia.

Transient increases in serum liver enzymes have been observed. In the majority of cases, these increases have normalized during therapy or shortly after drug has been discontinued. However, several cases of idiosyncratic hepatocellular dysfunction have been reported (see WARNINGS).

OVERDOSAGE
In the event of accidental overdosage, supportive measures, including gastric lavage with sodium bicarbonate, should be employed.

DOSAGE AND ADMINISTRATION
Adults: The recommended starting dose of NIZORAL® is a single daily administration of 200 mg (one tablet). In very serious infections or if clinical responsiveness is insufficient within the expected time, the dose of NIZORAL® may be increased to 400 mg (two tablets) once daily.

Children:

Children weighing 20 kg or less	50 mg (¼ tablet) once daily
Children weighing 20-40 kg	100 mg (½ tablet) once daily
Children weighing over 40 kg	200 mg (1 tablet) once daily

Generally, treatment should be continued until all clinical and laboratory tests indicate that active fungal infection has subsided. Inadequate periods of treatment may yield poor response and lead to early recurrence of clinical symptoms. Minimum treatment for candidiasis is one or two weeks. Patients with chronic mucocutaneous candidiasis usually require maintenance therapy. Minimum treatment for the other indicated systemic mycoses is six months.

HOW SUPPLIED
NIZORAL® is available as white, scored tablets containing 200 mg of ketoconazole debossed "JANSSEN" and on the reverse side debossed "K" and "200". They are supplied in bottles of 60 tablets and in blister packs of 10 x 10 tablets. Rev Feb 1982

U.S. Patent Pending
NDC 50458-220-01 (10 x 10 tablets-blister)
NDC 50458-220-06 (60 tablets)

Manufactured by
Janssen Pharmaceutica n.v.
B-2340 Beerse, Belgium

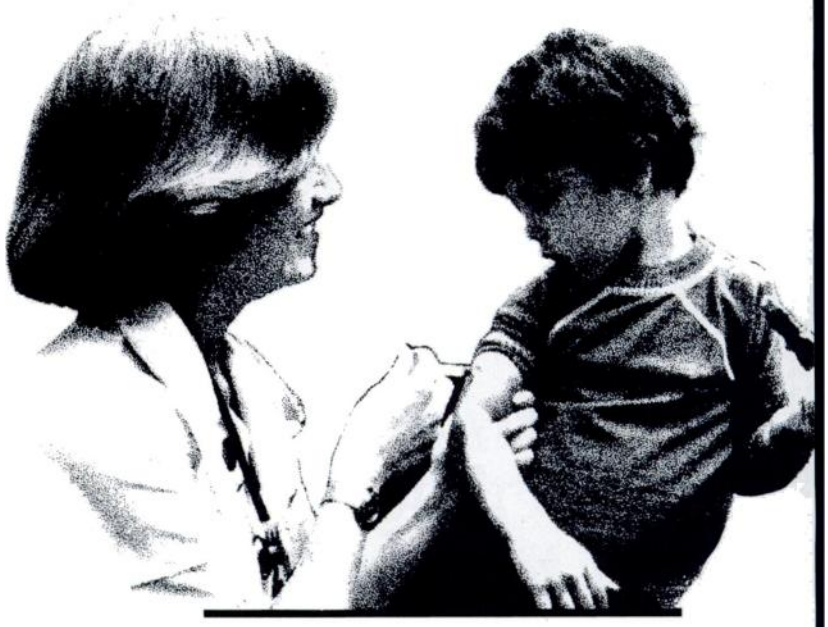
For
Janssen Pharmaceutica Inc.
New Brunswick, New Jersey 08903 USA

world leader in antimycotic research

JANSSEN PHARMACEUTICA

501 George St., New Brunswick, N.J. 08903

The new "Red Book" is here...



The 19th edition of the Academy's quick reference guide to more than 100 communicable diseases is now available for purchase.

New sections of this authoritative handbook, officially known as the "Report of the Committee on Infectious Diseases," include recently described diseases caused by coronaviruses, *Legionella pneumophilia*, hepatitis B and non A and non B hepatitis, Kawasaki disease and yersinia species, and use of new vaccines and specific immune globuline preparations for hepatitis, rabies, varicella-zoster, and pneumococcal infection. 1982; 32 tables; indexed; 379 pages.

Note: All Fellows and Junior Fellows will be mailed one complimentary copy in June.

Please send me:
____ copies, "Infectious Diseases" @ $15.00

Mail to:
American Academy of Pediatrics
Publications Department
P.O. Box 1034
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☐ Check for $ _____ is enclosed. Personal order must be prepaid. Make check payable to: American Academy of Pediatrics.

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HISTORY OF OXYGEN THERAPY AND RETROLENTAL FIBROPLASIA

As medical technology improves and more patients survive conditions which once meant certain death, the demand for better treatment of problems which may afflict these survivors has increased. This is particularly true for infants who develop retrolental fibroplasia. It is now known that the administration of oxygen which saves the lives of numerous premature and low birthweight infants also causes the development of retrolental fibroplasia—in many instances leading to permanent blindness.

The Committee on Fetus and Newborn of the American Academy of Pediatrics strives to make conditions ideal for all newborn infants, and it has become increasingly concerned about the infants who develop retrolental fibroplasia. In an attempt to compress the work done by researchers throughout the world into one document—and thus more easily see possible causes and solutions as well as stimulate more research—the Committee prepared and wrote the History of Oxygen Therapy and Retrolental Fibroplasia. This document, which was published as a supplement to *Pediatrics,* is available to all persons involved with or interested in the treatment of newborn infants, especially infants who are at high risk for developing retrolental fibroplasia.

The sequence of events concerning the use of oxygen and the development of retrolental fibroplasia is given. Considerable attention has been paid to the historical background of modern care for premature infants, the status of medical practice when oxygen was first used on premature infants, and the process of dissemination of new research data. Included are the Academy's recommendations on the use of oxygen through the years, the current state regulations on the use of oxygen, and six pages of references which go back as far as 1862.

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Prescribe

Coly-Mycin® S Otic

with Neomycin and Hydrocortisone

(colistin sulfate-neomycin sulfate-thonzonium bromide-hydrocortisone acetate otic suspension)

This season, when patients complain of pain and inflammation of "swimmer's ear" (or other summertime external ear disorders due to susceptible bacterial organisms) prescribe the comprehensive symptomatic relief of Coly-Mycin S Otic.

Each drop delivers:

Hydrocortisone Acetate—for fast reduction of inflammation and symptomatic pain relief

Colistin Sulfate/Neomycin Sulfate—for broad antibacterial coverage with emphasis on gram-negative Ps aeruginosa

Thonzonium Bromide—for enhanced efficiency by allowing penetration and dispersion of active ingredients through debris and exudate

Recommended Dosage: Adults—4 drops in each affected ear, 3-4 times daily.

Infants & Children: 3 drops in each affected ear, 3-4 times daily.

Available in 2 convenient sizes—each in a convenient, dropperless, breakproof, plastic bottle.

5 ml* for unilateral otic involvement
10 ml for bilateral otic involvement

*5-ml size supplies sufficient medication for an average course of therapy in one affected ear.

Before prescribing, please see full prescribing information. A brief summary appears on the opposite page.

PD-03-JA-0939-P-1(4-82)

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WARNER LAMBERT

VOLUME 70 • AUGUST 1982 • NUMBER 2

Pediatrics

Neonatal Seizures
I. Correlation of Prenatal and Perinatal Events with Outcomes

Kenton R. Holden, MD, E. David Mellits, ScD, and John M. Freeman, MD

From the Departments of Neurology and Pediatrics, Division of Pediatric Neurology, The Johns Hopkins University School of Medicine, Baltimore

ABSTRACT. A review of 277 newborns with neonatal seizures enrolled in the Collaborative Perinatal Project revealed a mortality of 34.8%. Of the 181 survivors, most followed up to age 7 years, 70% were normal. Thus, despite the fact that seizures are a major indicator of perinatal asphyxia and a predictor of subsequent neurologic deficit, most infants with neonatal seizures who survived did well. Thirteen percent had cerebral palsy, 19% had an IQ <70, and 20% had epilepsy. Thirteen percent of survivors had a combination of mental retardation, cerebral palsy, or epilepsy. A low Apgar score, the need for resuscitation after 5 minutes of age, low birth weight, and the early onset of seizures or prolonged seizures correlated with adverse outcome. *Pediatrics* 70:165–176, 1982; *seizures, neonate, mental retardation, cerebral palsy, epilepsy.*

During the neonatal period, as at later ages, seizures are a symptom of an acute disturbance of the brain. Although they have varied etiologies, most neonatal seizures are thought to result from perinatal asphyxia and/or intracranial hemorrhage.

Neonatal seizures appear to have value as an indicator of subsequent mortality[1,2] and morbidity[1-4] in survivors. If we are to decrease the morbidity and mortality that follow seizures in the newborn, we must first understand the sequence of events leading to the seizures, so that we can devise strategies for preventing or alleviating the causative events.

A unique opportunity to assess neonatal seizures, ie, seizures occurring in the first 28 days of life, was provided by the National Collaborative Perinatal Project (NCPP) of the National Institute of Neurological and Communicative Disorders and Stroke. This project prospectively registered 54,000 pregnant women whose infants were then observed for seven years. The project supplied data with which to examine both neonatal seizures per se and also the prenatal and perinatal factors associated with their appearance. In addition, the NCPP offered a basis for evaluating the prognosis of infants with neonatal seizures and the factors involved in, or predictive of, that prognosis.

This report presents in detail the outcomes of 277 infants with neonatal seizures from the National Collaborative Perinatal Project. Subsequent reports will detail antecedents of neonatal seizures and predictors of outcomes.

METHODOLOGY

The NCPP recorded events of pregnancy, labor, delivery, nursery course, and seven- to eight-year follow-ups in approximately 54,000 pregnancies registered at 12 urban, university-affiliated hospitals in different regions of the United States between 1959 and 1966. Included in the follow-up data were re-

Received for publication July 20, 1981; accepted Oct 1, 1981.
Reprint requests to (J.M.F.) Department of Neurology, The Johns Hopkins Hospital, 600 N Wolfe St, Baltimore, MD 21205.

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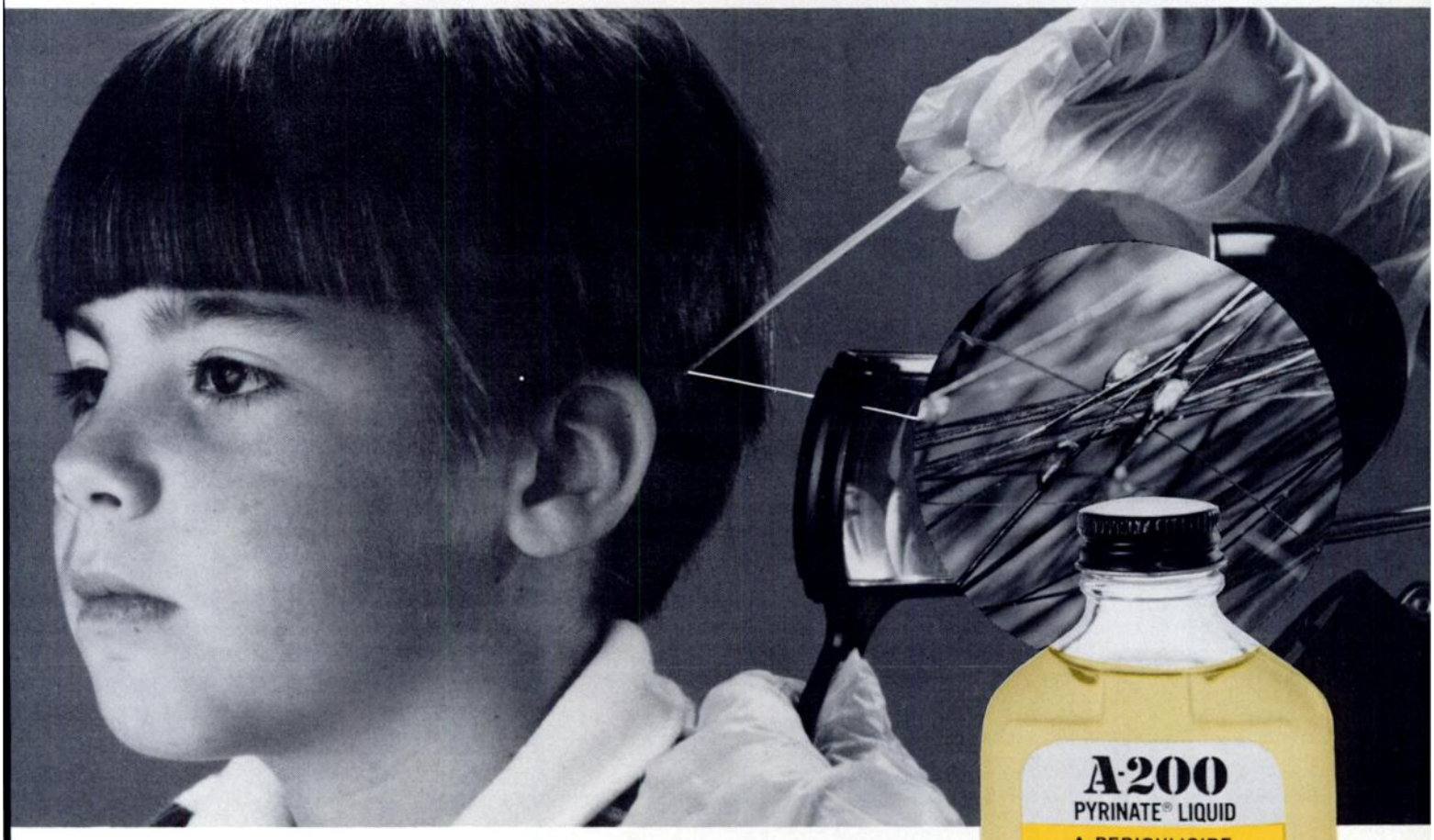

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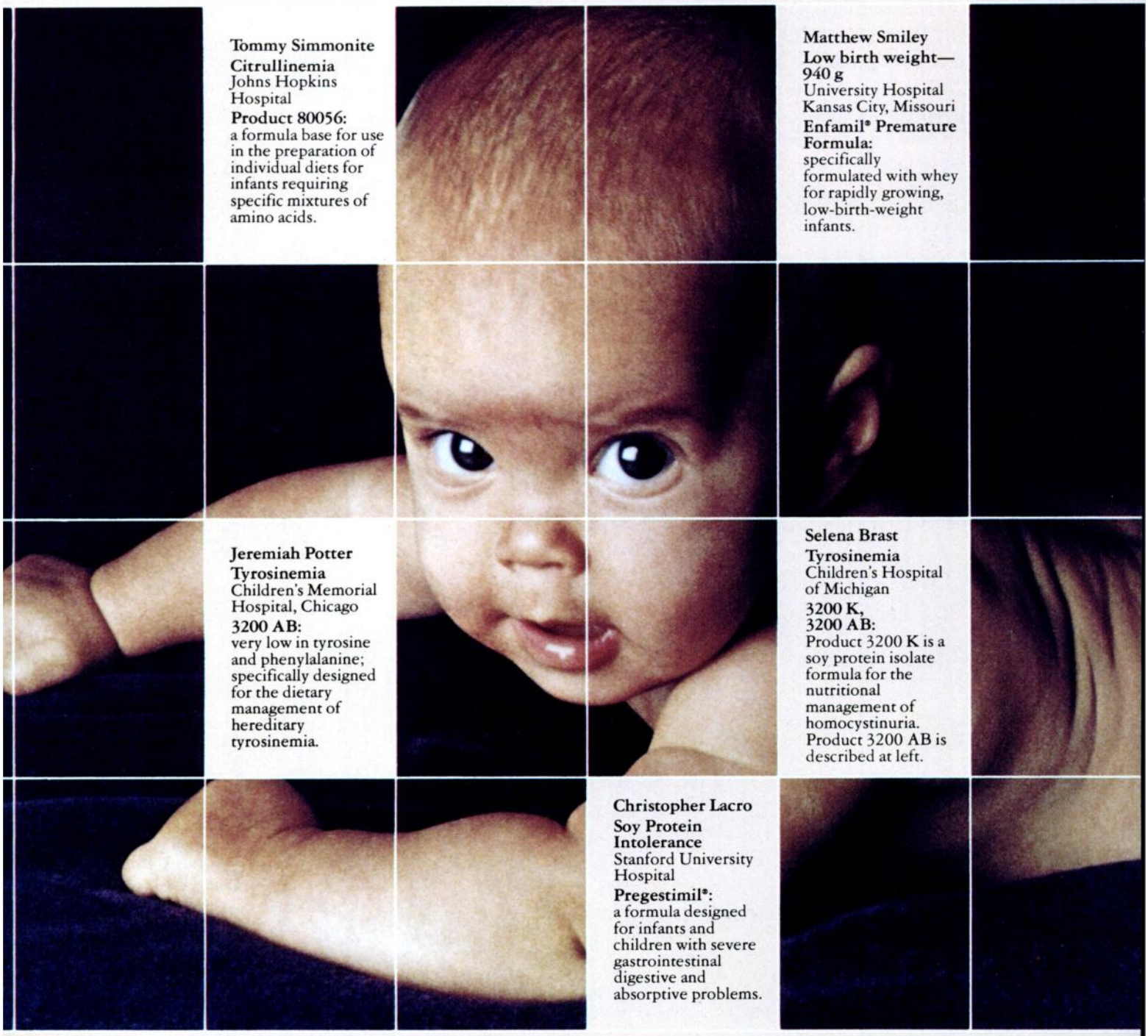

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Johns Hopkins Hospital
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a formula base for use in the preparation of individual diets for infants requiring specific mixtures of amino acids.

