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ELIXIR

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Summary of Prescribing Information
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Capsules: Contain codeine phosphate* No 3—30 mg (½ gr), No 4—60 mg (1 gr)—plus acetaminophen 300 mg
Elixir: Each 5 ml contains 12 mg codeine phosphate* plus 120 mg acetaminophen (alcohol 7%)
***Warning:** May be habit forming
Contraindications: Hypersensitivity to acetaminophen or codeine
Warnings: *Drug dependence* Codeine can produce drug dependence of the morphine type and may be abused Dependence and tolerance may develop upon repeated administration, prescribe and administer with same caution appropriate to other oral narcotics Subject to the Federal Controlled Substances Act
Precautions: General—*Head injury and increased intracranial pressure* Respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure Narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries
Acute abdominal conditions Codeine or other narcotics may obscure the diagnosis or clinical course of acute abdominal conditions
Special risk patients Administer with caution to certain patients such as the elderly or debilitated and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture
Information for Patients: *Usage in ambulatory patients* Codeine may impair mental and/or physical abilities required for performance of potentially hazardous tasks such as driving a car or operating machinery
Drug Interactions: Patients receiving other narcotic analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics or other CNS depressants (including alcohol) with this drug may exhibit additive CNS depression When such a combination is contemplated, reduce the dose of one or both agents
The use of MAO inhibitors or tricyclic antidepressants with codeine preparations may increase the effect of either the antidepressant or codeine
The concurrent use of anticholinergics with codeine may produce paralytic ileus
Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies in animals have been performed with acetaminophen or codeine to determine carcinogenic potential or effects on fertility
Acetaminophen and codeine have been found to have no mutagenic potential using the Ames Salmonella-Microsomal Activation test, the Basc test on Drosophila germ cells, and the Micronucleus test on mouse bone marrow
Teratogenic Effects: Pregnancy Category C Codeine has been shown to be teratogenic in mice when given in doses 17 times the maximum human daily dose There are no adequate and well controlled studies in pregnant women
TYLENOL with Codeine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus
Nursing Mothers: It is not known whether the components of this drug are excreted in human milk, caution should be exercised when TYLENOL with Codeine is administered to a nursing woman
Pediatric Use: Safe dosage of the elixir has not been established in children below the age of three, the tablets and capsules should not be administered to children under 12
Adverse Reactions: *Most frequent* Lightheadedness, dizziness, sedation, shortness of breath, nausea and vomiting, and are more prominent in ambulatory than in nonambulatory patients, some of these may be alleviated if the patient lies down *Others* euphoria, dysphoria, constipation, and pruritus
At higher doses codeine has most of the disadvantages of morphine including respiratory depression
Dosage and Administration: Dosage should be adjusted according to severity of pain and response of the patient
TYLENOL with Codeine tablets and capsules are given orally
The usual adult dose is Tablets No 1, No 2, and No 3 and Capsules No 3 One or two every four hours as required
Tablets and Capsules No 4 One every four hours as required
The recommended dose of codeine in children is 0 5 mg/kg body weight
TYLENOL with codeine elixir contains 12 mg of codeine/5 ml teaspoon and is given orally The usual doses are *Children (3 to 6 years)* 1 teaspoonful (5 ml) 3 or 4 times daily. *(7 to 12 years) 2 teaspoonsful (10 ml) 3 or 4 times daily. (under 3 years)* safe dosage has not been established *Adults* 1 tablespoonful (15 ml) every 4 hours as needed
Full directions for use should be read before administering or prescribing
For information on symptoms/treatment of overdosage, see full prescribing information

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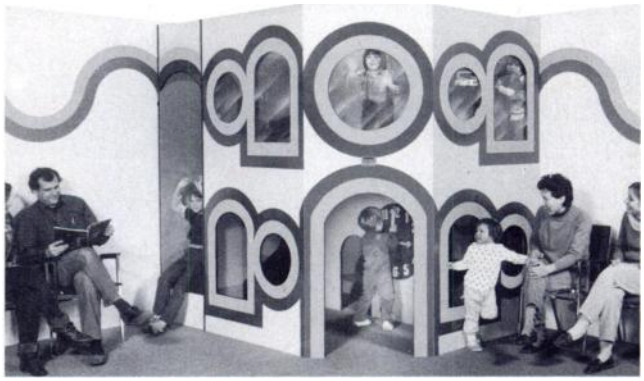

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Indications

Major indications for GRIFULVIN V griseofulvin microsize are

Tinea capitis	Tinea unguium
Tinea corporis	Tinea cruris
Tinea pedis	Tinea barbae

GRIFULVIN V (griseofulvin microsize) inhibits the growth of those genera of fungi that commonly cause ringworm infections of the hair, skin, and nails, such as

Trichophyton rubrum	Microsporum audouini
Trichophyton tonsurans	Microsporum canis
Trichophyton mentagrophytes	Microsporum gypseum
Trichophyton interdigitalis	Epidermophyton floccosum
Trichophyton verrucosum	Trichophyton megnini
Trichophyton sulphureum	Trichophyton gallinae
Trichophyton schoenleini	Trichophyton crateriform

Note: Prior to therapy, the type of fungi responsible for the infection should be identified. The use of the drug is not justified in minor or trivial infections which will respond to topical antifungal agents alone.

It is *not* effective in

Bacterial infections	Coccidioidomycosis
Candidiasis (Moniliasis)	North American Blastomycosis
Histoplasmosis	Cryptococcosis (Torulosis)
Actinomycosis	Tinea versicolor
Sporotrichosis	Nocardiosis
Chromoblastomycosis	

Contraindications

This drug is contraindicated in patients with porphyria, hepatocellular failure, and in individuals with a history of hypersensitivity to griseofulvin.

Warnings

Usage in Pregnancy: Safe use of GRIFULVIN V (griseofulvin microsize) in pregnancy has not been established.

Prophylactic Usage: Safety and efficacy of prophylactic use of this drug has not been established.

Chronic feeding of griseofulvin, at levels ranging from 0.5-2.5% of the diet, resulted in the development of liver tumors in several strains of mice, particularly in males. Smaller particle sizes result in an enhanced effect. Lower oral dosage levels have not been tested. Subcutaneous administration of relatively small doses of griseofulvin once a week during the first three weeks of life has also been reported to induce hepatomata in mice. Although studies in other animal species have not yielded evidence of tumorigenicity, these studies were not of adequate design to form a basis for conclusions in this regard.

In subacute toxicity studies, orally administered griseofulvin produced hepatocellular necrosis in mice, but this has not been seen in other species. Disturbances in porphyrin metabolism have been reported in griseofulvin-treated laboratory animals. Griseofulvin has been reported to have a colchicine-like effect on mitosis and cocarcinogenicity with methylcholanthrene in cutaneous tumor induction in laboratory animals.

Reports of animal studies in the Soviet literature state that a griseofulvin preparation was found to be embryotoxic and teratogenic on oral administration to pregnant Wistar rats. Rat reproduction studies done thus far in the United States and Great Britain have been inconclusive in this regard, and additional animal reproduction studies are underway. Pups with abnormalities have been reported in the litters of a few bitches treated with griseofulvin.

Suppression of spermatogenesis has been reported to occur in rats but investigation in man failed to confirm this.

Precautions

Patients on prolonged therapy with any potent medication should be under close observation. Periodic monitoring of organ system function, including renal, hepatic and hemopoietic, should be done.

Since griseofulvin is derived from species of penicillin, the possibility of cross sensitivity with penicillin exists, however, known penicillin-sensitive patients have been treated without difficulty.

Since a photosensitivity reaction is occasionally associated with griseofulvin therapy, patients should be warned to avoid exposure to intense natural or artificial sunlight. Should a photosensitivity reaction occur, lupus erythematosus may be aggravated.

Patients on warfarin-type anticoagulant therapy may require dosage adjustment of the anticoagulant during and after griseofulvin therapy. Concomitant use of barbiturates usually depresses griseofulvin activity and may necessitate raising the dosage.

Adverse Reactions

When adverse reactions occur, they are most commonly of the hypersensitivity type such as skin rashes, urticaria and rarely, angioneurotic edema, and may necessitate withdrawal of therapy and appropriate countermeasures. Paresthesias of the hands and feet have been reported rarely after extended therapy. Other side effects reported occasionally are oral thrush, nausea, vomiting, epigastric distress, diarrhea, headache, fatigue, dizziness, insomnia, mental confusion and impairment of performance of routine activities.

Proteinuria and leukopenia have been reported rarely. Administration of the drug should be discontinued if granulocytopenia occurs.

When rare, serious reactions occur with griseofulvin, they are usually associated with high dosages, long periods of therapy, or both.

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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

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Revised, July 1985

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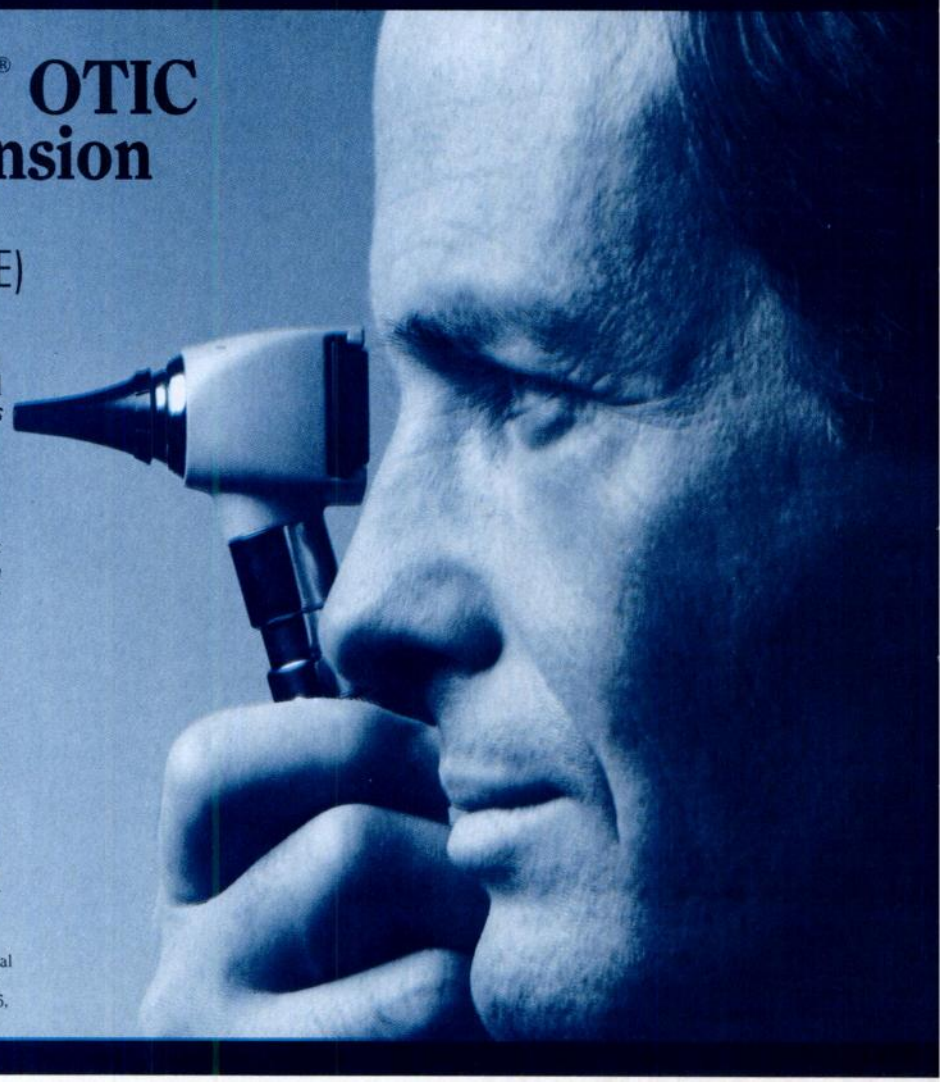
Responders	91 (97.8%)
Solution	
Total ears	107
Responders	104 (97.2%)
Combined suspension and solution	
Total ears	200
Responders	195 (97.5%)