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a formula designed for infants and children with severe gastrointestinal digestive and absorptive problems.

**Mead Johnson would like to thank the families of these infants for their cooperation in the development of this message.*

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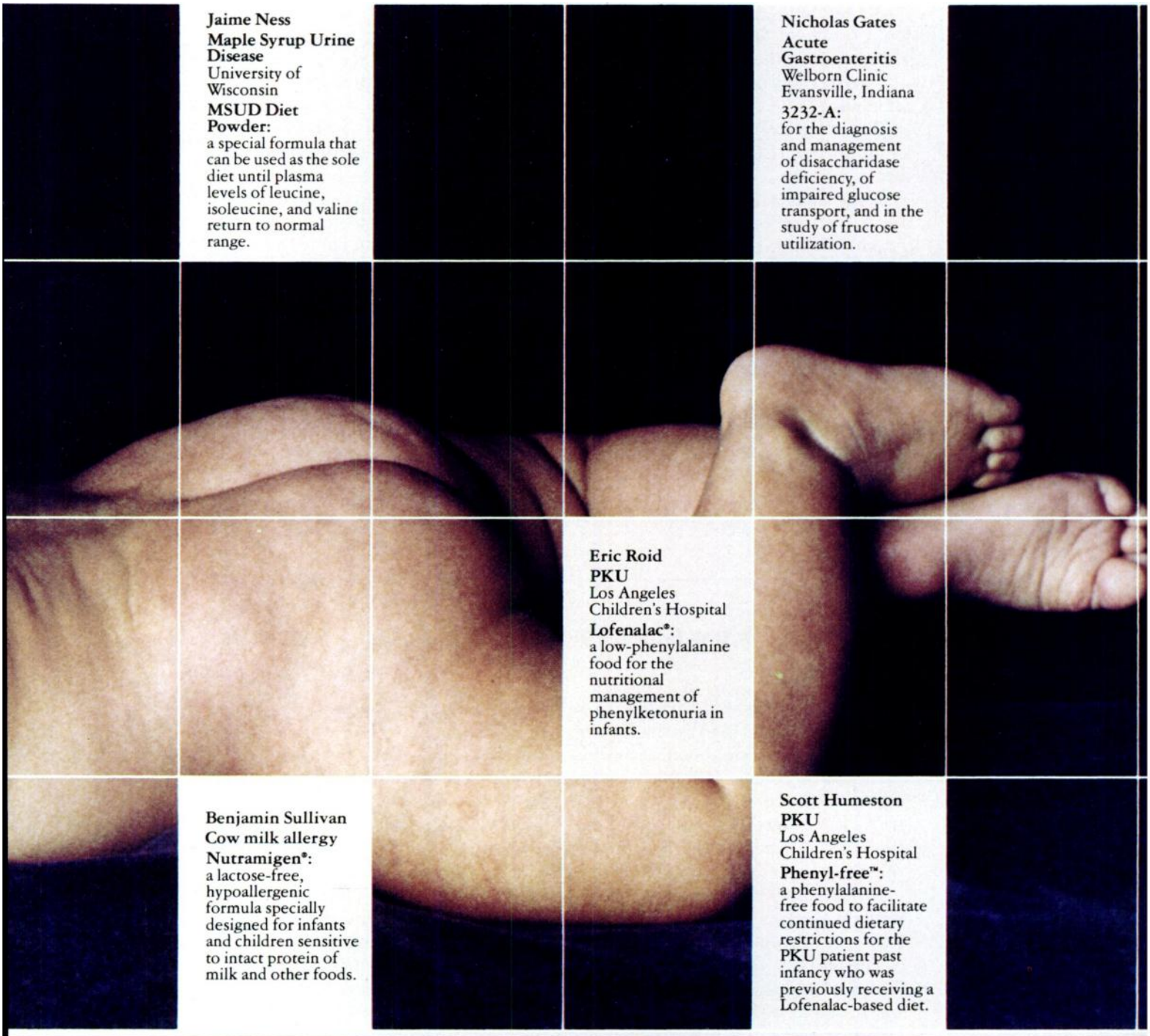
The only company dedicated to making a difference in special lives like these.



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If a very special company like Mead Johnson had not been around to solve the feeding problems of these infants, their lives might have been very different.

This is because our commitment to infant feeding goes far beyond good nutrition for normal infants.

Mead Johnson cares about those special babies whose nutritional well-being depends upon our continuing research and product development.

And *only* Mead Johnson supports you with this total commitment to good nutrition for all infants. And that's why we've earned your specification of Enfamil® for normal infants—when breast-feeding is not chosen—and ProSobee® for common feeding problems.

Mead Johnson
NUTRITIONAL DIVISION

IMPERFECT PARENTS

A year or so ago my calico cat produced two kittens and promptly embarked on a course of flawless child care: nursing, nuzzling, fetching and carrying. In three months the kittens were on their own, but until then the calico had been the perfect mother. The mother, in fact, that all women are presumed capable of being.

Only they are not: miracles don't happen when a woman gives birth. The child does not turn into an adult, or the sick become well, or the frightened become brave.

Some women know how to raise children—not out of instinct, as myth would have it, but probably because their mothers knew how. Other women should be taught, and some women should be trusted only with kittens. A cat with a litter may be identical to every other cat with a litter, but mothers are alike only in the fact of parturition.

A 14-year old with a baby doesn't fit the romantic image of mother and child; neither does a welfare mother with a houseful of fatherless kids. What they may symbolize for some, however, is sexual promiscuity—and the legislation that is presented as an economic measure may be, instead, a kind of punishment.

If motherhood were to be stripped of its myths and seen for what it is—a hard and painful job for which not everyone is fit but in which many can be helped, to their offspring's benefit—a few more women might lose their children.

From Mary Cantwell: *The New York Times*, Oct 30, 1981.

WORK HABITS IN CHILDHOOD FOUND TO PREDICT ADULT WELL-BEING

The willingness and capacity to work in childhood is the most important forerunner—more than native intelligence, social class or family situation—of mental health in adulthood, according to the results of a newly published study.

Among more than 450 white men from working-class families who were tested and interviewed periodically over a 35-year period, those who had been industrious as youngsters turned out to be the most well-adjusted adults and to have the most successful work lives and the most satisfying personal relationships, the study in The American Journal of Psychiatry showed.

A related conclusion of the report is that the capacity for adult work—even if this capacity is defined by something "as crass as wages and unemployment"—is closely related to both mental health and the capacity to love.

The authors, Dr. George E. Vaillant of Harvard Medical School and his wife, Caroline O. Vaillant, a social worker at University Health Services in Cambridge, Mass., see far-reaching implications in these findings. "Sociology should pause before it seeks the sole etiology of poverty and unemployment in external factors," they said in the article. "The sources of job failure do not always rest on ignorance, dropping out of school, the absence of a trade or faulty knowledge of the job market. Being chronically unemployed often has more to do with chronic depression and emotional instability than with prior training and ability."

From Dava Sobel: *The New York Times*, Nov 10, 1981.

ALL FOR ONE
ONE FOR ALL

Alexandre Dumas'
The Three Musketeers
and D'Artagnan

ONE FOR ALL – One tablet treats pinworm in any patient, regardless of age or body weight.* Obviates need to calculate individual dosages.

A single tablet eradicates pinworm in 95% of patients.

*Contraindicated in pregnant women and in persons who have shown hypersensitivity to the drug.

VERMOX® CHEWABLE TABLETS
(mebendazole)

JANSSEN PHARMACEUTICA

The #1 anthelmintic for pinworms and many other worm infestations

Please see complete Prescribing Information on adjacent page.

VERMOX® CHEWABLE TABLETS
(mebendazole)

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Vermox
Tabs #4
Sig 1 tab
each family
member

DESCRIPTION VERMOX (mebendazole) is methyl 5-benzoylbenzimidazole-2-carbamate.

ACTIONS VERMOX exerts its anthelmintic effect by blocking glucose uptake by the susceptible helminths, thereby depleting the energy level until it becomes inadequate for survival. In man, approximately 2% of administered mebendazole is excreted in urine as unchanged drug or a primary metabolite. Following administration of 100 mg of mebendazole twice daily for three consecutive days, plasma levels of mebendazole and its primary metabolite, the 2-amine, never exceeded 0.03 μg/ml and 0.09 μg/ml, respectively.

INDICATIONS VERMOX is indicated for the treatment of *Trichuris trichiura* (whipworm), *Enterobius vermicularis* (pinworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm) in single or mixed infections. Efficacy varies as a function of such factors as pre-existing diarrhea and gastrointestinal transit time, degree of infection and helminth strains. Efficacy rates derived from various studies are shown in the table below:

	Whipworm	Common Roundworm	Hookworm	Pinworm
cure rates				
mean	68%	98%	96%	95%
(range)	(61-75%)	(91-100%)	–	(90-100%)
egg reduction				
mean	93%	99.7%	99.9%	–
(range)	(70-99%)	(99.5%-100%)	–	–

CONTRAINDICATIONS VERMOX is contraindicated in pregnant women (see Pregnancy Precautions) and in persons who have shown hypersensitivity to the drug.

PRECAUTIONS *PREGNANCY:* VERMOX has shown embryotoxic and teratogenic activity in pregnant rats at single oral doses as low as 10 mg/kg. Since VERMOX may have a risk of producing fetal damage if administered during pregnancy, it is contraindicated in pregnant women.

PEDIATRIC USE: The drug has not been extensively studied in children under two years; therefore, in the treatment of children under two years the relative benefit/risk should be considered.

ADVERSE REACTIONS Transient symptoms of abdominal pain and diarrhea have occurred in cases of massive infection and expulsion of worms.

DOSAGE AND ADMINISTRATION The same dosage schedule applies to children and adults. The tablet may be chewed, swallowed or crushed and mixed with food. For the control of pinworm (enterobiasis), a single tablet is administered orally, one time. For the control of common roundworm (ascariasis), whipworm (trichuriasis), and hookworm infection, one tablet of VERMOX is administered, orally, morning and evening, on three consecutive days. If the patient is not cured three weeks after treatment, a second course of treatment is advised. No special procedures, such as fasting or purging, are required.

HOW SUPPLIED VERMOX is available as chewable tablets, each containing 100 mg of mebendazole, and is supplied in boxes of twelve tablets.
VERMOX (mebendazole) is an original product of Janssen Pharmaceutica, Belgium.

US Patent 3,657,267
December 1979

Committed to research...
because so much remains to be done.

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JPI-282

Dealing with the problems of school children

A new (1981) edition of School Health: A Guide for Health Professionals is now available. Revised by the AAP Committee on School Health, this manual gives practical information on how school health programs function and how these programs fit into the school structure. It discusses the problems of pre-school age children, elementary school children and adolescents, and has a section on children with special educational needs. In addition, it reports on screening tests needed as well as the essentials of history and physical examination, follow-up procedures and record keeping. Other points of interest are: health education, physical education, physical activities for children with handicaps, dental care, school sports programs, communicable disease, emergency care in schools, school personnel problems and school safety.

The book also includes 16 appendices and 3 tables. Indexed: 297 pages.

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The most immunized child in the history of medicine needs this added prophylaxis.

You immunize him against diphtheria, tetanus, pertussis, polio, mumps, rubella and measles. You also help protect him against dental caries and vitamin deficiencies. . . .

Now, help give him prophylaxis against the ravaging rays of the sun.

Running free—unprotected. Moderate overexposure may cause erythema, pain and sleep disturbances. Lengthy overexposure damages the epidermis and dermis, resulting in vesiculation, edema and fever. Repeated excessive exposure may lead to premature aging, solar keratosis and cancer.

High noon. Damaging ultraviolet rays, particularly the UVB band, are most intense from 10:00 to 2:00. They penetrate cloud cover, fog and haze, as well as lightweight summer clothing and are also reflected by sand and snow.

SUNDOWN Sunscreen for sand-castle architects and wandering Huck Finns.

SUNDOWN, like other JOHNSON & JOHNSON products, has a gentle formula for use on children's skin. SUNDOWN is an easy-to-use lightly scented skin lotion. Smooth and soft, it's not greasy or sticky, and won't sting or burn.

And most important, SUNDOWN is water resistant so it won't easily swim off or sweat away. . . providing continuous protection without constant reapplication. . . an economical consideration as well. But it is simple to remove with soap and water.

Lifetime prophylaxis. Like brushing teeth and taking vitamins, remind parents that sparing the skin should become a lifetime habit. . . and that SUNDOWN is protection for the entire family.

The most preferred protection under the sun.

60 MILLION LITTLE REASONS FOR TB TESTING...

plus a lot of big reasons

Exposed daily to crowded conditions, are not our 60 million school children prime candidates for routine annual TB testing?

And shouldn't adults—eg, customs inspectors, health care personnel, food handlers, salespeople—who are in daily contact with the public be tested annually, too?

APLITEST®

(TUBERCULIN PURIFIED PROTEIN DERIVATIVE) MULTIPLE-PUNCTURE DEVICE

convenient, sterile, disposable screening device

- for the detection of tuberculin-sensitive individuals in office or clinic
- greater overall test agreement with the Mantoux test than Old Tuberculin
- low incidence of false-positive reactions compared to Old Tuberculin-coated tine

Only Parke-Davis supplies both!

APLISOL®

(TUBERCULIN, PURIFIED PROTEIN DERIVATIVE, DILUTED [STABILIZED SOLUTION])

helps substantiate doubtful screening test results

- clinically equivalent in potency to the standard PPD-S (5 TU per 0.1 ml)
- Tuberculin PPD is recommended by the American Lung Association as an aid in the detection of infection with Mycobacterium tuberculosis

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PD-32-JA-0209-P-2 (5-82)

Before prescribing, please see full prescribing information. A Brief Summary follows:

Aplisol®
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Aplitest®
Tuberculin, Purified Protein Derivative Multiple-Puncture Device

INDICATIONS, Aplisol: Tuberculin PPD is recommended by the American Lung Association as an aid in the detection of infection with *Mycobacterium tuberculosis*. The standard tuberculin test recommended employs the intradermal (Mantoux) test using a 5 TU dose of tuberculin PPD. The 0.1 ml test dose of Aplisol (tuberculin PPD, diluted) is equivalent to the 5 TU dose recommended as clinically established and standardized with PPD-S.

Aplitest: Aplitest is indicated to detect tuberculin-sensitive individuals. Aplitest units are also useful in programs to establish priorities for additional testing (i.e. chest x-rays) and in epidemiological surveys to identify areas with high levels of infection.

Regular periodic (annual) testing of tuberculin-negative persons is recommended and is especially valuable because the conversion of an individual from negative to positive is highly indicative of recent tuberculosis infection. Repeated testing of the uninfected individual does not sensitize to tuberculin. In persons with waning sensitivity to homologous or heterologous mycobacterial antigens, however, the stimulus of a tuberculin test may "boost" or increase the size of reaction to a second test, even causing an apparent development of sensitivity in some instances.

WARNINGS Tuberculin should not be administered to known tuberculin-positive reactors because of the severity of reactions (eg, vesiculation, ulceration or necrosis) that may occur at the test site in very highly sensitive individuals.

Aplisol: Avoid injecting tuberculin subcutaneously. If this occurs, no local reaction develops, but a general febrile reaction and/or acute inflammation around old tuberculous lesions may occur in highly sensitive individuals.

PRECAUTIONS As with any biological product, epinephrine should be immediately available in case an anaphylactoid or acute hypersensitivity reaction occurs.

Aplisol: A separate heat sterilized syringe and needle, or a sterile disposable unit, should be used for each individual patient to prevent possible transmission of homologous serum hepatitis virus and other infectious agents from one person to another.

Syringes that have previously been used with histoplasmin, blastomycin and other antigens should not be used for tuberculin.

Aplitest: A separate, sterile unit must be used for each individual patient and disposed of after use.

Sensitivity may decrease or disappear temporarily during or immediately following severe febrile illness, measles, and other exanthemas, live virus vaccination, sarcoidosis, overwhelming miliary or pulmonary tuberculosis and the administration of corticosteroids or immunosuppressive drugs. Severe malnutrition may also have a similar effect.

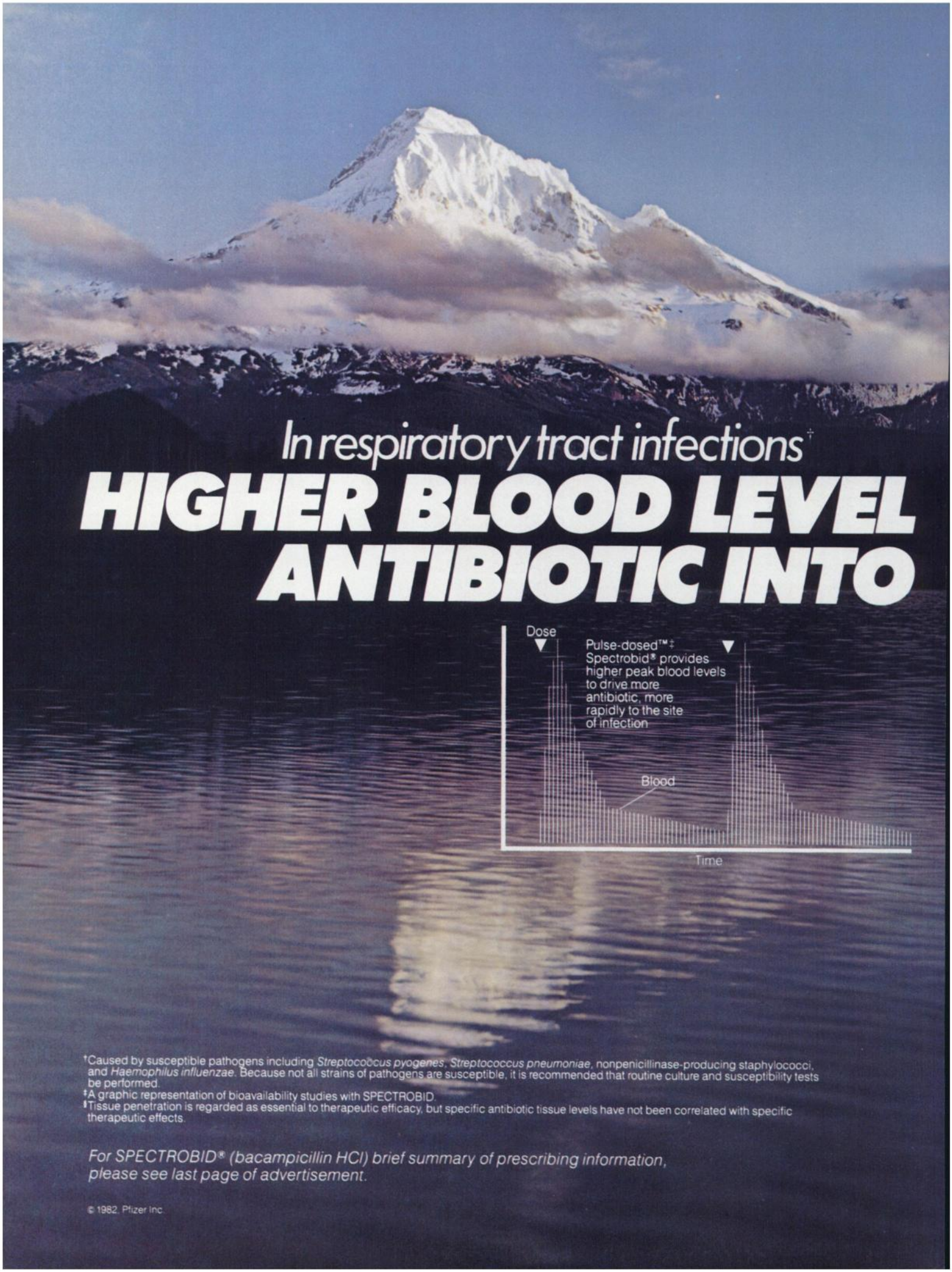
A positive tuberculin reaction does not necessarily signify the presence of active disease. Further diagnostic procedures should be carried out before a diagnosis of tuberculosis is made.

ADVERSE REACTIONS In highly sensitive individuals, strongly positive reactions including vesiculation, ulceration or necrosis may occur at the test site. Cold packs or topical steroid preparations may be employed for symptomatic relief of the associated pain, pruritus and discomfort.

Strongly positive test reactions may result in scarring at the test site.

Aplitest: Minimal bleeding may be experienced at a puncture site. This occurs infrequently and does not affect interpretation of the test.

ZD / ZF



†Caused by susceptible pathogens including *Streptococcus pyogenes*, *Streptococcus pneumoniae*, nonpenicillinase-producing staphylococci, and *Haemophilus influenzae*. Because not all strains of pathogens are susceptible, it is recommended that routine culture and susceptibility tests be performed.

‡A graphic representation of bioavailability studies with SPECTROBID.

‖Tissue penetration is regarded as essential to therapeutic efficacy, but specific antibiotic tissue levels have not been correlated with specific therapeutic effects.

For SPECTROBID® (bacampicillin HCl) brief summary of prescribing information, please see last page of advertisement.


PEAKS DRIVE MORE INFECTED TISSUE§...
WITH B.I.D. DOSING
Higher peak blood levels than with oral ampicillin,[1] amoxicillin,[2] erythromycin,[2] or tetracycline[3]
Higher peak tissue levels that are reached more rapidly than with oral ampicillin[4,5]
Outstanding clinical effectiveness in URI and LRI caused by susceptible pathogens[1]
Low incidence of diarrhea—low incidence of lower GI side effects, particularly diarrhea (2%). SPECTROBID is contraindicated in persons with a history of allergic reactions to penicillin antibiotics.
PULSE-DOSED™
SPECTROBID®
(bacampicillin HCl) 400 mg* tablets
*Chemically equivalent to 280 mg ampicillin
Now available for the infants you treat...
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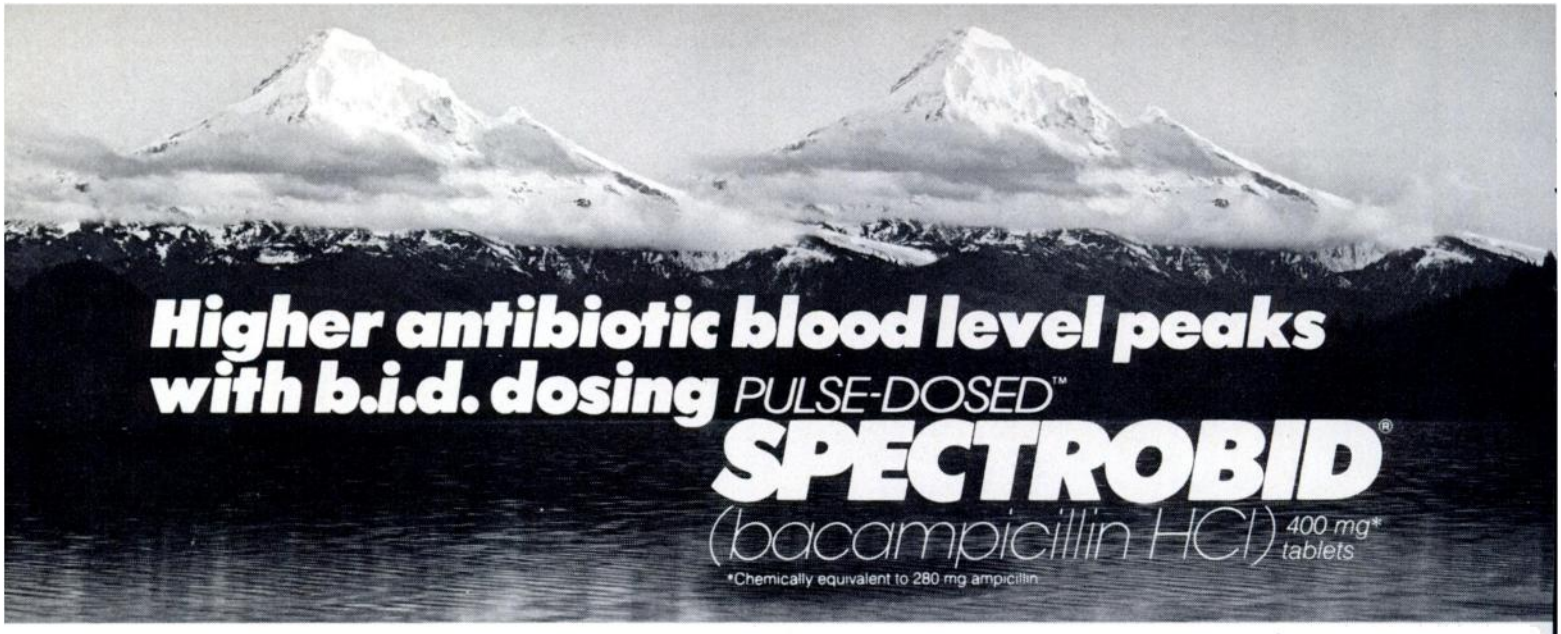
(bacampicillin HCl) 125 mg per 5 ml*
FOR ORAL SUSPENSION
*Chemically equivalent to 87.5 mg ampicillin
Dye free cherry flavor



Higher antibiotic blood level peaks with b.i.d. dosing

PULSE-DOSED™

SPECTROBID®

(bacampicillin HCl) 400 mg* tablets

*Chemically equivalent to 280 mg ampicillin

References: 1. Data on file, Roerig. 2. Manufacturer's product information. 3. Braude AI: *Antimicrobial Drug Therapy*, vol 7. Philadelphia, WB Saunders Co, 1976, p 68. 4. Bergogne-Berezin E, Berthelot G, Kafe H, et al: Penetration of ampicillin into human bronchial secretions. *Infection* 7 (suppl 5):463-464, 1979. 5. Bergogne-Berezin E, Lambert-Zechovsky N, Kafe H: Etude pharmacocinétique comparative de divers antibiotiques dans les sécrétions bronchiques. *Med Mal Infect* 6:134-137, 1976.

BRIEF SUMMARY

SPECTROBID® (bacampicillin HCl)

Bacampicillin is a member of the ampicillin class of acid resistant, orally administered semisynthetic penicillins. It is rapidly hydrolyzed to ampicillin in both tablet and suspension form.

Contraindications: Bacampicillin is contraindicated in individuals with a history of allergy to any of the penicillin antibiotics.

Warnings: Serious and occasionally fatal anaphylactic reactions have been reported in patients on penicillin therapy. Anaphylaxis is more frequent following parenteral therapy than with oral therapy. Severe reactions have also been reported in patients hypersensitive to penicillins who are treated with cephalosporins. Prior to penicillin therapy, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, and other allergens. IF AN ALLERGIC REACTION OCCURS, THE DRUG SHOULD BE DISCONTINUED AND APPROPRIATE THERAPY INSTITUTED. SERIOUS ANAPHYLACTIC REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE.

Precautions: Superinfections with mycotic and bacterial pathogens may occur during therapy. If these infections occur, discontinue the drug and initiate appropriate therapy. During prolonged therapy, periodically check for organ system dysfunction, including renal, hepatic, and hematopoietic systems, particularly in prematures, neonates, and patients with liver or renal impairment. Ampicillin class antibiotics should not be administered to patients with mononucleosis.

Clinically Significant Drug Interactions: The concurrent administration of allopurinol and ampicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to ampicillin alone. There are no data to date on the incidence of rashes in patients treated concurrently with SPECTROBID (bacampicillin HCl) and allopurinol. SPECTROBID should not be co-administered with Antabuse® (disulfiram).

Drug and Laboratory Test Interactions: It is recommended that glucose tests based on enzymatic glucose oxidase reactions (Clinistix® or Tes-Tape®) be used. Following administration of ampicillin to pregnant women a transient decrease in plasma concentration of total conjugated estriol, estriol-glucuronide, conjugated estrone, and estradiol has been noted.

Pregnancy Category B: Reproduction studies in mice and rats have revealed no evidence of impaired fertility or harm to the fetus due to SPECTROBID. There are no adequate and well controlled studies in pregnant women; therefore, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery: It is not known whether use of SPECTROBID during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor, or increases the likelihood that obstetrical intervention will be necessary.

Carcinogenicity, Mutagenicity, Impairment of Fertility: No carcinogenicity or mutagenicity studies have been conducted to date. There is no evidence of impaired fertility with SPECTROBID.

Nursing Mothers: Because ampicillin class antibiotics are excreted in milk, caution should be used when these antibiotics are administered to nursing mothers.

Pediatric Use: SPECTROBID tablets may be administered to children who weigh 25 kg or more. The oral suspension is indicated for children and infants who weigh less than 25 kg and in children who are unable to swallow tablets.

Adverse Reactions: As with other penicillins, untoward reactions will be limited essentially to sensitivity phenomena. These are more likely to occur in persons with hypersensitivity to penicillins and in those with a history of allergy, asthma, hay fever, or urticaria. In clinical trials the most frequent adverse reactions to SPECTROBID were epigastric upset (2%) and diarrhea (2%). Increased dosage may cause an increased incidence of diarrhea. The same clinical trials showed a 4% incidence of diarrhea and a 2% incidence of nausea with amoxicillin therapy.

The following adverse reactions to ampicillin have been reported:

Gastrointestinal: Diarrhea, gastritis, stomatitis, nausea and vomiting, glossitis, black "hairy" tongue, enterocolitis and pseudomembranous colitis.