Adapted from Cassisi et al.[1]

REFERENCE:

1. Cassisi N, Cohn A, Davidson T, et al: Diffuse otitis externa: Clinical and microbiologic findings in the course of a multicenter study on a new otic solution. *Ann Otol Rhinol Laryngol* 86(suppl 39, pt 3):1-16, 1977.



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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.

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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.

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DECEMBER 1985 VOL. 76 NO. 6

Pediatrics

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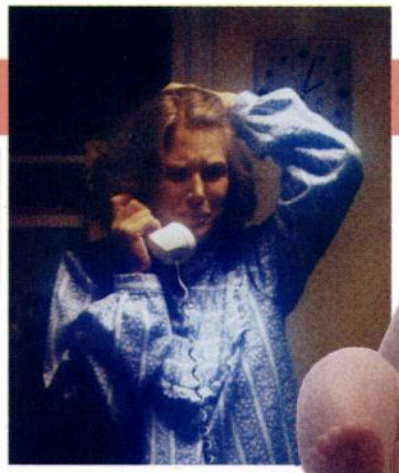

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1. Lothe L, Lindberg T, Jakobsson I: Cow's milk formula as a cause of infantile colic: A double-blind study. *Pediatrics* 1982;70:7-10.
2. American Academy of Pediatrics/Committee on Nutrition: Soy-protein formulas: Recommendations for use in infant feeding. *Pediatrics* 1983; 72:359-363.

*Seventeen infants had spontaneous recovery on cow milk-based formula.

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ANNUAL MEETINGS

1986
Washington, DC
November 1–6

1987
New Orleans
October 31–November 5

1988
San Francisco
October 22–27

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Chicago
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October 6–11

1991
New Orleans
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May 9–14

1988
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May 14–19

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950 **Recurrent Bacterial Meningitis: Coronal Thin-Section Cranial Computed Tomography to Delineate Anatomic Defects**—Russell W. Steele, James R. McConnell, Richard F. Jacobs, and John R. Mawk

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958 **Urinary β_2-Microglobulin in Full-Term Newborns: Evidence for Proximal Tubular Dysfunction in Infants With Meconium-Stained Amniotic Fluid**—J. W. Cole, R. J. Portman, Y. Lim, J. M. Perlman, and A. M. Robson

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975 **Bromate Poisoning From Hair Permanent Preparations**—Barry L. Warshaw, Melody C. Carter, Leonard C. Hymes, Barbara S. Bruner, and Albert P. Rauber

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981 **Infantile Myofibromatosis**—Thomas E. Wiswell, E. Lawrence Sakas, Stephen R. Stephenson, John J. Lesica, and Shirley R. Reddoch

984 **Proteus Syndrome: Report of Two Cases With Pelvic Lipomatosis**—Teresa Costa, Naomi Fitch, and E. Michael Azouz

989 **Diffuse Retinopathy Following Measles, Mumps, and Rubella Vaccination**—Gary S. Marshall, Peter F. Wright, Gerald M. Fenichel, and David T. Karzon

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993 **Where to Now, Henry? A Commentary on the Battered Child Syndrome**—Ray E. Helfer

998 **Intrauterine Growth Retardation: Adaptation or Pathology?**—Joseph B. Warshaw

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*American Dental Association, Accepted Dental Therapeutics, Edition 39 1982, page 349. American Academy of Pediatrics, Committee on Nutrition, Fluoride supplementation: revised dosage schedule. Pediatrics 63:150-152, 1979.

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REFERENCES:
(1) Arnold F.A. Jr., McClure, F.J., and White, C.L. Sodium fluoride tablets for children. D. Progress 1:8-12, 1960.

(2) Aasenden, R., and Peebles, T.C. Effects of fluoride supplementation from birth on human deciduous and permanent teeth. Arch. Oral Biol. 19:321-326, 1974; 23:111-115, 1978.

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March 14–16

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Vancouver, British Columbia
June 1–3

Connective Tissue Disease, Pulmonology, and Intensive Care
Hilton Head, South Carolina
June 12–14

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1000 **Annual Meeting of the Section on Pediatric Urology**—Kenneth I. Glassberg

1004 **1984 Milk-Feeding Patterns in the United States**—Gilbert A. Martinez and Fritz W. Krieger

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1009 **Smokeless Tobacco—A Carcinogenic Hazard to Children**—Committee on Environmental Hazards

1012 TRIBUTE TO THE REVIEWERS 1984–1985

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1018 **Bifid Uvula**—Roland D. Eavey; Reply by Robert J. Shprintzen

1020 **Hepatitis B Immunoprophylaxis of Low-Birth-Weight Infants**—Joan Genesca, Juan I. Esteban, and Rafael Esteban

1020 **Penny Eaters Beware!**—Steven Seifert and James H. McLaughlin

1020 **Are Granulocyte Transfusions of Value in Septic Neonates Without Neutrophil Storage Pool Depletion?**—Richard S. Newman and Jose A. Ocariz; Reply by Mitchell S. Cairo

1021 **Health Hazards of Cow's Milk**—Swiss Pediatric Association, Committee on Nutrition; Reply by Frank A. Oski; and Lewis A. Barness

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BOOKS RECEIVED

Cystic Fibrosis. L. M. Taussig. New York, Thieme-Stratton Inc, 1984, $48.50, 498 pp.
French's Index of Differential Diagnosis, ed 12. F. D. Hart. Bristol, England, John Wright & Sons Ltd, 1985, 1032 pp.
Pocket Examiner in Paediatrics. T. Lissauer and A. Goldman. Baltimore, Urban and Schwarzenberg Medical Publishers, 1985, $9.50, 170 pp.
The Pediatric Spine. D. S. Bradford and R. Hensinger. New York, Thieme Inc, 1985, $80 (US), $96 (outside US), 544 pp.
Vaccine Supply and Innovation. Institute of Medicine. Washington, DC, National Academy Press, 1985, $21 (US, Canada, and Mexico), $25.50 (export), 210 pp.
Pediatric Endocrinology: A Clinical Guide. F. Lifshitz. New York, Marcel Dekker, Inc, 1985, $95 (US and Canada), $114 (all other countries), 680 pp.
School's Out-Now What? Creative Choices for Your Child. J. M. Bergstrom. Berkeley, CA, Ten Speed Press, 1984, $10.95, 321 pp.

PEDIATRICS IN REVIEW: February 1986 Contents

New Immunizations for Children—Phillips
Severe Croup: The Child With Fever and Upper Airway Obstruction—Battaglia
Pulmonary Function Testing—Eigen
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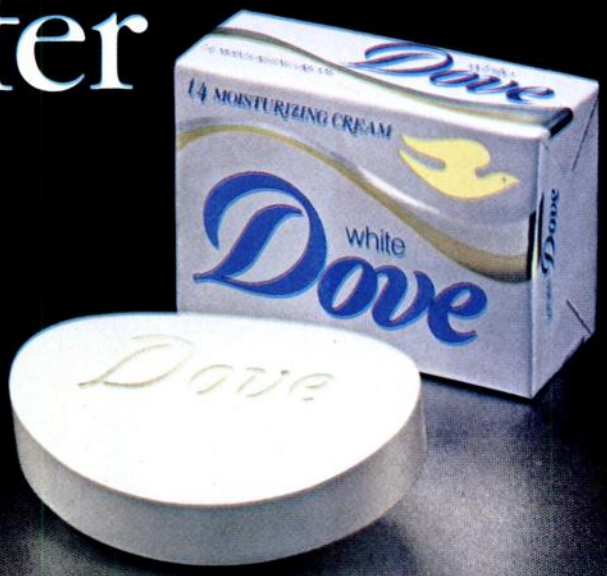