Hypersensitivity Reactions: Skin rashes, urticaria, erythema multiforme; an occasional case of exfoliative dermatitis may occur, but may be controlled with antihistamines or systemic corticosteroids. Serious and occasionally fatal hypersensitivity reactions (anaphylactic) can occur with oral penicillins (See Warnings).

Liver: A moderate rise in serum glutamic oxaloacetic transaminase (SGOT) has been found in some ampicillin treated patients, but the significance of this finding is unknown. Studies indicate no difference between ampicillin and SPECTROBID in regard to liver function test abnormalities.

Hemic and Lymphatic Systems: Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reported during penicillin therapy. These reactions are usually reversible when therapy is discontinued.

Dosage and Administration (for susceptible organisms): SPECTROBID tablets may be given without regard to meals. SPECTROBID oral suspension should be administered to fasting patients.

Upper respiratory tract (including otitis media), urinary tract, and skin and skin structure infections.

Adults: 1 x 400 mg tablet every 12 hours (patients weighing 25 kg or more).

Children: 25 mg/kg/day tablets or suspension in 2 equally divided doses at 12 hour intervals.

In severe infections, lower respiratory infections, or those caused by less susceptible organisms.

Adults: 2 x 400 mg tablets every 12 hours (patients weighing 25 kg or more).

Children: 50 mg/kg/day tablets or suspension in 2 equally divided doses at 12 hour intervals.

Gonorrhea.

Adults: 4 x 400 mg tablets plus one gram of probenecid administered in a single dose.

No pediatric dosage has been established for treatment of gonorrhea.

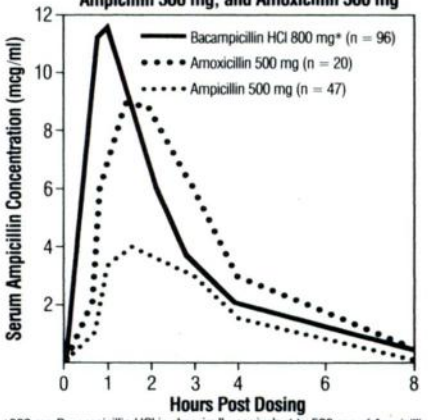
This is the usual dose in uncomplicated gonorrhea. In cases with suspected lesion of syphilis, perform a dark field examination before administering SPECTROBID. Monthly serological tests should be done for a minimum of four months. In the treatment of chronic urinary tract infections, frequent bacteriologic and clinical appraisals may be necessary. Stubborn infections may require several weeks' therapy, and it may be necessary to continue clinical and bacteriologic follow-up for several months following therapy. Except for gonorrhea, treatment should be continued for a minimum of 48 to 72 hours beyond the time the patient becomes asymptomatic or evidence of bacterial eradication has been obtained.

AT LEAST TEN DAYS' TREATMENT IS RECOMMENDED FOR INFECTIONS CAUSED BY HEMOLYTIC STREPTOCOCCI, TO PREVENT OCCURRENCE OF ACUTE RHEUMATIC FEVER OR GLOMERULONEPHRITIS.

How Supplied: SPECTROBID (bacampicillin HCl) is available as 400 mg white, film coated, oblong, unscored tablets, in bottles of 100; and in 70 ml, 100 ml, 140 ml, 200 ml bottles of powder for oral suspension. Each 5 ml of reconstituted suspension contains 125 mg bacampicillin HCl.

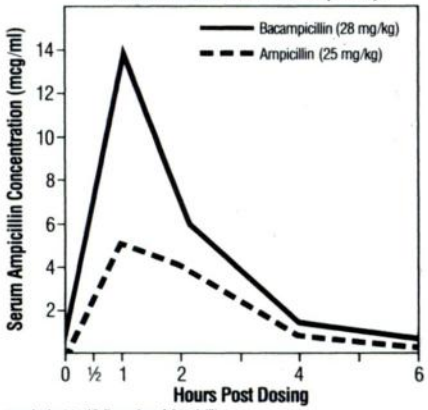
More detailed professional information is available on request.

Comparison of Bacampicillin HCl 800 mg, Ampicillin 500 mg, and Amoxicillin 500 mg



*800 mg Bacampicillin HCl is chemically equivalent to 560 mg of Ampicillin

Crossover Comparison of Bacampicillin HCl Oral Suspension (28 mg/kg)* with Ampicillin Oral Suspension (25 mg/kg) in Fasted Infants and Children (n = 7).



*equivalent to 19.5 mg/kg of Ampicillin

An important innovation in antibiotic therapy from

ROERIG Pfizer

A division of Pfizer Pharmaceuticals
New York, New York 10017

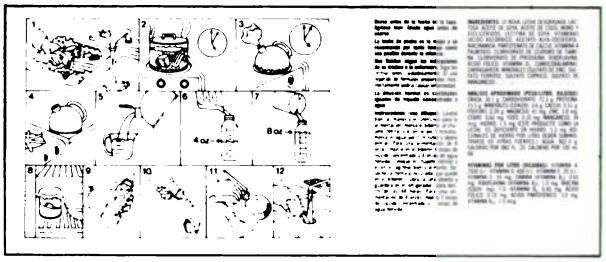
News From Ross Laboratories

At the cutting edge of infant nutrition

New Symbols For Familiar Labels

This symbol represents an innovation in infant formula labeling. It is the beginning of a new program designed to bring users more information on proper product preparation and use.

Using the universal language of pictures, this symbol directs the user to "cut the label."



One Pictogram Is Worth A Thousand Words

This pictogram is from the reverse side of the Similac® With Iron Infant Formula Concentrated Liquid label. It shows the user a proper method of preparing the formula in clear, easy-to-follow, numbered steps. This side of the label also includes information in Spanish, an added convenience for persons who read that language.

Labels with pictogram preparation instructions and information in Spanish are available only on Ross Laboratories infant formulas.

From Arabic To Vietnamese

Now, information on newborn care, breast-feeding, weaning, and formula preparation is available in Arabic, Cambodian, Chinese, French-Haitian, German, Greek, Hebrew, Hmong, Italian, Japanese, Korean, Laotian, Polish, Portuguese, Russian, Spanish, and Vietnamese.

Until now, non-English-language materials in the United States on infant care and nutrition have been almost nonexistent.

Only From Ross Laboratories

All Ross Laboratories Concentrated Liquid, Powder, and Ready To Feed infant formulas in cans now have new labels. Information on these new label products and the new non-English-language materials is available from your Ross Laboratories Territory Manager or by completing and returning the coupon below.

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Division of Abbott Laboratories, USA

B440/2850

COSTS AND BENEFITS OF SKULL RADIOGRAPHY FOR HEAD INJURY: A National Study by the Royal College of Radiologists

Over a period of 10 weeks, nine accident-and-emergency units in England, Wales, and Scotland took part in an investigation into the use of skull radiography in the management of patients with head injury. The yield of potentially important radiological findings in 4829 patients with uncomplicated head injury was 2 basal, 1 frontal, and 64 vault fractures. In 4 of these patients intracranial haematomas developed, of which 3 would have been suspected clinically and the patients admitted for observation even if skull radiography had not been available. At best, skull radiography could have contributed to the detection of only 1 of the 4 intracranial haematomas. The incidence of unsuspected intracranial haematoma with skull fracture among patients with uncomplicated head injury currently radiographed in the United Kingdom is therefore 1 in 4800. The radiological cost of identifying this 1 patient in our series was £43,200 (approximately $86,000).

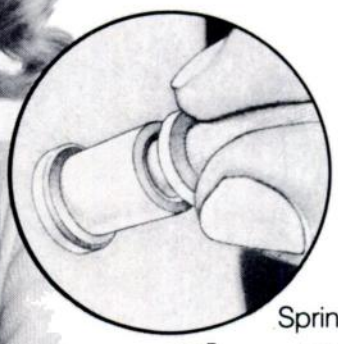
From *The Lancet*, Oct 10, 1981, p 791.

SERUM SALICYLATE CONCENTRATIONS IN REYE'S DISEASE

Serum salicylate concentration was measured at admission in 130 children with liver-biopsy-confirmed Reye's disease. Mean serum salicylate was 12.3 mg/dl and mean salicylate concentrations by neurological grade (Lovejoy) were: stage I, 12, stage II, 13, stage III, 11, Stage IV, 13, and stage V, 13 mg/dl. However, mean serum salicylate (15 mg/dl) at admission in 21 patients who died or had serious neurological deficits was significantly higher than that in 103 patients who survived without neurological sequelae (10 mg/dl). Serum salicylate in a group of 27 age-matched, community-matched control children collected consecutively over the period 1978–80 was less than 2 mg/dl, and children with varicella or influenza had salicylate concentrations indistinguishable from apparently well classmates or siblings. It is impossible to determine from this data whether salicylates are involved in the aetiology of or in determining the outcome of Reye's disease. Increased concentrations of salicylates at admission could be the result of excessive dosage because of a greater severity of the prodromal illness, or to diminished excretion because of impaired hepatic metabolism. It seems likely that serum salicylate concentrations entered the toxic range in many patients with Reye's disease before they presented for treatment. Most had been vomiting and had had diminished oral intake for 33–55 h before hospital admission. Since the average number of hours from the beginning of vomiting to admission was no diffrent in non-comatose and comatose cases, the time at which salicylate concentration was measured in relation to the last dose was probably similar in the two groups and therefore does not account for the higher levels in children with poor outcome. Salicylates are mitochondrial toxins and mitochondria are known to be significantly injured in Reye's disease; therefore, it seems wise to avoid the use of aspirin in children during outbreaks of Reye's disease.

From Partin JS, Partin JC, Schubert WK, et al: Serum salicylate concentrations in Reye's disease: A study of 130 biopsy-proven cases. *The Lancet*, Jan 23, 1982, pp 191–192.

Take the fear out of TB screening.



Spring-activated

SclavoTest®-PPD

Tuberculin Purified
Protein Derivative (PPD)

Because the unique design of SclavoTest-PPD hides the points from view, patients are less apprehensive. And since hidden points are projected only after the device is placed on the skin, the risk of pain or bleeding due to accidental twisting is minimized.

Results are easy to read and compare favorably with the reference method.[*] In a comparative study of 102 bacteriologically confirmed cases, there were more reactors to SclavoTest-PPD than to the reference method.

SclavoTest-PPD contains tuberculin *purified* protein derivative (PPD), not the "old" tuberculin (OT) used in some other tine-type tests.

Product, samples and patient Record Cards available through 200 Dealers nation-wide

[*] PPD-S 5 TU administered by the Mantoux method.

Warnings and Precautions: Dispose of safely after use—never reuse. Intensity of reaction may be diminished by delayed hypersensitivity caused by such factors as acute viral infection, vaccination with live virus vaccine, immunosuppression by disease or medication, anergic status (eg, sarcoidosis, malignancy), malnutrition (especially in children), overwhelming infections, advancing age. Also, some individuals with tuberculosis infection but with none of the above conditions do not react to ordinary doses of tuberculin. In patients seriously ill with tuberculosis, test usually becomes positive after a few weeks of treatment. Antituberculosis chemotherapy should not be started solely on basis of one positive test but only after further diagnosis (eg, chest x-rays, bacteriologic examination of sputa). Consider INH treatment for recent converters and other high-risk groups without evidence of active disease.

Adverse Reactions: Vesiculation, occasionally necrosis, ulceration.

How Supplied: 20 or 250 units individually blister-sealed with Lot number and expiration date stamped on each blister

Biologicals Sclavo

COMPLETE AND MAIL TO: SCLAVO INC., 5 Mansard Court, Wayne, N.J. 07479

NAME _____

- ☐ Please send me trial samples of SclavoTest-PPD.
- ☐ Please have your representative call.
- ☐ Please send me technical brochures.
- ☐ Please send me hospital formulary kit.

ADDRESS _____ PHONE _____

CITY _____ STATE _____ ZIP _____

IN ACUTE OTITIS EXTERNA

VōSoL® Otic Solution
(acetic acid—nonaqueous 2%)

VōSoL® HC Otic Solution
(hydrocortisone 1%,
acetic acid—nonaqueous 2%)

Before prescribing, please consult complete product information; a brief summary of important information follows:

† **Indications:** (VōSoL only)
Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications as follows:
Effective: For the treatment of superficial infections of the external auditory canal caused by organisms susceptible to the action of the antimicrobial.
"Possibly" effective: For prophylaxis of otitis externa in swimmers and susceptible subjects.
Final classification of the less-than-effective indication requires further investigation.

POWER TO RELIEVE PAIN

The hydrocortisone in VōSol HC provides rapid relief from the inflammation that causes pain, swelling and itching in acute otitis externa, while the nonaqueous acetic acid works to eliminate infections due to susceptible pathogens.

POWER TO ELIMINATE PATHOGENS

VōSol HC has been shown to achieve earlier microbial cures than Cortisporin®.*[1] In addition, no known resistant strains of organisms susceptible to the antibacterial/antifungal action of VōSol HC have been reported.

POWER TO RESTORE pH

A pH of 3 helps restore the acid mantle so vital to the external ear's natural defenses.

Dosage: 5 drops 3 or 4 times daily.
How supplied: in 10 ml plastic squeeze bottle with safety tip.

For prophylaxis in susceptible patients,† specify VōSol® Otic Solution (acetic acid—nonaqueous 2%)

Dosage: 2 drops twice daily. ‡
How supplied: in 30 ml plastic squeeze bottle with safety tip.

POWER OF VōSol® HC

OTIC SOLUTION

(hydrocortisone 1%, acetic acid—nonaqueous 2%)

Indications: (VōSol **HC** only) For the treatment of superficial infections of the external auditory canal caused by organisms susceptible to the action of the antimicrobial, complicated by inflammation.

Contraindications: Hypersensitivity to any of the components; perforated tympanic membranes are frequently considered a contraindication. VōSol **HC** is also contraindicated in vaccinia and varicella.

Precautions: VōSol **HC:** As safety of topical steroids during pregnancy has not been confirmed, they should not be used for an extended period during pregnancy. Systemic side effects may occur with extensive use of steroids. VōSol and VōSol **HC:** If sensitization or irritation occurs, discontinue promptly.

How Supplied: VōSol Otic Solution, in 15 ml and 30 ml measured-drop, safety-tip plastic bottles.
VōSol **HC** Otic Solution, in 10 ml measured-drop, safety-tip plastic bottle. Rev. 5/78

1. Ordonez GE, Kime CE, Updegraff WR, et al: Effective treatment of acute, diffuse otitis externa: I. A controlled comparison of hydrocortisone—acetic acid, nonaqueous and hydrocortisone—neomycin—polymyxin B otic solutions. *Curr Ther Res* 23 (May suppl): SS3-SS14, 1978.

*Cortisporin (a combination of polymyxin B, neomycin, and hydrocortisone) is a registered trademark of Burroughs Wellcome Co.
‡For primary treatment of acute infection, recommended dosage is 5 drops three or four times daily.

WALLACE LABORATORIES
Division of Carter-Wallace, Inc.
Cranbury, New Jersey 08512

 WY1194 April 1982

Don't let allergies or colds get in the way of summer fun.

Recommend

TRIAMINIC-12™

Sustained Release Tablets

for your older patients

Strong, 12-hour relief from nasal and postnasal symptoms.

Each tablet contains: phenylpropanolamine hydrochloride 75.0 mg, chlorpheniramine maleate 12.0 mg.

Recommend

TRIAMINIC® Syrup

for your younger patients

The "Orange Medicine" for stuffy and runny noses.

Part of The Recommendables® Line

Each teaspoonful (5 ml) contains: phenylpropanolamine hydrochloride 12.5 mg and chlorpheniramine maleate 2 mg.