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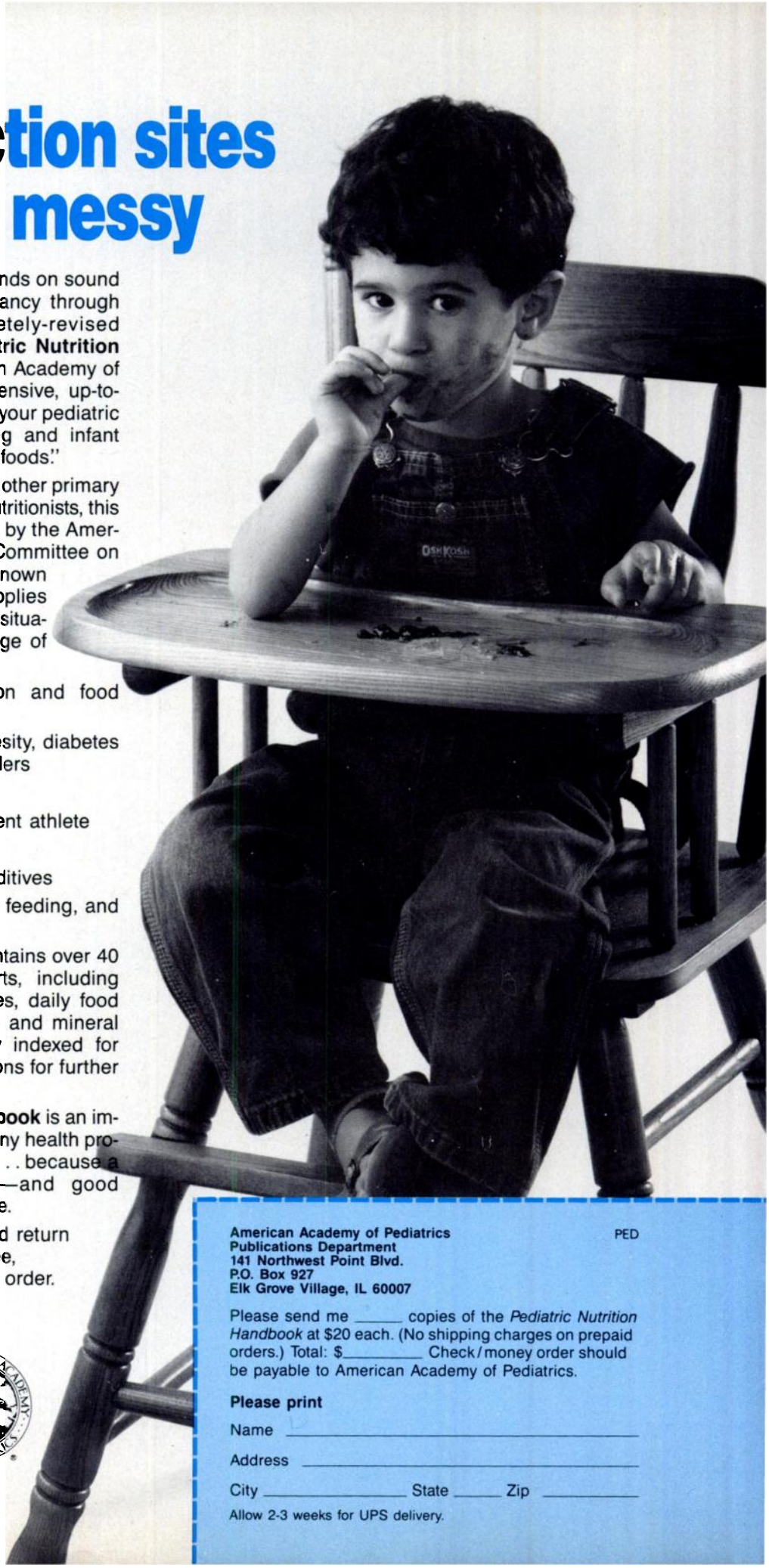

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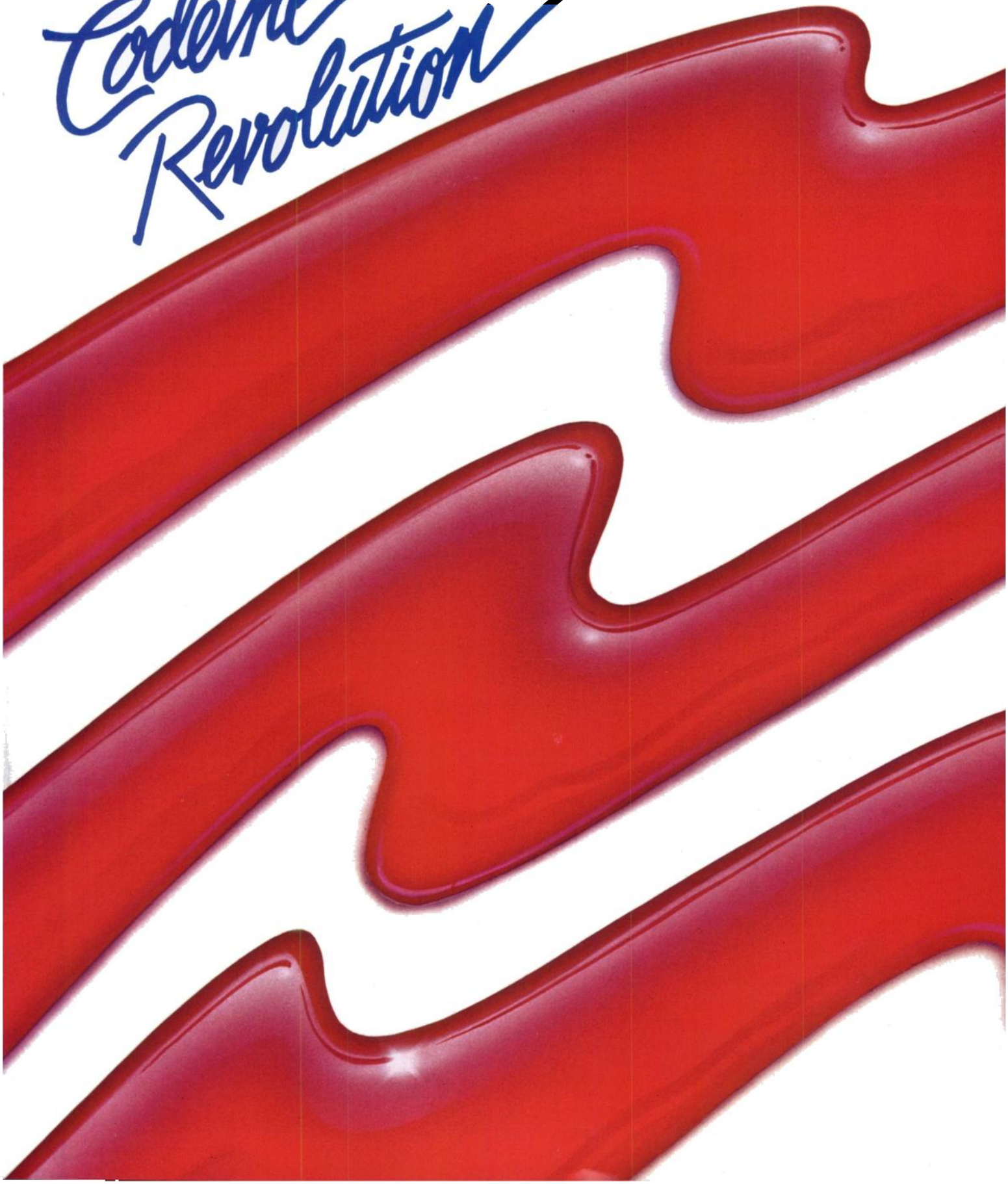

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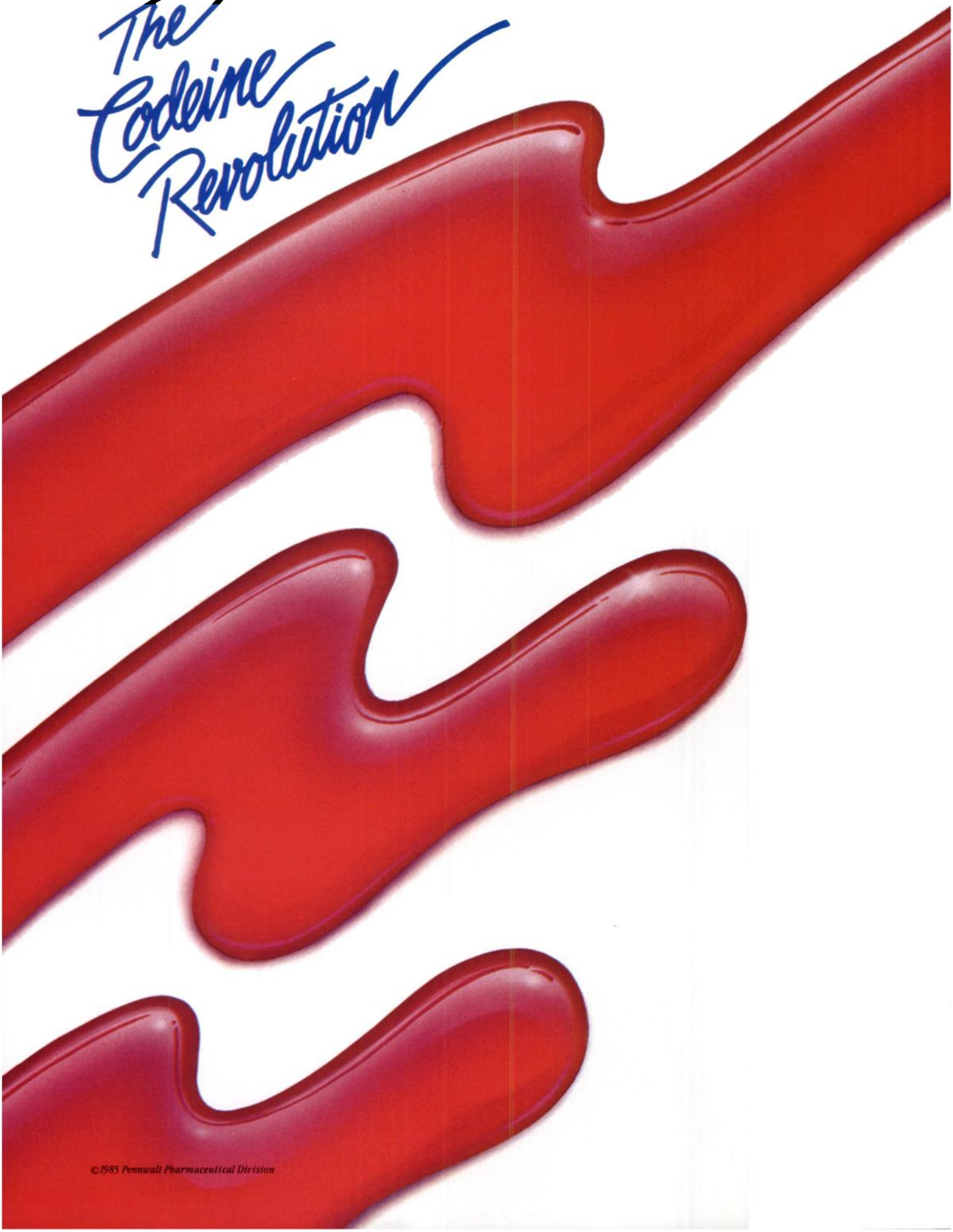

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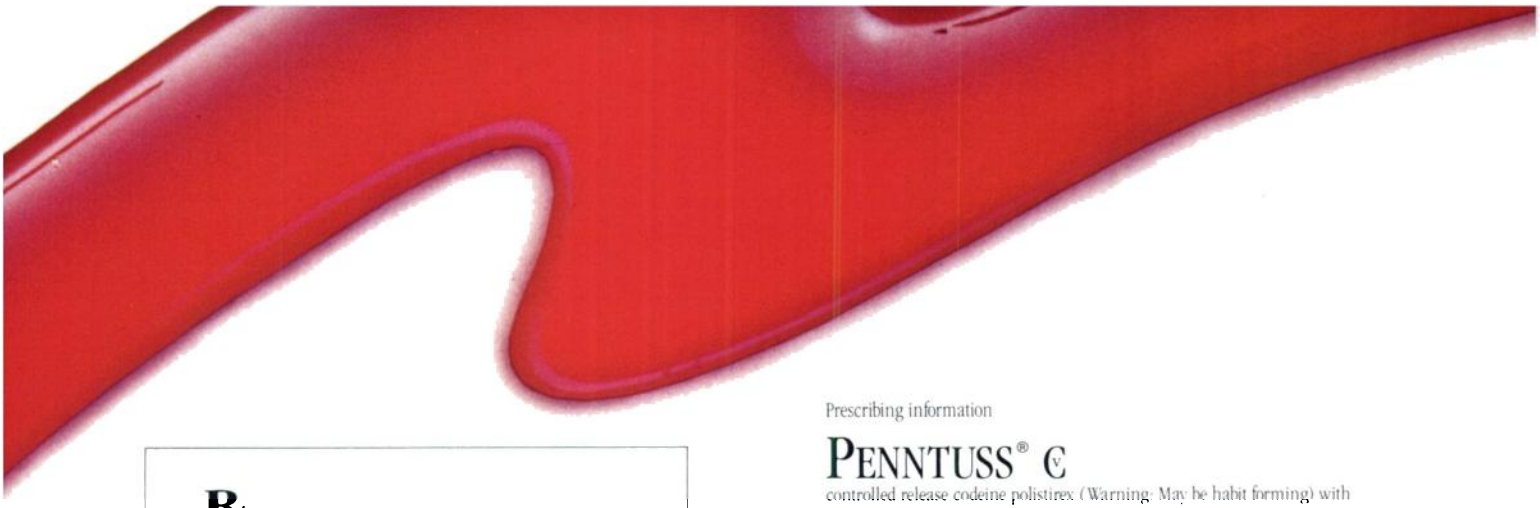

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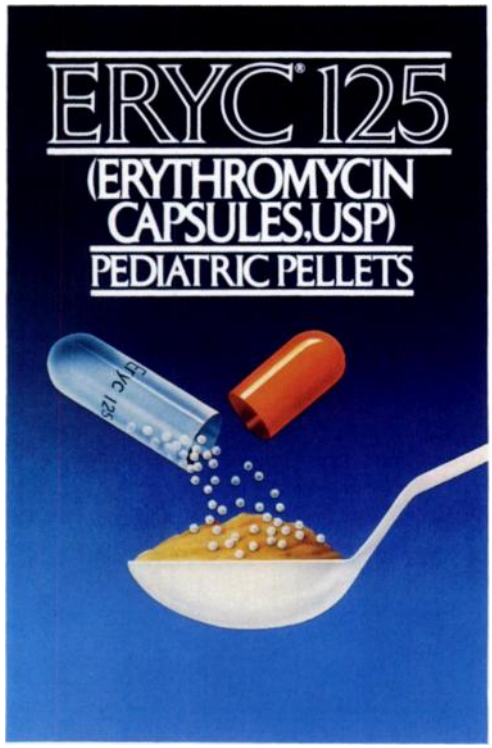

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Lower respiratory tract infections of mild to moderate severity caused by *Streptococcus pyogenes* (group A beta hemolytic streptococci); *Streptococcus pneumoniae (Diplococcus pneumoniae)*

Respiratory tract infections due to *Mycoplasma pneumoniae* (Eaton's agent)

Skin and skin structures infections of mild to moderate severity caused by *Streptococcus pyogenes* and *Staphylococcus aureus* (resistant staphylococci may emerge during treatment)

Pertussis (whooping cough) caused by *Bordetella pertussis*. Erythromycin is effective in eliminating the organism from the nasopharynx of infected individuals, rendering them noninfectious. Some clinical studies suggest that erythromycin may be helpful in the prophylaxis of pertussis in exposed susceptible individuals.

Diphtheria—As an adjunct to antitoxin in infections due to *Corynebacterium diphtheriae*, to prevent establishment of carriers and to eradicate the organism in carriers.

Erythrasma—In the treatment of infections due to *Corynebacterium minutissimum*.

Intestinal amebiasis caused by *Entamoeba histolytica* (oral erythromycins only). Extraenteric amebiasis requires treatment with other agents.

Infections due to *Listeria monocytogenes*.

Erythromycin is indicated for treatment of the following infections caused by *Chlamydia trachomatis*: conjunctivitis of the newborn, pneumonia of infancy and urogenital infections during pregnancy. When tetracyclines are contraindicated or not tolerated, erythromycin is indicated for the treatment of uncomplicated urethral, endocervical, or rectal infections in adults due to *Chlamydia trachomatis*.

When tetracyclines are contraindicated or not tolerated erythromycin is indicated for the treatment of nongonococcal urethritis caused by *Ureaplasma urealyticum*.

Primary syphilis caused by *Treponema pallidum*. Erythromycin (oral forms only) is an alternative choice of treatment for primary syphilis in patients allergic to the penicillins. In treatment of primary syphilis, spinal fluid should be examined before treatment and as part of the follow-up after therapy.

Legionnaires' Disease caused by *Legionella pneumophila*. Although no controlled clinical efficacy studies have been conducted, in vitro and limited preliminary clinical data suggest that erythromycin may be effective in treating Legionnaires' Disease.

Prevention of Initial Attacks of Rheumatic Fever—Penicillin is considered by the American Heart Association to be the drug of choice in the prevention of initial attacks of rheumatic fever (treatment of group A beta-hemolytic streptococcal infections of the upper respiratory tract, e.g. tonsillitis or pharyngitis).

Erythromycin is indicated for the treatment of penicillin-allergic patients. A therapeutic dose should be administered for ten days.

Prevention of Recurrent Attacks of Rheumatic Fever—Penicillin or sulfonamides are considered by the American Heart Association to be the drugs of choice in the prevention of recurrent attacks of rheumatic fever.

In patients who are allergic to penicillin and sulfonamides, oral erythromycin is recommended by the American Heart Association in the long-term prophylaxis of streptococcal pharyngitis (for the prevention of recurrent attacks of rheumatic fever).

Prevention of Bacterial Endocarditis—Although no controlled clinical efficacy trials have been conducted, oral erythromycin has been recommended by the American Heart Association for prevention of bacterial endocarditis in penicillin-allergic patients with prosthetic cardiac valves, most congenital cardiac malformations, surgically constructed systemic-pulmonary shunts, rheumatic or other acquired valvular dysfunction, idiopathic hypertrophic subaortic stenosis (IHSS), previous history of bacterial endocarditis and mitral valve prolapse with insufficiency when they undergo dental procedures and surgical procedures of the upper respiratory tract.

CONTRAINDICATION: ERYC 125 is contraindicated in patients with known hypersensitivity to this antibiotic.

WARNING: There have been a few reports of hepatic dysfunction, with or without jaundice, occurring in patients receiving erythromycin ethylsuccinate, base, estolate and stearate products.

PRECAUTIONS: Caution should be exercised when erythromycin is administered to patients with impaired hepatic function (see CLINICAL PHARMACOLOGY and WARNING section).

Prolonged or repeated use of erythromycin may result in an overgrowth of nonsusceptible bacteria or fungi. If superinfection occurs, erythromycin should be discontinued and appropriate therapy instituted. When indicated, incision and drainage or other surgical procedures should be performed in conjunction with antibiotic therapy.

Laboratory Tests: Erythromycin interferes with the fluorometric determination of urinary catecholamines.

Drug Interactions: Erythromycin use in patients who are receiving high doses of theophylline may be associated with an increase in 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.

Erythromycin administration in patients receiving carbamazepine has been reported to cause increased blood levels of carbamazepine with subsequent development of signs of carbamazepine toxicity.

Pregnancy Category B—Reproduction studies have been performed in rats, mice and rabbits using erythromycin and its various salts and esters, at doses which were several times the usual human dose. No evidence of impaired fertility or harm to the fetus that appeared related to erythromycin was reported in these studies. There are, however, no adequate 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.

Labor and Delivery—The effect of ERYC 125 on labor and delivery is unknown.

Nursing Mothers—Erythromycin is excreted in milk (see CLINICAL PHARMACOLOGY).

Pediatric Use—See INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION.

ADVERSE REACTIONS: The most frequent side effects of oral erythromycin preparations are gastrointestinal and are dose-related. They include nausea, vomiting, abdominal pain, diarrhea and anorexia. Symptoms of hepatic dysfunction and/or abnormal liver function test results may occur (see WARNING).

Mild allergic reactions such as rashes with or without pruritus, urticaria, bullous fixed eruptions, and eczema have been reported with erythromycin. Serious allergic reactions, including anaphylaxis, have been reported.

There have been isolated reports of reversible hearing loss occurring chiefly in patients with renal insufficiency and in patients receiving high doses of erythromycin.

DOSAGE AND ADMINISTRATION: The entire contents of an ERYC 125 Capsule should be sprinkled on a small amount of applesauce immediately prior to ingestion. SUBDIVIDING THE CONTENTS OF A CAPSULE IS NOT RECOMMENDED. If desired ERYC 125 Capsule may be swallowed whole.

Optimum and uniform serum levels of erythromycin are obtained when ERYC 125 is administered in the fasting state (at least 1 hour before meals).

ADULTS: The usual dose is 250 mg every 6 hours. If twice-a-day dosage is desired, the recommended dose is 500 mg every 12 hours. Dosage may be increased up to 4 grams per day, according to the severity of infection. Twice-a-day dosing is not recommended when doses larger than 1 gram daily are administered.

CHILDREN: Age, weight, and severity of the infection are important factors in determining the proper dosage. The usual dosage is 30-50 mg/kg/day in equally divided doses. For the treatment of more severe infections this dosage may be doubled.

In the treatment of group A beta-hemolytic streptococcal infections of the upper respiratory tract (eg tonsillitis or pharyngitis) a therapeutic dosage of erythromycin should be administered for ten days.

The American Heart Association suggests a dosage of 250 mg of erythromycin orally twice a day in long-term prophylaxis of streptococcal upper respiratory tract infections for the prevention of recurrent attacks of rheumatic fever in patients allergic to penicillin and sulfonamide.