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Please see combined brief summary of prescribing information on adjoining page.

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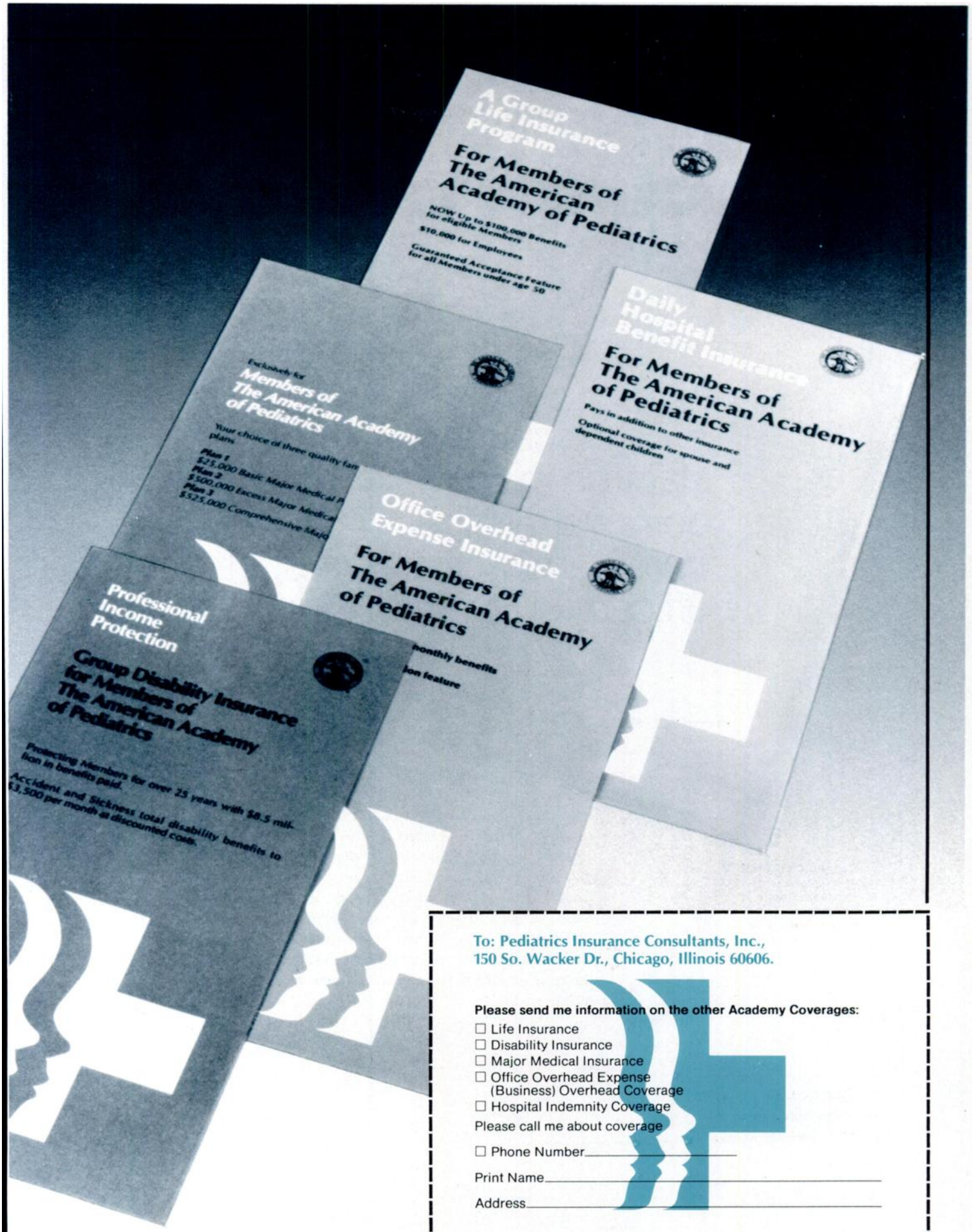

To: Pediatrics Insurance Consultants, Inc.,
150 So. Wacker Dr., Chicago, Illinois 60606.

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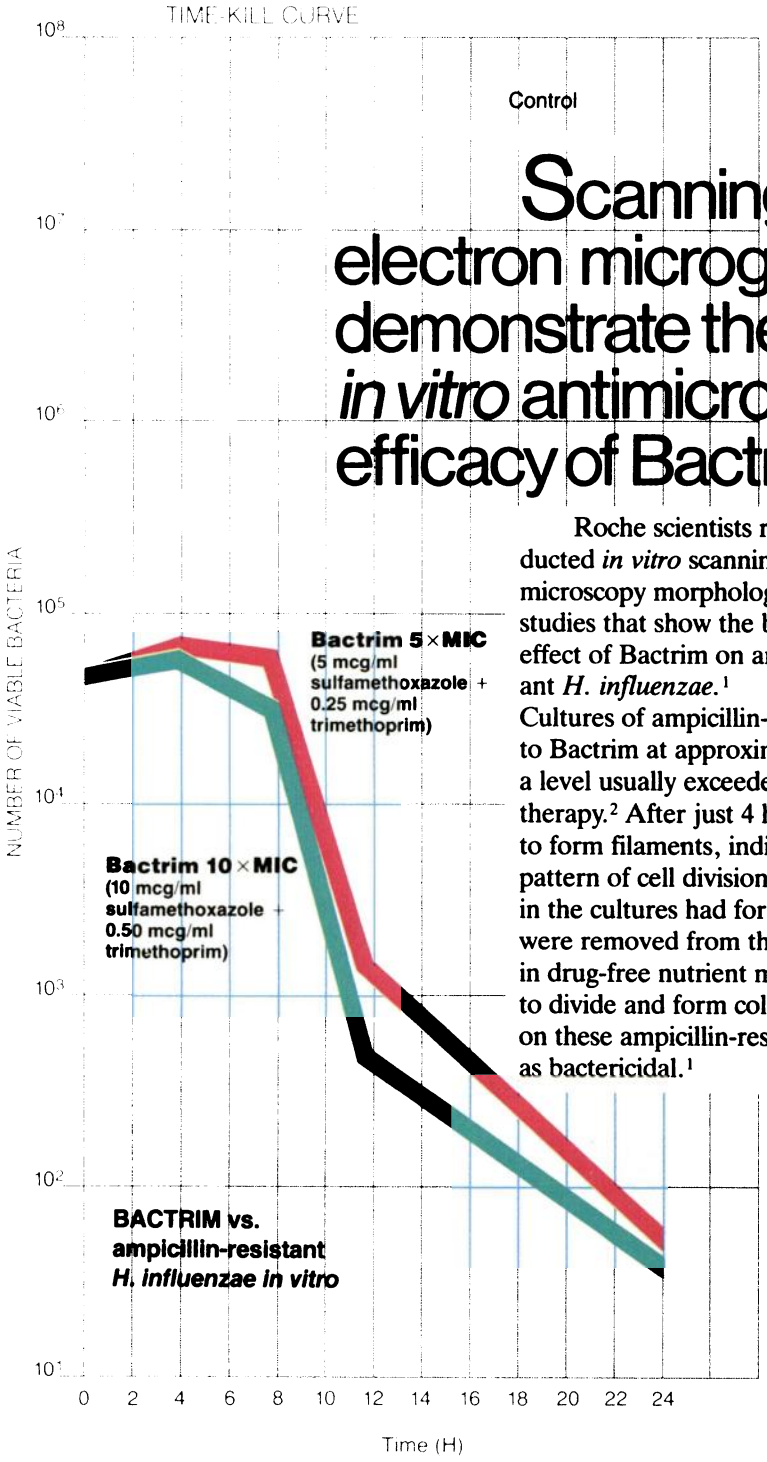
new *in vitro* study shows how

Bactrim™ destroys

(trimethoprim and sulfamethoxazole/Roche)

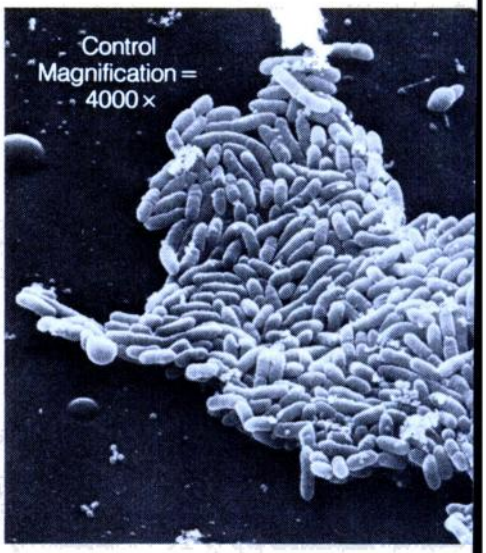


Scanning electron micrographs demonstrate the *in vitro* antimicrobial efficacy of Bactrim

Roche scientists recently conducted *in vitro* scanning electron microscopy morphology and viability studies that show the bactericidal effect of Bactrim on ampicillin-resistant *H. influenzae*.[1]

Cultures of ampicillin-resistant *H. influenzae* were exposed to Bactrim at approximately 5× the MIC for *H. influenzae*—a level usually exceeded in serum and middle-ear fluid during therapy.[2] After just 4 hours, cultures exposed to Bactrim began to form filaments, indicating an alteration in the normal pattern of cell division. After 12 hours, virtually all bacteria in the cultures had formed filaments. When these bacteria were removed from the Bactrim-treated cultures and recultured in drug-free nutrient medium, almost all of them were unable to divide and form colonies. Thus, the effect of Bactrim on these ampicillin-resistant *H. influenzae* was interpreted as bactericidal.[1]

1. CONTROL.
Ampicillin-resistant *H. influenzae*.

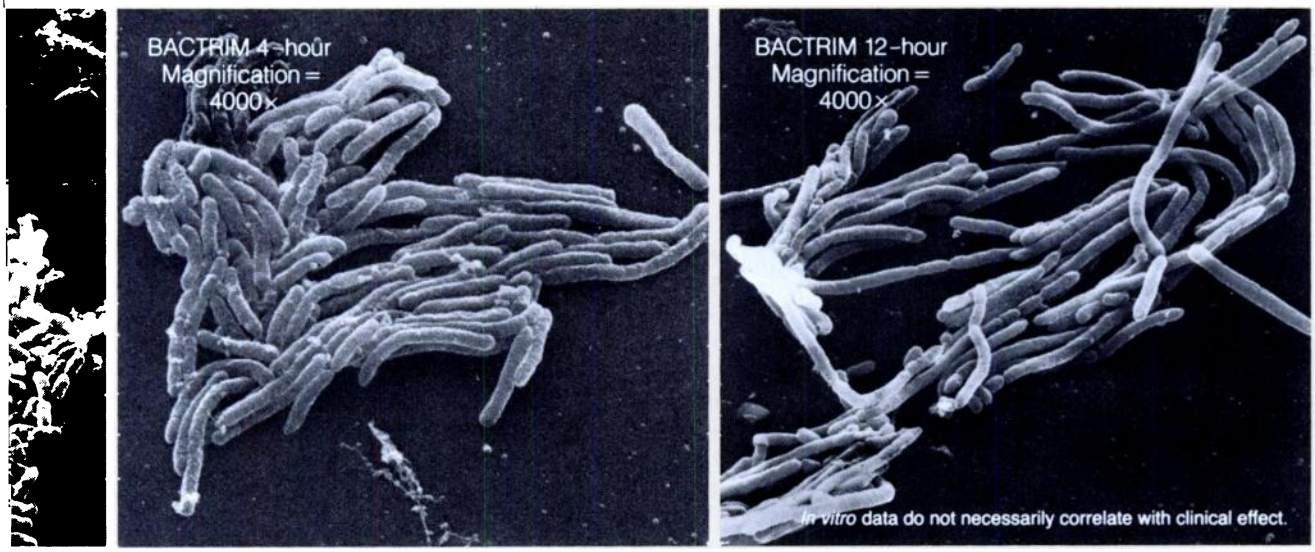


ROCHE

*H. influenzae**
even ampicillin-resistant strains

2. BACTRIM-TREATED: 4 HOURS. Primary morphologic effect of Bactrim (5 mcg/ml sulfamethoxazole and 0.25 mcg/ml trimethoprim) on ampicillin-resistant *H. influenzae* is the formation of filaments.

3. BACTRIM-TREATED: 12 HOURS. Filaments of varying lengths observed in cultures of ampicillin-resistant *H. influenzae*. Number of viable bacteria from this culture was substantially below that of the 0-hour titer, indicating a bactericidal effect.



Clinical results in acute otitis media‡—93% efficacy[1,3]

Pathogen	*In Vitro* Sensitivity to Ampicillin Prior to Study †	#Successful/#Evaluated Bactrim
	Resistant	15/16
H. influenzae	Sensitive ..... ◗ resistant	1/1
	Sensitive ..... ◗ failed	9/10
	Total resistant or unresponsive to aminopenicillins	25/27 (93%)

†In *in vitro* sensitivity tests prior to the study, *H. influenzae* isolates were classified as being 1) resistant to ampicillin; originally sensitive to ampicillin but either 2) developed resistance or 3) nevertheless failed to respond to a standard course of therapy with an aminopenicillin; or 4) sensitive to ampicillin.

Bactrim is contraindicated in infants less than two months of age, hypersensitivity to either component and documented megaloblastic anemia due to folate deficiency.

In acute otitis media‡ in children
Bactrim™ Pediatric suspension
(trimethoprim and sulfamethoxazole/Roche)
succeeds

*Susceptible strains
‡Due to susceptible *H. influenzae* and *S. pneumoniae*.

Please see next page for references and summary of product information.

References: 1. Data on file. Hoffmann-La Roche Inc. Nutley, NJ. 2. Klimek JJ *et al. J Pediatr* 96:1087-1089, Jun 1980. 3. Schwartz R *et al. Ann Otol Rhinol Laryngol* 89 (Suppl 68): 281-284, May-Jun 1980.

HISTORY OF OXYGEN THERAPY AND RETROLENTAL FIBROPLASIA

As medical technology improves and more patients survive conditions which once meant certain death, the demand for better treatment of problems which may afflict these survivors has increased. This is particularly true for infants who develop retrolental fibroplasia. It is now known that the administration of oxygen which saves the lives of numerous premature and low birthweight infants also causes the development of retrolental fibroplasia—in many instances leading to permanent blindness.

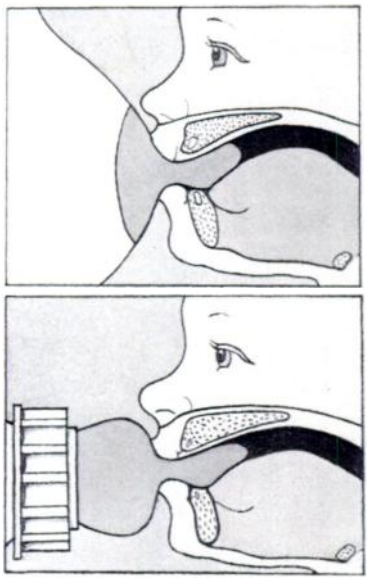
The Committee on Fetus and Newborn of the American Academy of Pediatrics strives to make conditions ideal for all newborn infants, and it has become increasingly concerned about the infants who develop retrolental fibroplasia. In an attempt to compress the work done by researchers throughout the world into one document—and thus more easily see possible causes and solutions as well as stimulate more research—the Committee prepared and wrote the History of Oxygen Therapy and Retrolental Fibroplasia. This document, which was published as a supplement to *Pediatrics*, is available to all persons involved with or interested in the treatment of newborn infants, especially infants who are at high risk for developing retrolental fibroplasia.

The sequence of events concerning the use of oxygen and the development of retrolental fibroplasia is given. Considerable attention has been paid to the historical background of modern care for premature infants, the status of medical practice when oxygen was first used on premature infants, and the process of dissemination of new research data. Included are the Academy's recommendations on the use of oxygen through the years, the current state regulations on the use of oxygen, and six pages of references which go back as far as 1862.

AMERICAN ACADEMY OF PEDIATRICS
Department P, P.O. Box 1034
Evanston, Illinois 60204

MOTHERS WHO BREAST-FEED WILL BE GLAD TO KNOW ABOUT NUK.®

The NUK system of nipples and orthodontic exercisers is a natural supplement to breast-feeding. Nothing comes closer to duplicating the actual breast-feeding experience. And more importantly, NUK offers benefits your patients who breast-feed should know about.



NUK

designed like a mother's nipple during breast-feeding.

Designed by a German orthodontist, the NUK Nipple simulates the shape and feel of a mother's nipple in a child's mouth during breast-feeding. It even controls the flow of milk. The hole is on top of the baglet rather than at the tip, which forces the baby to strip milk from the nipple. Milk doesn't squirt or come out fast as with conventional nipples.

NUK

provides lasting benefits, too.

The NUK Nipple expands and contracts during feeding to satisfy the baby's sucking urge and provide important oral exercise. It keeps the tongue from thrusting to encourage the baby to move the jaw forward and back, as in breast-feeding. The purpose is to help prevent abnormal jaw alignment and malocclusion.

Recommend NUK

Your patients will be glad you did.

The NUK Nipple is a natural supplement to breast-feeding, or can be recommended for total bottle-feeding programs. There's a NUK Nipple to fit every standard and disposable nursing system. And the NUK Orthodontic Exerciser offers the same advantages in a convenient pacifier. Tell your patients about the natural benefits of NUK — they'll be glad you did.

NUK

The Original. Ask for it by name.

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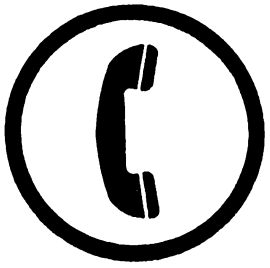

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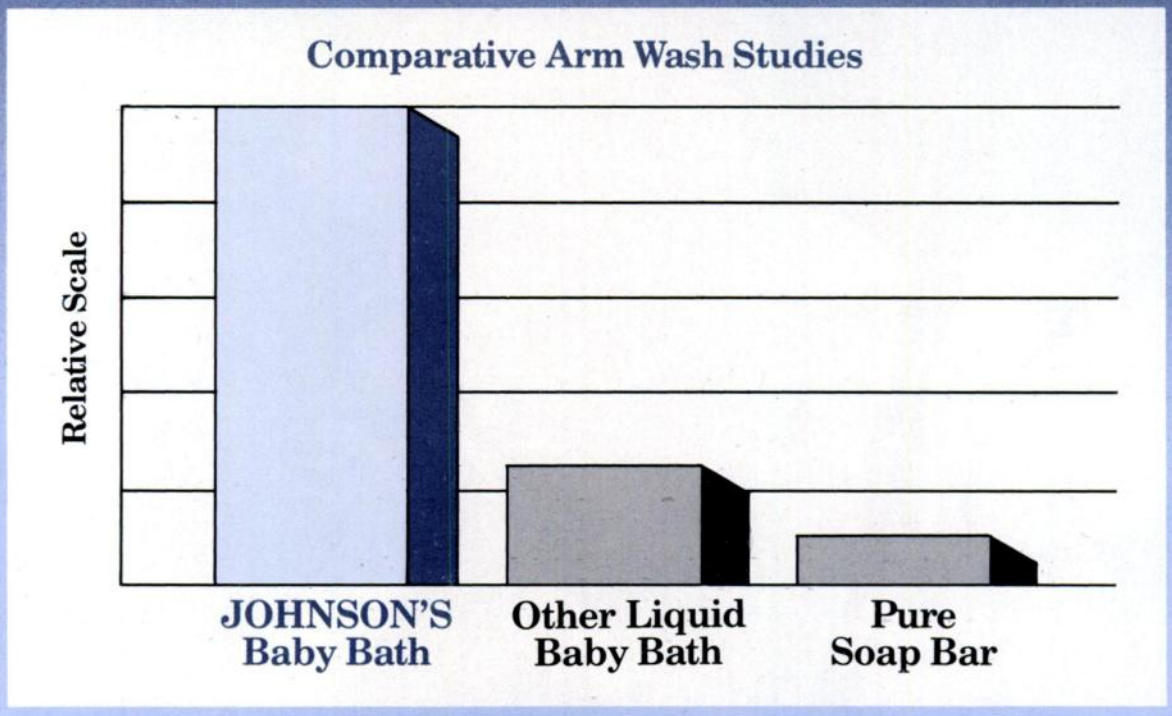

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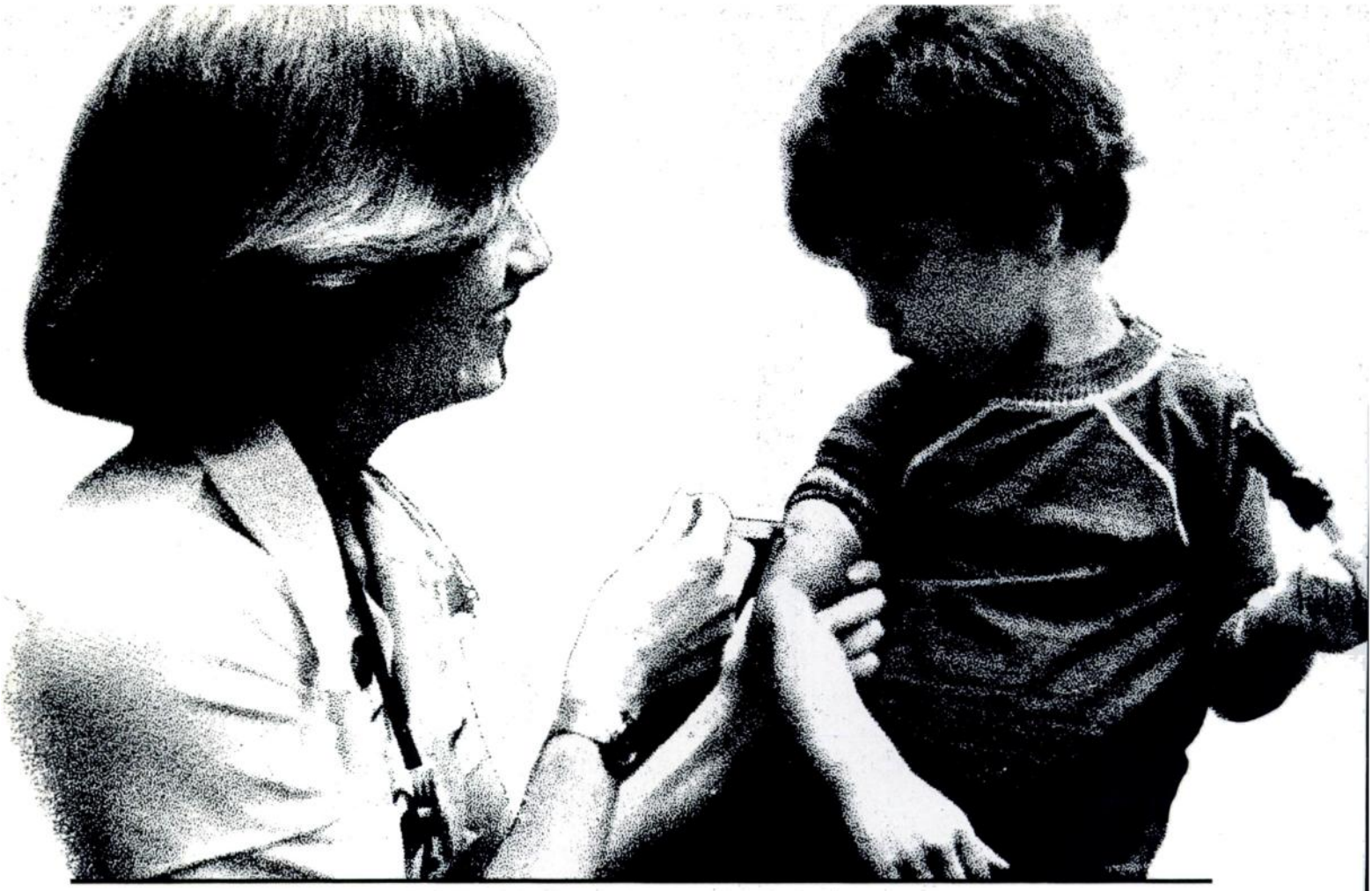

The new "Red Book" is here...

The 19th edition of the Academy's quick reference guide to more than 100 communicable diseases is now available for purchase. Officially known as the "Report of the Committee on Infectious Diseases," this authoritative handbook gives the etiology, epidemiology, incubation period, period of communicability, clinical forms and differential diagnosis, diagnostic procedures, treatment and control measures for diseases ranging from actinomycosis to yersinia infections.

The "Red Book" has been a "must" for child health professionals since the first edition in 1938. Part one discusses active and passive immunization, including informed consent; part two is a summary of infectious diseases; and part three is composed of a number of tables and information on services of the Center for Disease Control.

New sections in this edition include recently described diseases caused by *Chlamydia trachomatis*, corona viruses, *Legionella pneumophilia*, hepatitis B and non A and non B hepatitis, Kawasaki disease and yersinia species, and use of new vaccines and specific immune globulin preparations for hepatitis, rabies and varicella-zoster.

Also new are sections on diagnostic virology, information sheets for immunization, 32 tables on etiologic agents of common pediatric diseases, and information used for isolation techniques in hospitals. The tables for use of antimicrobial agents have been revised to include new drugs and changes in dosage schedules for old drugs. 1982 Indexed: 379 pages.

Note: All Fellows and Junior Fellows will be mailed one complimentary copy in June.

Please send me:

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Babylax, the gentle, effective solution to children's constipation that's easier on both mother and child.

Another healthy innovation from C.B. Fleet Co.

Fleet pharmaceuticals

DEATH AT AN EARLY AGE

By now it's a familiar refrain: if juvenile crime is on the rise, don't fool around with goody-goody programs for youthful offenders; prosecute them as adults.

In Vermont, where folks normally take pride in their independence and caution, lawmakers went for the idea in a big way; not content to lower the age for adult criminality to 16, as countless states have done, they moved it all the way back to 10.

That was in July. Now Vermonters are having second thoughts, for a salient reason: the state still permits the death penalty, and the new law makes it possible to executé fourth graders. Having belatedly focused on this point, the legislators may now decide to modify the law.

We don't approve of the death penalty in any case, but the absurdity of this situation serves as an important reminder: no matter how mean their behavior, children must be treated as children.

From *The New York Times*, Nov 7, 1981.

REST PERIODS, CHANGING TIMES AND ATTITUDES

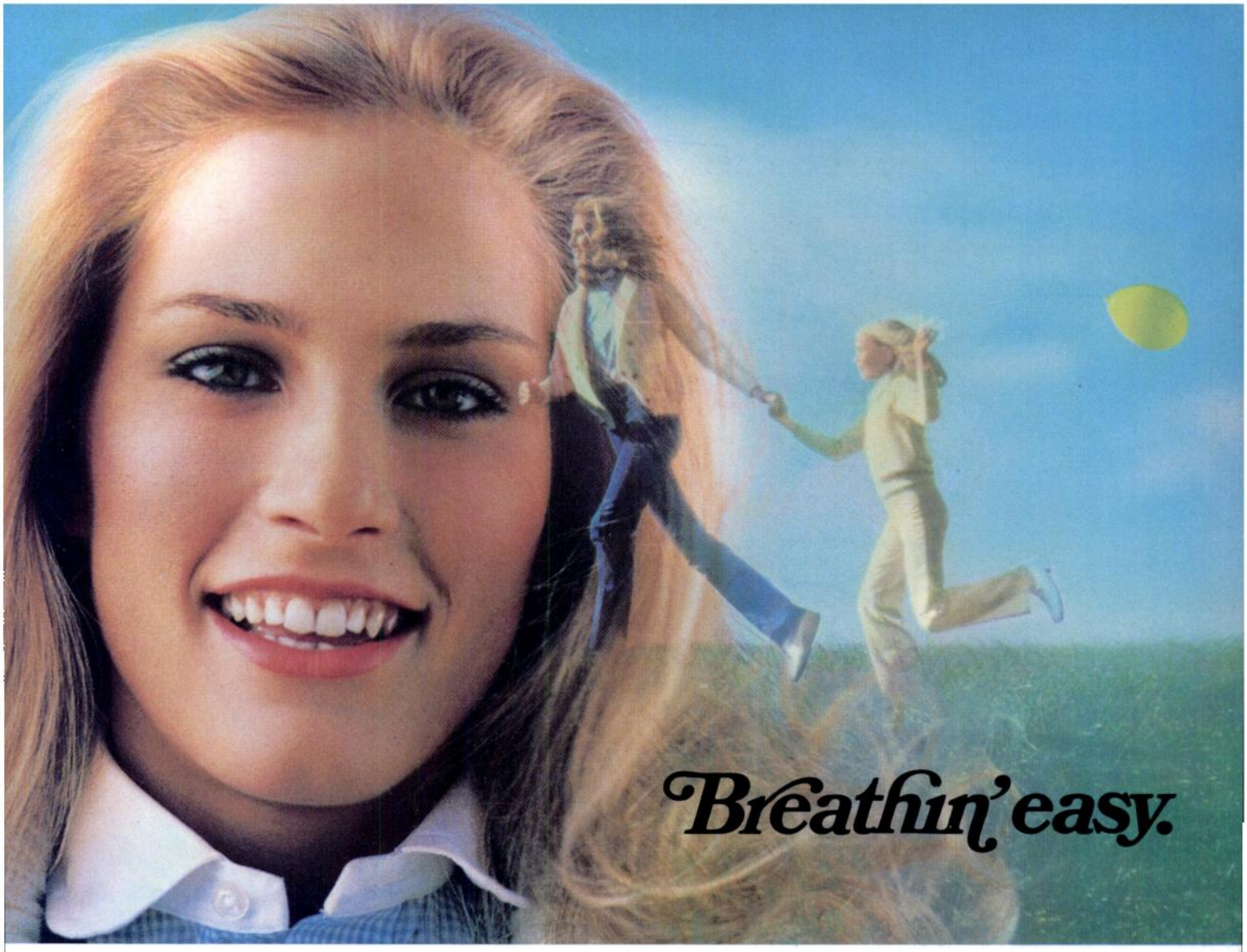
The University of Washington housestaff physicians recently delayed renewing their contracts in a dispute over on-duty and on-call working hours. Complaining that some residents must work as much as 120 hours a week, the residents asked for a flat 80-hour work week. The University of Washington Housestaff Association issued guidelines (which were never accepted) for residents' working hours, including the following: Residents should not be on-call on two consecutive nights. They should not be on-call any more often than every third night. Housestaff physicians need at least 48 consecutive hours of off-time a month.

"The public doesn't want to be taken care of by physicians who have been up for 36 hours," said a resident in obstetrics and gynecology.

The acting dean at the school of medicine, countered that the residents' hours were no different from those in other graduate training programs around the country.

The housestaff group had suggested a compromise that "reasonable hours" be established at the departmental level. That had been rejected on the grounds that the term "reasonable hours" was too difficult to define and could lead to disputes. Under the unsuccessful proposal, each individual department would have had until October 1 to reach a decision, and the *rest periods* would have been implemented by July 1982.

From *Resident & Staff Physician* 27—12, December 1981, p 119.



SLO-PHYLLIN® (theophylline, anhydrous) the drug of choice in chronic asthma. Offers the widest range of dosages and forms of any 100% theophylline.