In prophylaxis against bacterial endocarditis (see Indications), the oral regimen for penicillin-allergic patients is erythromycin 1.0 g one hour before the procedure followed by 500 mg six hours later.

Conjunctivitis of the newborn caused by *Chlamydia trachomatis*: Oral erythromycin syrup 50 mg/kg/day in four divided doses for at least two weeks.

Pneumonia of infancy caused by *Chlamydia trachomatis*: Although the optimal duration of therapy has not been established, the recommended therapy is oral erythromycin syrup 50 mg/kg/day in four divided doses for at least three weeks.

Urogenital infections during pregnancy due to *Chlamydia trachomatis*: Although the optimal dose and duration of the therapy have not been established, the suggested treatment is erythromycin 500 mg, by mouth, four times a day on an empty stomach for at least seven days. For women who cannot tolerate this regimen, a decreased dose of 250 mg, by mouth, four times a day should be used for at least fourteen days.

For adults with uncomplicated urethral, endocervical, or rectal infections caused by *Chlamydia trachomatis* in whom tetracyclines are contraindicated or not tolerated: 500 mg, by mouth, four times a day for at least seven days.

For patients with nongonococcal urethritis caused by *Ureaplasma urealyticum* in whom tetracyclines are contraindicated or not tolerated: 500 mg, by mouth, four times a day for at least seven days.

Primary syphilis: 30-40 grams given in divided doses over a period of ten to fifteen days.

Intestinal amebiasis: 250 mg four times daily for ten to fourteen days for adults; 30 to 50 mg/kg/day in divided doses for ten to fourteen days for children.

Legionnaires' Disease: Although optimal doses have not been established, doses utilized in reported clinical data were those recommended above (1 to 4 grams daily in divided doses).

Pertussis: Although optimum dosage and duration of therapy have not been established, doses of erythromycin utilized in reported clinical studies were 40-50 mg/kg/day, given in divided doses for five to fourteen days.

Caution—Federal law prohibits dispensing without prescription.

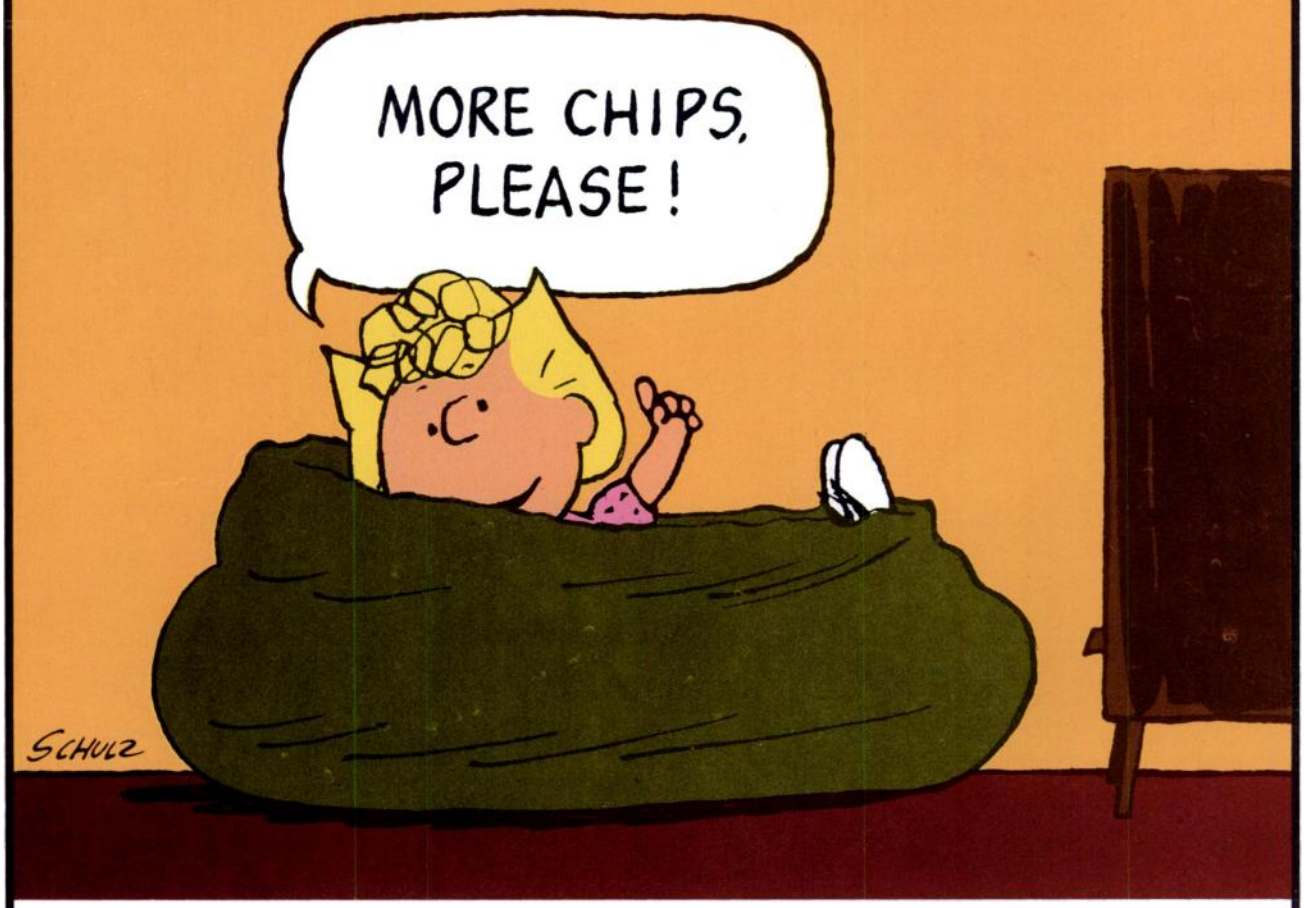
Distributed by

PARKE-DAVIS

Division of Warner-Lambert Company
Morris Plains, New Jersey 07950 USA

PD-10-JA-3482-P-2(9-85)

THIS IS HOW TODAY'S KIDS STAY HEALTHY.



In fact, our kids' health is declining.

The real problem is that most kids don't know how to stay healthy. They have poor habits in every way—physically, mentally, emotionally, and socially.

School programs attacking individual problems may help but just aren't enough, so...

Metropolitan Life Foundation announces "Healthy Me."

"Healthy Me" is a multi-million dollar initiative, the first ever developed by the private sector to encourage comprehensive health education programs by schools and communities.

Cash awards are offered by Metropolitan Life Foundation to schools with exemplary programs and to community groups that actively promote them.

For more information contact "Healthy Me," Health and Safety Education (16UV), One Madison Avenue, New York, NY 10010-3690.

These are our kids and they're our future. What could be more important?

Metropolitan Life Foundation

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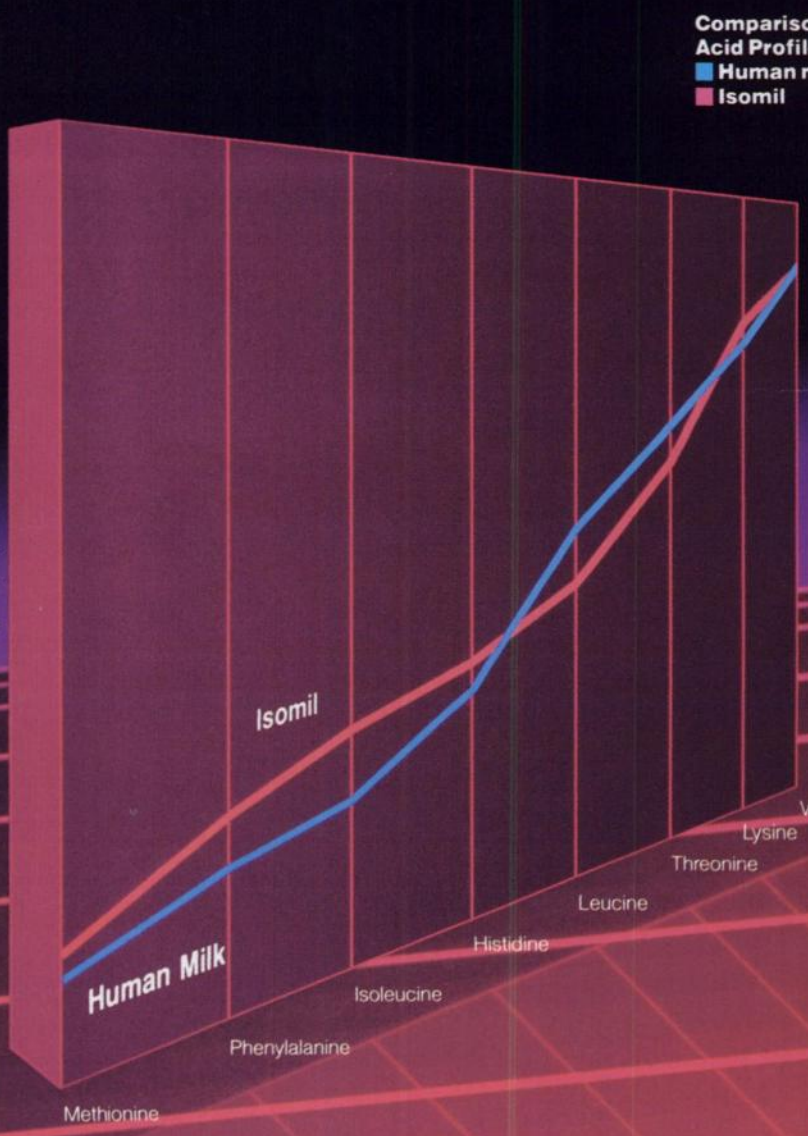
in vivo performance...

Plasma amino acid* profile—similar to that of breast-fed babies.

New clinical evidence demonstrates that the plasma amino acid profile of infants fed Isomil® is similar to that of breast-fed infants.[1]

For optimal development, amino acid metabolism of the formula-fed infant should be as close as possible to that of the breast-fed infant, the nutritional norm.[2-5]



***Essential amino acids.**

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Plasma carnitine level—similar to that of breast-fed babies.

Clinical evidence confirms that the plasma carnitine level of infants fed carnitine-supplemented soy protein formula was more like that of breast-fed babies than that of infants given unsupplemented soy-based formula.[6,7]

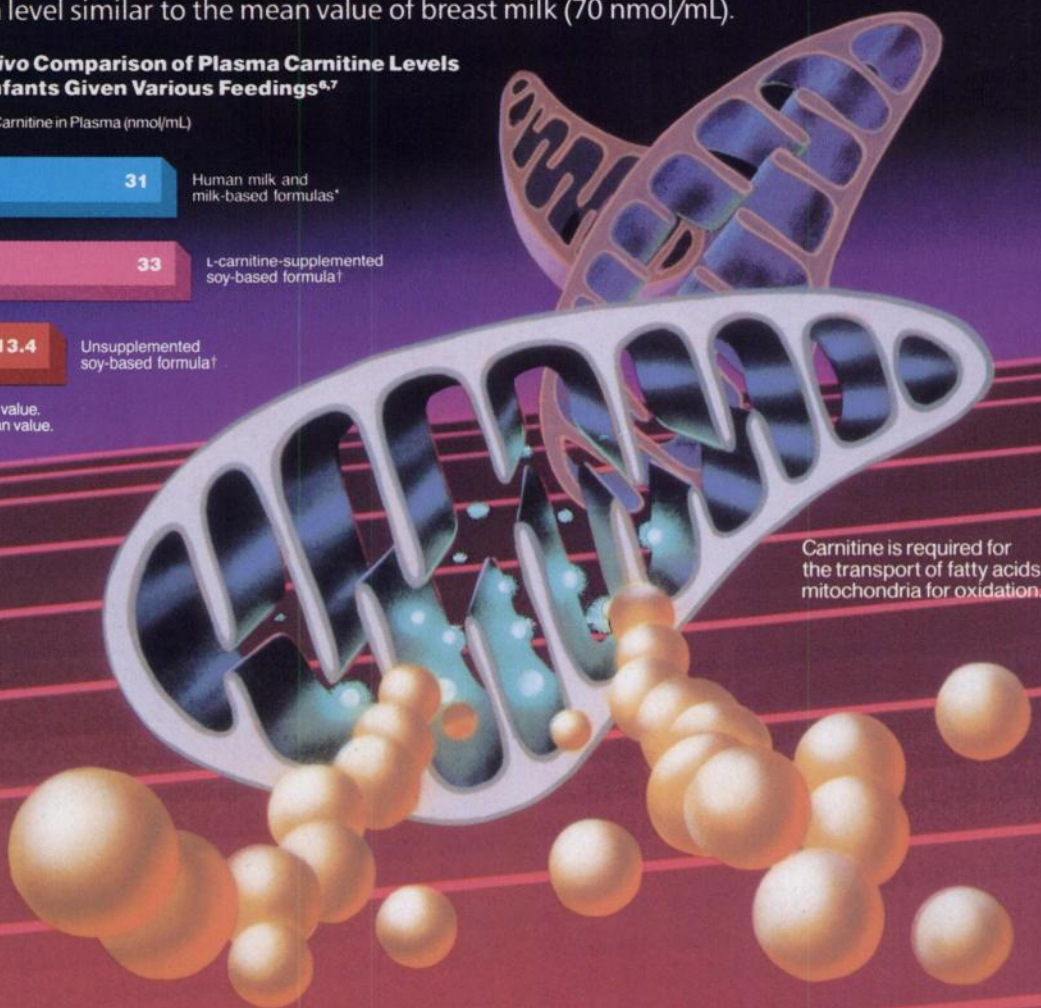
Breast milk and milk-based formulas contain carnitine[8,9] —now so does Isomil.

Carnitine allows for optimal oxidation of fatty acids—the major source of energy for infants.[10]

Isomil is the soy protein formula that is supplemented with L-carnitine at a level similar to the mean value of breast milk (70 nmol/mL).

***In Vivo* Comparison of Plasma Carnitine Levels in Infants Given Various Feedings[6,7]**

*Mean value.
†Median value.



Carnitine is required for the transport of fatty acids into mitochondria for oxidation.

Meeting the standard of *in vivo* performance...

ISOMIL®

SOY PROTEIN FORMULA

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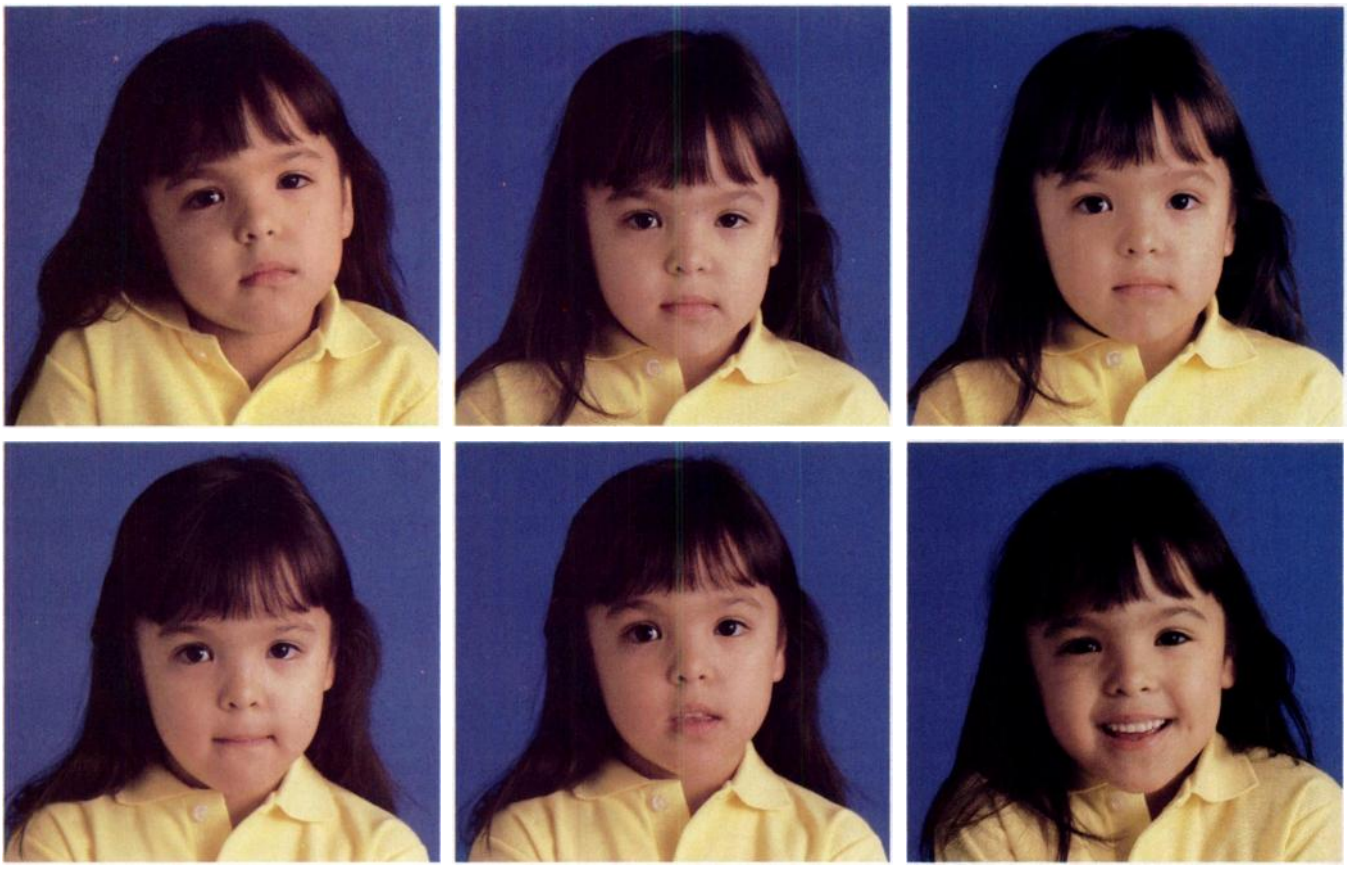
ROSS

B721/5820

Fast relief to put back the smiles that runny, stuffy noses take away

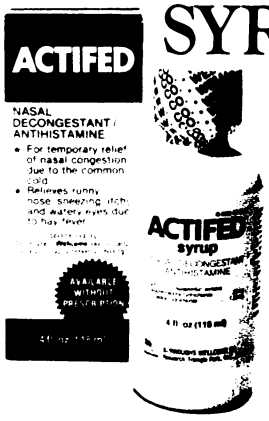


Thank you, Doctor

Prescription-strength cold relief you can recommend with confidence. When runny, stuffy noses need rapid decongestant/antihistamine action, remember ACTIFED SYRUP starts working quickly so your patients can return to play or school without cold miseries. ACTIFED SYRUP delivers the same effective, well-tolerated relief that NASA has relied on for every manned space flight since 1968.

To be given every 4 to 6 hours.
Do not exceed 4 doses in 24 hours.
Adults and children 12 years of age and over: 1 tablet or 2 teaspoonfuls syrup.
Children 6 to under 12 years of age, ½ tablet or 1 teaspoonful syrup.
Children 4 to under 6 years of age, ¾ teaspoonful syrup.
Children 2 to under 4 years of age, ½ teaspoonful syrup.
Children 4 months to under 2 years of age, ¼ teaspoonful syrup.

ACTIFED® SYRUP



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Bicillin® C-R 900/300

(penicillin G benzathine and penicillin G procaine suspension)

IN STREPTOCOCCAL PHARYNGITIS: THE PEDIATRIC PENICILLIN FOR THE '80s

- Eliminates dosage compliance concerns for working parents
- Solves dosage compliance problems in clinic and emergency room settings

for deep IM injection only.

Description Each TUBEX cartridge (2 ml size) contains 1,200,000 units of penicillin comprising: 900,000 units penicillin G benzathine and 300,000 units penicillin G procaine in a stabilized aqueous suspension with sodium citrate buffer; and as w/v, approximately 0.5% lecithin, 0.55% carboxymethylcellulose, 0.55% povidone, 0.1% methylparaben, and 0.01% propylparaben.

Bicillin C-R 900/300 suspension is viscous and opaque. Read "Contraindications," "Warnings," "Precautions," and "Dosage and Administration" sections prior to use.

Indications In children of all ages in treatment of moderately severe infections due to penicillin-G-susceptible microorganisms susceptible to serum levels common to this dosage form. Therapy should be guided by bacteriological studies (including susceptibility testing) and clinical response.

NOTE: When high, sustained serum levels are required, penicillin G sodium or potassium, IM or IV, should be used. This drug should *not* be used in venereal diseases, including syphilis, gonorrhea, yaws, bejel and pinta.

Following infections usually respond to adequate dosages:

Streptococcal infections Group A (without bacteremia). Moderately severe to severe infections of the upper respiratory tract, skin and soft-tissue infections, scarlet fever, and erysipelas.