Single-entity 100% theophylline. SLO-PHYLLIN® (theophylline, anhydrous) contains only theophylline, to preclude toxic synergism that could occur with combinations.

Proven bioavailability. Virtually 100% of administered SLO-PHYLLIN® reaches the blood. Both onset of action and peak effect occur rapidly with tablets and syrup. GYROCAPS® have the additional advantage of sustained action. B.i.d. dosage is effective in many adult patients.

Predictable bronchodilation. Once optimum dosage of SLO-PHYLLIN® is determined, patients can usually be maintained long-term without lessening of effect.

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SLO-PHYLLIN® 80 Syrup 80 mg/15 ml—100% theophylline (anhydrous) in a pleasant tasting, non-alcoholic syrup. *Especially recommended for infants and young children.*

SLO-PHYLLIN® GYROCAPS® timed release capsules of 100% theophylline (anhydrous) 60 mg, 125 mg, 250 mg. *Recommended for use b.i.d. in many adults and t.i.d. in children. (Conveniently filled with individual time-release pellets.)*

SLO-PHYLLIN® Tablets 100 mg and 200 mg—100% theophylline (anhydrous)—scored, dye-free.

SLO-PHYLLIN®
(theophylline, anhydrous)

ROHER
WILLIAM H. RORER, INC.
Fort Washington, Pennsylvania U.S.A. 19034

(See next page for a brief summary of prescribing information)

Brief Summary

SLO-PHYLLIN® (theophylline, anhydrous)
SYRUP, TABLETS,
GYROCAPS® (timed release capsules)

Indications: For relief and or prevention of symptoms from asthma and reversible bronchospasm associated with chronic bronchitis and emphysema.

Contraindications: In individuals who have shown hypersensitivity to any of its components.

Warnings: Status asthmaticus is a medical emergency. Optimal therapy frequently requires additional medication including corticosteroids when the patient is not rapidly responsive to bronchodilators.

Excessive theophylline doses may be associated with toxicity and measurement of serum theophylline levels is recommended to assure maximal benefit without excessive risk. Incidence of toxicity increases at levels greater than 20 mcg. ml. Morphine, curare, and stilbamidine should be used with caution in patients with airflow obstruction since they stimulate histamine release and can induce asthmatic attacks. They may also suppress respiration leading to respiratory failure. Alternative drugs should be chosen whenever possible.

There is an excellent correlation between high blood levels of theophylline resulting from conventional doses and associated clinical manifestations of toxicity in (1) patients with lowered body plasma clearances (due to transient cardiac decompensation), (2) patients with liver dysfunction or chronic obstructive lung disease, (3) patients who are older than 55 years of age, particularly males.

There are often no early signs of less serious theophylline toxicity such as nausea and restlessness, which may appear in up to 50 percent of patients prior to onset of convulsions. Ventricular arrhythmias or seizures may be the first signs of toxicity.

Many patients who have higher theophylline serum levels exhibit a tachycardia.

Theophylline products may worsen pre existing arrhythmias.

Usage in Pregnancy: Safe use in pregnancy has not been established relative to possible adverse effects on fetal development, but neither have adverse effects on fetal development been established. This is, unfortunately, true for most antiasthmatic medications. Therefore, use of theophylline in pregnant women should be balanced against the risk of uncontrolled asthma.

Precautions: Mean half life in smokers is shorter than non smokers, therefore, smokers may require larger doses of theophylline. Theophylline should not be administered concurrently with other xanthine medications. Use with caution in patients with severe cardiac disease, severe hypoxemia, hypertension, hyperthyroidism, acute myocardial injury, cor pulmonale, congestive heart failure, liver disease, and in the elderly (especially males) and in neonates. Great caution should especially be used in giving theophylline to patients in congestive heart failure. Such patients have shown markedly prolonged theophylline blood level curves with theophylline persisting in serum for long periods following discontinuation of the drug.

Use theophylline cautiously in patients with history of peptic ulcer. Theophylline may occasionally act as a local irritant to G.I. tract although gastrointestinal symptoms are more commonly central and associated with serum concentrations over 20 mcg. ml.

Adverse Reactions: The most consistent adverse reactions are usually due to overdose and are:

1. Gastrointestinal: nausea, vomiting, epigastric pain, hematemesis, diarrhea.
2. Central nervous system: headaches, irritability, restlessness, insomnia, reflex hyperexcitability, muscle twitching, clonic and tonic generalized convulsions.
3. Cardiovascular: palpitation, tachycardia, extrasystoles, flushing, hypotension, circulatory failure, life threatening ventricular arrhythmias.
4. Respiratory: tachypnea.
5. Renal: albuminuria, increased excretion of renal tubular cells and red blood cells; potentiation of diuresis.
6. Others: hyperglycemia and inappropriate ADH syndrome.

Drug Interactions: Toxic synergism with ephedrine has been documented and may occur with some other sympathomimetic bronchodilators.

DRUG	EFFECT
Aminophylline with lithium carbonate	Increased excretion of lithium carbonate
Aminophylline with propranolol	Antagonism of propranolol effect
Theophylline with furosemide	Increased diuresis of furosemide
Theophylline with hexamethonium	Decreased hexamethonium–induced chromatropic effect
Theophylline with reserpine	Reserpine – induced tachycardia
Theophylline with chlordiazepoxide	Chlordiazepoxide – induced fatty acid mobilization
Theophylline with cyclamycin (TAO troleandomycin); erythromycin, lincomycin	Increased theophylline plasma levels

How Supplied:

Slo Phyllin® 80 Syrup (80 mg. 15 ml), 4 oz., pint, and gallon bottles, 5 ml and 15 ml unit dose bottles.

Slo Phyllin® 100 mg and 200 mg Tablets, bottles of 100 and 1000, unit dose packages.

Slo Phyllin® Gyrocaps® 60 mg bottles of 100 and 1000.

Slo Phyllin® Gyrocaps® 125 mg and 250 mg bottles of 100 and 1000, unit dose strip packages.

SLO-PHYLLIN® (theophylline, anhydrous)

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Fort Washington, Pennsylvania U.S.A. 19034

How often should my baby eat?

Good question...one that concerned parents are likely to ask. But your answer won't always be the same because experience shows that the requirements of no two babies are exactly the same.

A baby who is breast feeding more than eight to 10 times each 24-hour period and is fussy or hungry between feedings may be signaling a need for foods supplemental to milk. Seventy-nine percent of the physicians in a recent survey recommended breast milk as the best first food.[1] But even breast-fed babies will, in time, need the extra calories and choice provided by supplementary foods.

Other factors – like reaching 13 pounds, doubling birthweight or drinking more than a quart of liquid per day – may also be signs that a baby is ready for supplements. These signs usually occur when the infant is 4-6 months of age. Supplementary foods will satisfy caloric needs[2] and complement the calories and nutrients already supplied by breast milk or formula while avoiding the need to feed more than 32 ounces of liquid per day.

Gerber offers a wide variety of single-ingredient foods in each of the four food groups so that you can recommend a well-balanced diet suitable for the individual infant.

Hungry babies respond favorably to the new tastes and textures of Gerber strained foods. The safety, variety, uniformity and convenience of Gerber baby foods are good reasons to recommend them with confidence.

When it's time to introduce and feed supplements, mothers will appreciate Gerber's reliable quality.

---

1. "Pediatrician and Family Physician Infant Feeding Study," #1007, Gerber, 1981.
2. "Recommended Daily Dietary Allowances," Food and Nutrition Board, NAS/NRC, 1980.

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There are more than 50 million* children in the United States, and every one† of them should be protected against polio

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Poliovirus Vaccine, Live, Oral, Trivalent

*Bureau of the Census, 1980 (children 14 years and under).

†For any special circumstances see the contraindications section of the Brief Summary of Prescribing Information.

Please see following page for Brief Summary of Prescribing Information.

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acetaminophen
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for more fever relief
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Drops

- Now increased to 80 mg/dropperful, with recalibrated dropper (0.4 ml-0.8 ml)
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Chewable Tablets

- Dosage increased for optimal efficacy

NEW DOSAGE RECOMMENDATIONS

Age Group	0-3 mos	4-11 mos	12-23 mos	2-3 yrs	4-5 yrs	6-8 yrs	9-10 yrs	11-12 yrs
Weight (lbs)	6-11	12-17	18-23	24-35	36-47	48-59	60-71	72-95
Dose of TYLENOL in milligrams	40	80	120	160	240	320	400	480
DROPS (80 mg/0.8 ml) dropperfuls	½	1	1½	2	3	4	5	—
ELIXIR (160 mg/5 ml) teaspoonfuls	—	½	¾	1	1½	2	2½	3
CHEWABLE TABLETS (80 mg each)	—	—	1½	2	3	4	5	6

Doses should be administered 4 or 5 times daily—but not to exceed 5 doses in 24 hours.

NOTE: Since TYLENOL pediatric products are available without a prescription, parents are warned on the package label to consult a physician for use by children under two or for use longer than ten days, and to contact a physician immediately in case of accidental overdosage.

There's nothing better!

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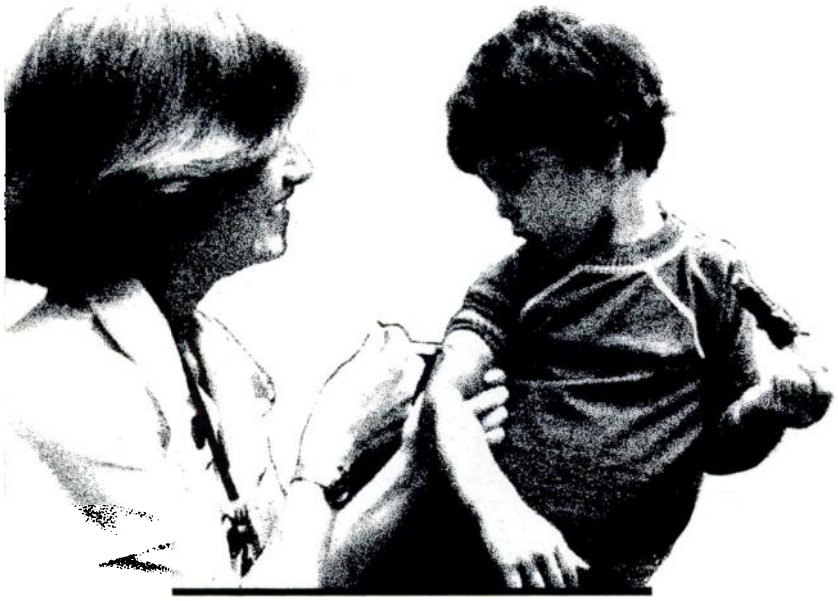
The new "Red Book" is here...



The 19th edition of the Academy's quick reference guide to more than 100 communicable diseases is now available for purchase.

New sections of this authoritative handbook, officially known as the "Report of the Committee on Infectious Diseases," include recently described diseases caused by coronaviruses, *Legionella pneumophilia,* hepatitis B and non A and non B hepatitis, Kawasaki disease and yersinia species, and use of new vaccines and specific immune globuline preparations for hepatitis, rabies, varicella-zoster, and pneumococcal infection. 1982; 32 tables; indexed; 379 pages.

Note: All Fellows and Junior Fellows will be mailed one complimentary copy in June.

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Cyclapen®-W (cyclacillin)

Indications
Cyclacillin has less in vitro activity than other drugs in the ampicillin class and its use should be confined to these indications: Treatment of the following infections:

RESPIRATORY TRACT
Tonsillitis and pharyngitis caused by Group A beta-hemolytic streptococci
Bronchitis and pneumonia caused by *S. pneumoniae* (formerly *D. pneumoniae*)
Otitis media caused by *S. pneumoniae* (formerly *D. pneumoniae*), *H. influenzae*, and Group A beta-hemolytic streptococci
Acute exacerbation of chronic bronchitis caused by *H. influenzae**
*Though clinical improvement has been shown, bacteriologic cures cannot be expected in all patients with chronic respiratory disease due to *H. influenzae*.

SKIN AND SKIN STRUCTURES (integumentary) infections caused by Group A beta-hemolytic streptococci and staphylococci, non-penicillinase producers.

URINARY TRACT INFECTIONS caused by *E. coli* and *P. mirabilis*. (This drug should not be used in any *E. coli* and *P. mirabilis* infections other than urinary tract.)

NOTE: Perform cultures and susceptibility tests initially and during treatment to monitor effectiveness of therapy and susceptibility of bacteria. Therapy may be instituted prior to results of sensitivity testing.

Contraindications Contraindicated in individuals with history of an allergic reaction to penicillins.

Warnings Cyclacillin should only be prescribed for the indications listed herein.

Cyclacillin has less *in vitro* activity than other drugs of the ampicillin class. However, clinical trials demonstrated it is efficacious for recommended indications.

Serious and occasional fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin. Although anaphylaxis is more frequent following parenteral use, it has occurred in patients on oral penicillins. These reactions are more apt to occur in individuals with history of sensitivity to multiple allergens. There are reports of patients with history of penicillin hypersensitivity reactions who experienced severe hypersensitivity reactions when treated with a cephalosporin. Before penicillin therapy, carefully inquire about previous hypersensitivity reactions to penicillins, cephalosporins and other allergens. If allergic reaction occurs, discontinue drug and initiate appropriate therapy. Serious anaphylactoid reactions require immediate emergency treatment with epinephrine. Oxygen, I.V. steroids, airway management, including intubation, should also be administered as indicated.

Precautions Prolonged use of antibiotics may promote overgrowth of nonsusceptible organisms. If superinfection occurs, take appropriate measures.

PREGNANCY: Pregnancy Category B. Reproduction studies performed in mice and rats at doses up to 10 times the human dose revealed no evidence of impaired fertility or harm to the fetus due to cyclacillin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, use this drug during pregnancy only if clearly needed.

NURSING MOTHERS: It is not known whether this drug is excreted in human milk. Because many drugs are, exercise caution when cyclacillin is given to a nursing woman.

Adverse Reactions Oral cyclacillin is generally well tolerated. As with other penicillins, untoward sensitivity reactions are likely, particularly in those who previously demonstrated penicillin hypersensitivity or with history of allergy, asthma, hay fever, or urticaria. Adverse reactions reported with cyclacillin: diarrhea (in approximately 1 out of 20 patients treated), nausea and vomiting (in approximately 1 in 50), and skin rash (in approximately 1 in 60). Isolated instances of headache, dizziness, abdominal pain, vaginitis, and urticaria have been reported. (See WARNINGS) Other less frequent adverse reactions which may occur and are reported with other penicillins are anemia, thrombocytopenia, thrombocytopenic purpura, leukopenia, neutropenia and eosinophilia. These reactions are usually reversible on discontinuation of therapy.

As with other semisynthetic penicillins, SGOT elevations have been reported.

As with antibiotic therapy generally, continue treatment at least 48 to 72 hours after patient becomes asymptomatic or until bacterial eradication is evidenced. In Group A beta-hemolytic streptococcal infections, at least 10 days' treatment is recommended to guard against risk of rheumatic fever or glomerulonephritis. In chronic urinary tract infection, frequent bacteriologic and clinical appraisal is necessary during therapy and possibly for several months after. Persistent infection may require treatment for several weeks.

Cyclacillin is not indicated in children under 2 months of age.

Patients with Renal Failure Cyclacillin may be safely administered to patients with reduced renal function. Due to prolonged serum half-life, patients with various degrees of renal impairment may require change in dosage level (see DOSAGE AND ADMINISTRATION in package insert).