NOTE: Streptococci in groups A, C, G, H, L, and M are very sensitive to penicillin G. Other groups, including group D (enterococci), are resistant. Penicillin G sodium or potassium is recommended for streptococcal infections with bacteremia.

Pneumococcal infections: Moderately severe pneumonia and otitis media.

NOTE: Severe pneumonia, empyema, bacteremia, pericarditis, meningitis, peritonitis, and arthritis of pneumococcal etiology are better treated with penicillin G sodium or potassium during the acute stage.

Contraindications Previous hypersensitivity reaction to any penicillin or to procaine.

Do not inject into or near an artery or nerve.

Warnings Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. Although anaphylaxis is more frequent following parenteral therapy, it has occurred with oral penicillins. These reactions are more apt to occur in individuals with history of sensitivity to multiple allergens.

There have been well-documented reports of individuals 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 penicillin and treat patient with usual agents, e.g., pressor amines, antihistamines, and corticosteroids.

Inadvertent intravascular administration, including inadvertent direct intraarterial injection or injection immediately adjacent to arteries, of Bicillin C-R 900/300 and other penicillin preparations has resulted in severe neurovascular damage, including transverse myelitis with permanent paralysis, gangrene requiring amputation of digits and more proximal portions of extremities, and necrosis and sloughing at and surrounding the injection site. Such severe effects have been reported following injections into the buttock, thigh, and deltoid areas. Other serious complications of suspected intravascular administration which have been reported include immediate pallor, mottling or cyanosis of the extremity both distal and proximal to the injection site followed by bleb formation; severe edema requiring anterior and/or posterior compartment fasciotomy in the lower extremity. The above- described severe effects and complications have most often occurred in infants and small children. Prompt consultation with an appropriate specialist is indicated if any evidence of compromise of the blood supply occurs at, proximal to, or distal to the site of injection. See "Contraindications," "Precautions," and "Dosage and Administration."

Quadriceps femoris fibrosis and atrophy have been reported following repeated intramuscular injections of penicillin preparations into the anterolateral thigh.

Injection into or near a nerve may result in permanent neurological damage.

Precautions Use penicillin with caution in individuals with histories of significant allergies and/or asthma.

Care should be taken to avoid intravenous or intraarterial administration, or injection into or near major peripheral nerves or blood vessels, since such injections may produce neurovascular damage. See "Contraindications," "Warnings," and "Dosage and Administration."

In streptococcal infections, therapy must be sufficient to eliminate the organism; otherwise sequelae of streptococcal disease may occur. Take cultures following completion of treatment to determine if streptococci have been eradicated.

A small percentage of patients are sensitive to procaine. If there is a history of sensitivity make the usual test: Inject intradermally 0.1 ml of a 1 to 2% procaine solution. Development of an erythema, wheal, flare, or eruption indicates procaine sensitivity. Treat sensitivity by usual methods, including barbiturates, and avoid procaine penicillin. Antihistaminics appear beneficial to procaine reactions.

Antibiotics may result in overgrowth of nonsusceptible organisms. Constant observation of the patient is essential. If new infections due to bacteria or fungi appear during therapy, discontinue drug and take appropriate measures.

Whenever allergic reactions occur, withdraw penicillin unless, in the opinion of the physician, the condition being treated is life-threatening and amenable only to penicillin.

In prolonged therapy with penicillin, and particularly with high-dosage schedules, periodic evaluation of the renal and hematopoietic systems is recommended.

Adverse Reactions Penicillin is a substance of low toxicity but does possess a significant index of sensitization. These hypersensitivity reactions have been reported: skin rashes, ranging from maculopapular eruptions to exfoliative dermatitis; urticaria; serum-sicknesslike reactions, including chills, fever, edema, arthralgia, and prostration. Severe and often fatal anaphylaxis has been reported (see "Warnings").

Dosage and Administration Administer by DEEP, INTRAMUSCULAR INJECTION in the upper, outer quadrant of the buttock. In infants and small children, the midlateral aspect of the thigh may be preferable. When doses are repeated, vary the injection site.

The Wyeth TUBEX cartridge for this product incorporates several features designed to facilitate visualization of blood on aspiration if a blood vessel is inadvertently entered.

The design of this cartridge is such that blood which enters its needle will be quickly visualized as a red or dark-colored "spot." This "spot" will appear on the barrel of the glass cartridge immediately proximal to the blue hub. Prior to injection, to determine where this "spot" can be seen, operator should first insert and secure the cartridge in the TUBEX syringe in usual fashion. The needle cover should then be removed and the cartridge and syringe held in one hand with the needle pointing away from the operator. The glass cartridge should then be rotated by turning the plunger of the syringe clockwise until the flat bevel at the tip of the needle is pointing upward and is horizontal when viewed directly from above. An imaginary straight line, then drawn from the middle of the flat bevel to the back edge of the blue hub where it joins the glass, will point to the area on the glass cartridge where the "spot" can be visualized. (In this same area in some cartridges, a dark spot may sometimes be visualized prior to injection. This is the proximal end of the needle and does not represent a foreign body in, or other abnormality of, the suspension.)

Thus, before the needle is inserted into the selected muscle, it is important for the operator to orient the flat bevel of the needle so that any blood which might enter after its insertion and during aspiration can be visualized in the area of the cartridge where it will appear and not be obscured by the metal syringe or other obstructions.

After selection of the proper site and insertion of the needle into the selected muscle, aspirate by pulling back on the plunger. While maintaining negative pressure for 2-3 seconds, carefully observe the barrel of the cartridge in the area previously identified (see above) for the appearance of a red or dark-colored "spot."

Blood or "typical blood color" may not be seen if a blood vessel has been entered—only a mixture of blood and Bicillin C-R 900/300. The appearance of *any* discoloration is reason to withdraw the needle and discard the glass TUBEX cartridge. If it is elected to inject at another site, a new cartridge should be used. If no blood or discoloration appears, inject the contents of the cartridge slowly. Discontinue delivery of the dose if the subject complains of severe immediate pain at the injection site or if, especially in infants and young children, symptoms or signs occur suggesting onset of severe pain.

Some TUBEX cartridges may contain a small air bubble which may be disregarded since it does not affect administration of the product. Because of the high concentration of suspended material in this product, the needle may be blocked if the injection is not made at a slow, steady rate.

Streptococcal infections Group A—Infections of the upper respiratory tract, skin and soft-tissue infections, scarlet fever, and erysipelas.

A single injection of Bicillin C-R 900/300 (penicillin G benzathine and penicillin G procaine suspension) is usually sufficient for the treatment of Group A streptococcal infections in children of all ages.

Pneumococcal infections (except pneumococcal meningitis): One TUBEX Bicillin C-R 900/300 repeated at 2- or 3-day intervals until the temperature is normal for 48 hours. Other forms of penicillin may be necessary for severe cases.

How Supplied In 2 ml TUBEX® Sterile Cartridge-Needle Units in packages of 10.

See package insert for references.

3/25/83

Wyeth Laboratories
Philadelphia, Pa 19101

Pediazole®

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)	1/2 teaspoonful (2.5 ml)
16 kg (35 lb)	1 teaspoonful (5 ml)
24 kg (53 lb)	1 1/2 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).

ROSS LABORATORIES
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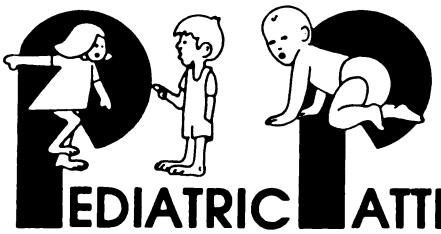

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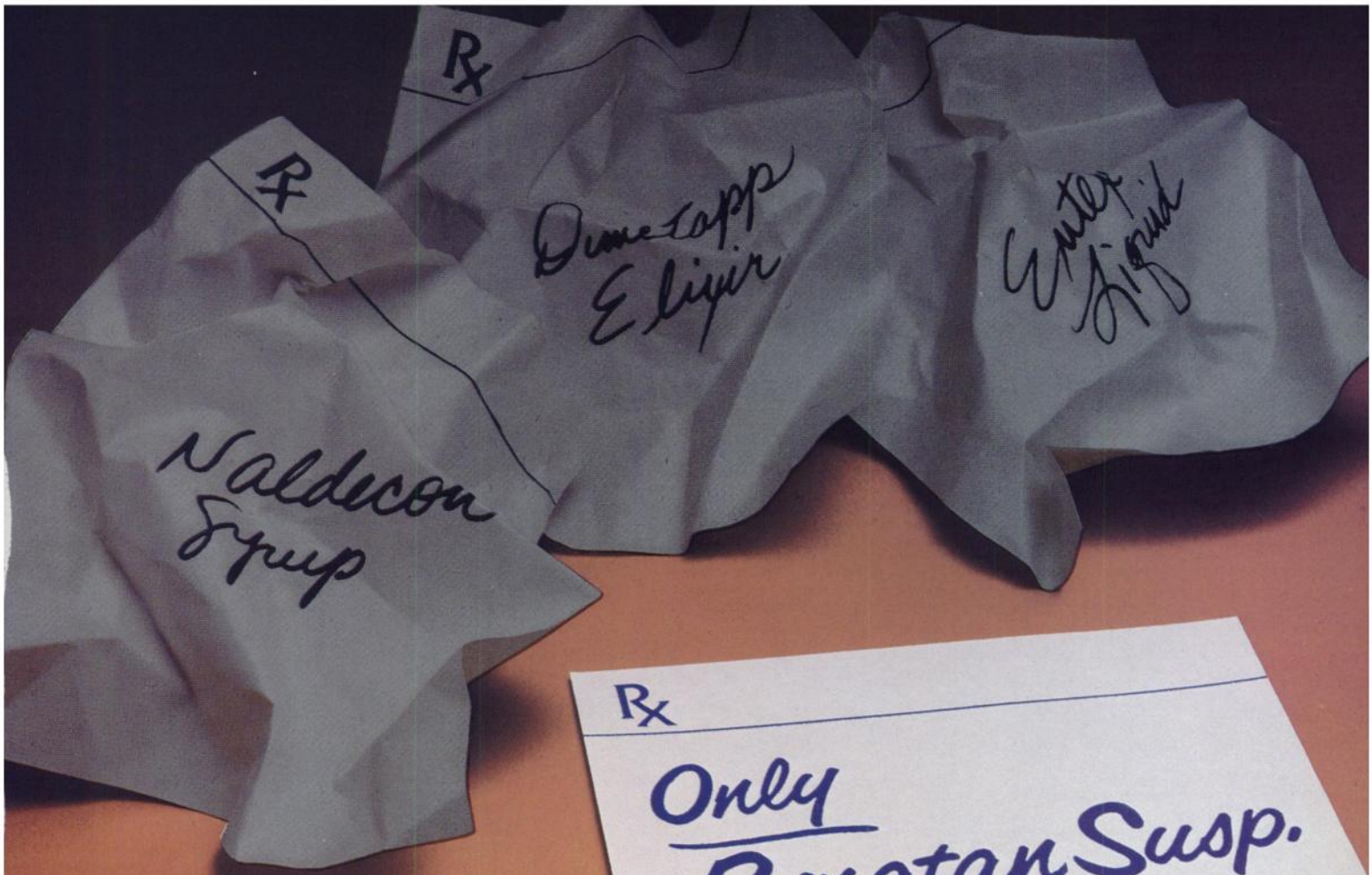

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Indications and Usage: 'Rynatan' is indicated for symptomatic relief of the coryza and nasal congestion associated with the common cold, sinusitis, allergic rhinitis and other upper respiratory tract conditions. Appropriate therapy should be provided for the primary disease.