Dosage (Give in equally spaced doses)

INFECTION	ADULTS	CHILDREN*
Respiratory Tract		
Tonsillitis & Pharyngitis	250 mg q.i.d.	body weight ≤ 20 kg (44 lbs) 125 mg t.i.d. body weight > 20 kg (44 lbs) 250 mg t.i.d.
Bronchitis and Pneumonia		
Mild or Moderate Infections	250 mg q.i.d.	50 mg/kg/day q.i.d.
Chronic Infections	500 mg q.i.d.	100 mg/kg/day q.i.d.
Otitis Media	250 mg to 500 mg q.i.d.†	50 to 100 mg/kg/day t.i.d.†
Skin & Skin Structures	250 mg to 500 mg q.i.d.†	50 to 100 mg/kg/day†
Urinary Tract	500 mg q.i.d.	100 mg/kg/day

*Dosage should not result in a dose higher than that for adults.
†depending on severity

How Supplied Tablets 250 mg and 500 mg in bottles of 100. Oral Suspension 125 mg and 250 mg per 5 ml in bottles to make 100 ml and 200 ml of Suspension.

Wyeth Laboratories
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Compared to amoxicillin

Faster peak. Fewer problems.

. . . in infants and children

Cyclapen®-W (cyclacillin) produces twice the peak serum concentration* (15.6 mcg/ml versus 7.3 mcg/ml) in half the time (30 minutes versus 60 minutes).[1]

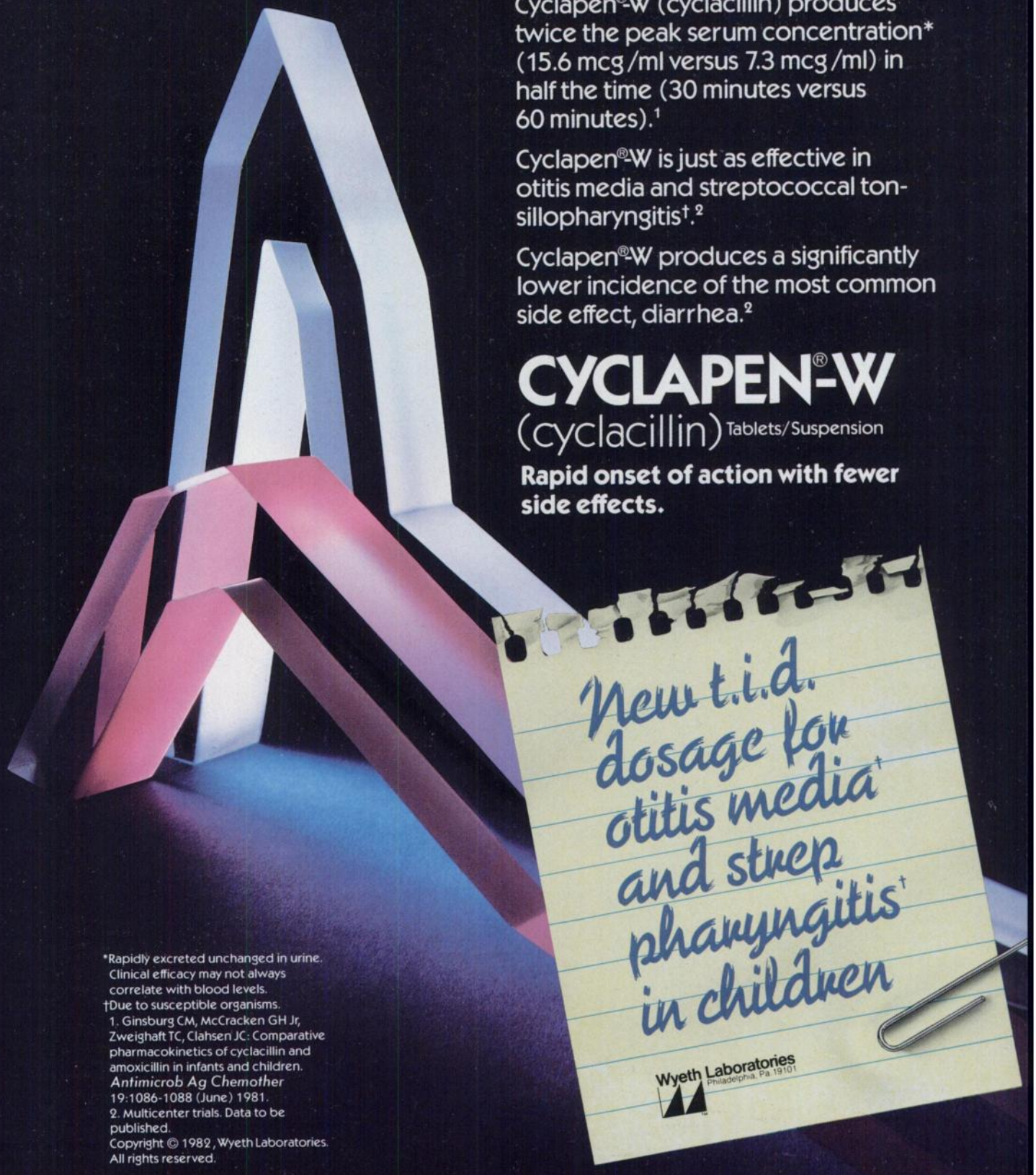
Cyclapen®-W is just as effective in otitis media and streptococcal tonsillopharyngitis†.[2]

Cyclapen®-W produces a significantly lower incidence of the most common side effect, diarrhea.[2]

CYCLAPEN®-W

(cyclacillin) Tablets/Suspension

Rapid onset of action with fewer side effects.



*Rapidly excreted unchanged in urine. Clinical efficacy may not always correlate with blood levels.
†Due to susceptible organisms.

1. Ginsburg CM, McCracken GH Jr, Zweighaft TC, Clahsen JC: Comparative pharmacokinetics of cyclacillin and amoxicillin in infants and children. *Antimicrob Ag Chemother* 19:1086-1088 (June) 1981.
2. Multicenter trials. Data to be published.

See important information on adjoining column.

For acute otitis media in children*

*caused by susceptible strains of *Hemophilus influenzae* (including ampicillin-resistant strains)

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B131/2810

Pediazole®

erythromycin ethylsuccinate and sulfisoxazole acetyl for oral suspension

(200 mg erythromycin activity and the equivalent of 600 mg sulfisoxazole per 5 ml)

Please see adjacent column for brief summary of prescribing information.

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erythromycin ethylsuccinate
and sulfisoxazole acetyl
for oral suspension

BRIEF SUMMARY:
Please see package enclosure for full prescribing information

Indication
For treatment of ACUTE OTITIS MEDIA in children caused by susceptible strains of *Hemophilus influenzae*.

Contraindications
Known hypersensitivity to either erythromycin or sulfonamides.
Infants less than 2 months of age.
Pregnancy at term and during the nursing period, because sulfonamides pass into the placental circulation and are excreted in human breast milk and may cause kernicterus in the infant.

Warnings
Usage in Pregnancy (SEE ALSO: CONTRAINDICATIONS): The safe use of erythromycin or sulfonamides in pregnancy has not been established. The teratogenic potential of most sulfonamides has not been thoroughly investigated in either animals or humans. However, a significant increase in the incidence of cleft palate and other bony abnormalities of offspring has been observed when certain sulfonamides of the short, intermediate and long-acting types were given to pregnant rats and mice at high oral doses (7 to 25 times the human therapeutic dose).
Reports of deaths have been associated with sulfonamide administration from hypersensitivity reactions, agranulocytosis, aplastic anemia and other blood dyscrasias. The presence of clinical signs such as sore throat, fever, pallor, purpura or jaundice may be early indications of serious blood disorders. Complete blood counts should be done frequently in patients receiving sulfonamides.
The frequency of renal complications is considerably lower in patients receiving the most soluble sulfonamides such as sulfisoxazole. Urinalysis with careful microscopic examination should be obtained frequently in patients receiving sulfonamides.

Precautions
Erythromycin is principally excreted by the liver. Caution should be exercised in administering the antibiotic to patients with impaired hepatic function. There have been reports of hepatic dysfunction, with or without jaundice occurring in patients receiving oral erythomycin products.
Recent data from studies of erythromycin reveal that its use in patients who are receiving high doses of theophylline may be associated with an increase of serum theophylline levels and potential theophylline toxicity. In case of theophylline toxicity and or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy.
Surgical procedures should be performed when indicated.
Sulfonamide therapy should be given with caution to patients with impaired renal or hepatic function and in those patients with a history of severe allergy or bronchial asthma. In the presence of a deficiency in the enzyme glucose-6-phosphate dehydrogenase, hemolysis may occur. This reaction is frequently dose-related. Adequate fluid intake must be maintained in order to prevent crystalluria and renal stone formation.

Adverse Reactions
The most frequent side effects of oral erythromycin preparations are gastrointestinal, such as abdominal cramping and discomfort, and are dose-related. Nausea, vomiting and diarrhea occur infrequently with usual oral doses. During prolonged or repeated therapy, there is a possibility of overgrowth of nonsusceptible bacteria or fungi. If such infections occur, the drug should be discontinued and appropriate therapy instituted. The overall incidence of these latter side effects reported for the combined administration of erythromycin and a sulfonamide is comparable to those observed in patients given erythromycin alone. Mild allergic reactions such as urticaria and other skin rashes have occurred. Serious allergic reactions, including anaphylaxis, have been reported with erythromycin.
The following untoward effects have been associated with the use of sulfonamides:
Blood dyscrasias: Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, hemolytic anemia, purpura, hypoprothrombinemia and methemoglobinemia.
Allergic reactions: Erythema multiforme (Stevens-Johnson syndrome), generalized skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritus, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia and allergic myocarditis.
Gastrointestinal reactions: Nausea, emesis, abdominal pains, hepatitis, diarrhea, anorexia, pancreatitis and stomatitis.
C.N.S. reactions: Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia.
Miscellaneous reactions: Drug fever, chills and toxic nephrosis with oliguria or anuria. Periarteritis nodosa and L.E. phenomenon have occurred.
The sulfonamides bear certain chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents. Goiter production, diuresis and hypoglycemia have occurred rarely in patients receiving sulfonamides. Cross-sensitivity may exist with these agents.
Rats appear to be especially susceptible to the goitrogenic effects of sulfonamides, and long-term administration has produced thyroid malignancies in the species.

Dosage and Administration
PEDIAZOLE SHOULD NOT BE ADMINISTERED TO INFANTS UNDER 2 MONTHS OF AGE BECAUSE OF CONTRAINDICATIONS OF SYSTEMIC SULFONAMIDES IN THIS AGE GROUP.
For Acute Otitis Media in Children: The dose of Pediazole can be calculated based on the erythromycin component (50 mg kg day) or the sulfisoxazole component (150 mg kg day to a maximum of 6 g day). Pediazole should be administered in equally divided doses four times a day for 10 days. It may be administered without regard to meals.
The following approximate dosage schedule is recommended for using Pediazole:
Children: Two months of age or older.

Weight	Dose—every 6 hours
Less than 8 kg (less than 18 lb)	Adjust dosage by body weight
8 kg (18 lb)	½ teaspoonful (2.5 ml)
16 kg (35 lb)	1 teaspoonful (5 ml)
24 kg (53 lb)	1½ teaspoonfuls (7.5 ml)
Over 45 kg (over 100 lb)	2 teaspoonfuls (10 ml)

How Supplied
Pediazole Suspension is available for teaspoon dosage in 100 ml (**NDC** 0074-8030-13) and 200-ml (**NDC** 0074-8030-53) bottles, in the form of granules to be reconstituted with water. The suspension provides erythromycin ethylsuccinate equivalent to 200 mg erythromycin activity and sulfisoxazole acetyl equivalent to 600 mg sulfisoxazole per teaspoonful (5 ml).

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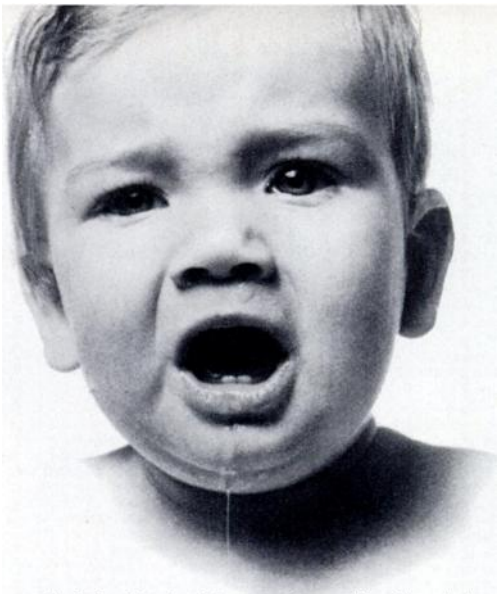

The Signs of Teething

The erupting primary tooth may produce multiple discomforting signs in the infant. Night crying, restlessness, drooling, lip and hand biting are most commonly reported.[1] And a distressed infant often means an agitated parent asking for your advice.

Reassurance and Baby Orajel

It's good advice to give, since Baby Orajel will provide almost immediate relief when applied to inflamed gingival areas.

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Baby Orajel, unlike other teething remedies such as Numzit® Teething Lotion, contains no alcohol. Alcohol can irritate sensitive gum tissue.[2]

You can recommend Baby Orajel with confidence. When baby feels better, so does mother.

References:
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All Bobby-Macs meet the new Federal Safety Standard for child restraints.

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PROCEDURES OF UNPROVED VALUE

Medical history is full of instances where previously accepted therapies and investigative practices have been rightly discarded after their ineffectiveness has been demonstrated. Regrettably, a few procedures of unproved value still linger in many hospitals. Paramount among these are the time-honored and time-consuming routine nursing procedures of counting respiration rates on all patients twice daily, and preoperative administration of enemas whether or not large-bowel surgery is contemplated. The recommended abolition of the former procedure does not of course belittle its value when specifically required and accurately performed.

Nearly a quarter of a century ago an American physician, Dr R. C. Kory, published in this journal what is probably the best article ever written on the subject (*JAMA* 165: 448, 1957). After a careful study of hospital patients he concluded that in less than 5% were routine respiration counts of any clinical value and that few physicians showed any interest in them. This inevitably led to the fabrication of records. In a carefully controlled experiment, measurements taken within a few minutes of the official recording showed no correlation whatever with the record. In 57 of 58 patients, respiration rates were recorded as between 18 and 22 breaths per minute, and 40 were entered as 20 per minute. The real range was 11 to 33 breaths per minute with only five patients having a rate of 20 breaths per minute.

Kory concluded: "It is suggested that routine recording of respiration rates be limited to those cases with recognized abnormal breathing patterns or on those hospitals wards where the physician specifically orders such measurements. This not only would improve the accuracy of the measurement and clinical records, but also would save millions of hours of personnel time each year." He estimated that 3½ milion hours of personnel time were expended annually on this useless and outmoded procedure, and calculated this as representing a cost of $5½ million. Inflation must have increased this fivefold or more, and the figure must be further multiplied to account for the increase in hospital beds.

It is tragic that Kory's logical recommendations went unheeded.

From Burkitt DP (St Thomas Hospital, London): *JAMA* 247:1278, 1982.

tobacco products be phased out as rapidly as possible. Such funds would be better used for the support of research and education.

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DELINQUENT STUDENT LOANS

A Federal crackdown on doctors, dentists and other professionals who are not repaying student loans on time shows that 63,000 of them are delinquent in paying nearly $31 million.

The breakdown showed that 7,000 medical doctors owed $5.2 million in delinquent payments; 340 osteopaths owed $271,000; 3,700 dentists owed $3.1 million, and 626 optometrists owed $502,000.

Richard McGowan, a spokesman for the inspector general's office, said 401 doctors who owed a total of $443,000 on their loans had received more than $10 million from Medicare and Medicaid in the last two years.

Eighty-three faculty members at 17 medical schools and 80 doctors employed by the Health and Human Services department are delinquent in repaying their loans, he said.

From *The New York Times*, April 10, 1982.