Contraindications: 'Rynatan' is contraindicated for newborns, nursing mothers and patients sensitive to any of the ingredients or related compounds.

Warnings: Use with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes, narrow angle glaucoma or prostatic hypertrophy. Use with caution or avoid use in patients taking monoamine oxidase (MAO) inhibitors. This product contains antihistamines which may cause drowsiness and may have additive central nervous system (CNS) effects with alcohol or other CNS depressants (e.g., hypnotics, sedatives, tranquilizers).

Precautions: *General*: Antihistamines are more likely to cause dizziness, sedation and hypotension in elderly patients. Antihistamines may cause excitation, particularly in children, but their combination with sympathomimetics may cause either mild stimulation or mild sedation.

Information for Patients: Caution patients against drinking alcoholic beverages or engaging in potentially hazardous activities requiring alertness, such as driving a car or operating machinery, while using this product.

Drug Interactions: MAO inhibitors may prolong and intensify the anticholinergic effects of antihistamines and the overall effects of sympathomimetic agents.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long term animal studies have been performed with 'Rynatan'.

Pregnancy: Teratogenic Effects: Pregnancy Category C. Animal reproduction studies have not been conducted with Rynatan. It is also not known whether 'Rynatan' can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 'Rynatan' should be given to a pregnant woman only if clearly needed.

Nursing Mothers: 'Rynatan' should not be administered to a nursing woman.

Adverse Reactions: Adverse effects associated with 'Rynatan' at recommended doses have been minimal. The most common have been drowsiness, sedation, dryness of mucous membranes, and gastrointestinal effects. Serious side effects with oral antihistamines or sympathomimetics have been rare.

Note: The following sections are optional and may be omitted.

Overdosage: *Signs & Symptoms*—may vary from CNS depression to stimulation (restlessness to convulsions). Antihistamine overdosage in young children may lead to convulsions and death. Atropine-like signs and symptoms may be prominent.

Treatment—Induce vomiting if it has not occurred spontaneously. Precautions must be taken against aspiration especially in infants, children and comatose patients. If gastric lavage is indicated, isotonic or half-isotonic saline solution is preferred. Stimulants should not be used. If hypotension is a problem, vasopressor agents may be considered.

Dosage and Administration: Administer the recommended dose every 12 hours.
'Rynatan' Tablets: Adults—1 or 2 tablets.
'Rynatan' Pediatric Suspension: *Children over six years of age*—5 to 10 ml (1 to 2 teaspoonfuls); *Children two to six years of age*—2.5 to 5 ml (½ to 1 teaspoonful); *Children under two years of age*—Titrate dose individually.

How Supplied
'Rynatan' Tablets: buff, capsule-shaped, compressed tablets in bottles of 100 (NDC 0037-0713-92) and bottles of 500 (NDC 0037-0713-96).

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Storage: 'Rynatan' Tablets—Store at room temperature, avoid excessive heat—(above 40°C/104°F).

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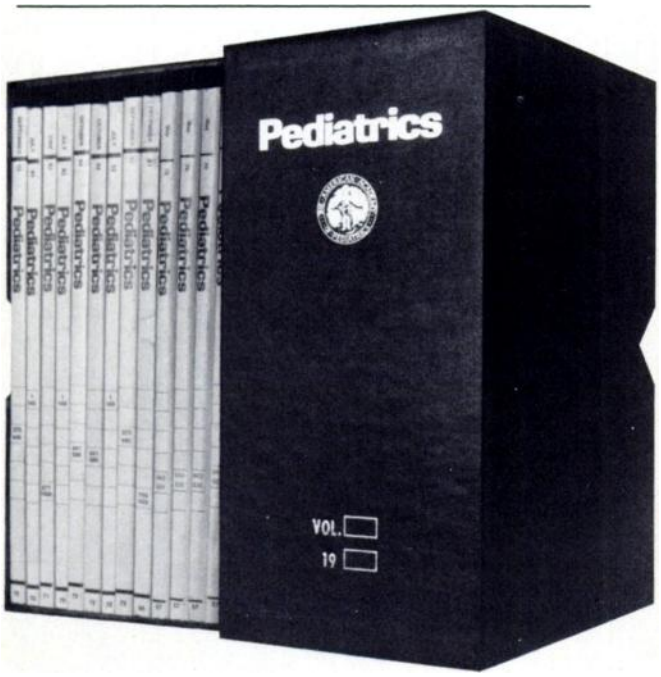

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Ilosone® (erythromycin estolate)

Brief Summary. Consult the package literature for prescribing information.

Warning

Hepatic dysfunction with or without jaundice has occurred, chiefly in adults, in association with erythromycin estolate administration. It may be accompanied by malaise, nausea, vomiting, abdominal colic, and fever. In some instances, severe abdominal pain may simulate an abdominal surgical emergency.

If the above findings occur, discontinue Ilosone promptly.

Ilosone is contraindicated for patients with a known history of sensitivity to this drug and for those with preexisting liver disease.

Indications: *Streptococcus pyogenes* (Group A Beta-Hemolytic)—Upper and lower respiratory tract, skin, and soft-tissue infections of mild to moderate severity.

Injectable penicillin G benzathine is considered by the American Heart Association to be the drug of choice in the treatment and prevention of streptococcal pharyngitis and in long-term prophylaxis of rheumatic fever.

When oral medication is preferred for treating the above-mentioned conditions, penicillin G or V or erythromycin is the alternate drug of choice.

The importance of the patient's strict adherence to the prescribed dosage regimen must be stressed when oral medication is given. A therapeutic dose should be administered for at least ten days.

Alpha-Hemolytic Streptococci (Viridans Group)—Although no controlled clinical efficacy trials have been conducted, oral erythromycin has been suggested by the American Heart Association and American Dental Association for use in a regimen for prophylaxis against bacterial endocarditis in patients hypersensitive to penicillin who have congenital heart disease or rheumatic or other acquired valvular heart disease when they undergo dental procedures and surgical procedures of the upper respiratory tract! Erythromycin is not suitable for such prophylaxis prior to genitourinary or gastrointestinal tract surgery.

Note: When selecting antibiotics for the prevention of bacterial endocarditis, the physician or dentist should read the full joint statement of the American Heart Association and the American Dental Association!

Staphylococcus aureus—Acute infections of skin and soft tissue which are mild to moderately severe. Resistance may develop during treatment.

S. (Diplococcus) pneumoniae—Infections of the upper respiratory tract (e.g., otitis media, pharyngitis) and lower respiratory tract (e.g., pneumonia) of mild to moderate severity.

Mycoplasma pneumoniae (Eaton Agent, PPLO)—In the treatment of respiratory tract infections due to this organism.

Haemophilus influenzae—May be used concomitantly with adequate doses of sulfonamides in treating upper respiratory tract infections of mild to moderate severity. Not all strains of this organism are susceptible at the erythromycin concentrations ordinarily achieved (see appropriate sulfonamide labeling for prescribing information).

Treponema pallidum—Erythromycin is an alternate choice of treatment for primary syphilis in penicillin-allergic patients. In primary syphilis, spinal-fluid examinations should be done before treatment and as part of follow-up after therapy.

Corynebacterium diphtheriae—As an adjunct to antitoxin, to prevent establishment of carriers, and to eradicate the organism in carriers.

C. minutissimum—In the treatment of erythrasma.

Entamoeba histolytica—In the treatment of intestinal amebiasis only. Extraenteric amebiasis requires treatment with other agents.

Listeria monocytogenes—Infections due to this organism.

Bordetella pertussis—Erythromycin is effective in eliminating the organism from the nasopharynx of infected individuals, rendering them noninfectious. Some clinical studies suggest that erythromycin may be helpful in the prophylaxis of pertussis in exposed susceptible individuals.

Legionnaires' Disease—Although no controlled clinical efficacy studies have been conducted, in vitro and limited preliminary clinical data suggest that erythromycin may be effective in treating Legionnaires' disease.

Chlamydia trachomatis—Erythromycins are indicated for treatment of the following infections caused by *C. trachomatis:* conjunctivitis of the newborn, pneumonia of infancy, urogenital infections during pregnancy (*see* Warnings). When tetracyclines are contraindicated or not tolerated, erythromycin is indicated for the treatment of adults with uncomplicated urethral, endocervical, or rectal infections due to *C. trachomatis*[2]

Contraindication: Erythromycin is contraindicated in patients with known hypersensitivity to this antibiotic.

Warnings: *(See* Warning box above.) The administration of erythromycin estolate has been associated with the infrequent occurrence of cholestatic hepatitis. Laboratory findings have been characterized by abnormal hepatic function test values, peripheral eosinophilia, and leukocytosis. Symptoms may include malaise, nausea, vomiting, abdominal cramps, and fever. Jaundice may or may not be present. In some instances, severe abdominal pain may simulate the pain of biliary colic, pancreatitis, perforated ulcer, or an acute abdominal surgical problem. In other instances, clinical symptoms and results of liver fuction tests have resembled findings in extrahepatic obstructive jaundice.

Initial symptoms have developed in some cases after a few days of treatment but generally have followed one or two weeks of continuous therapy. Symptoms reappear promptly, usually within 48 hours after the drug is readministered to sensitive patients. The syndrome seems to result from a form of sensitization, occurs chiefly in adults, and has been reversible when medication is discontinued.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile.* Other causes of colitis should be ruled out.

Usage in Pregnancy—Safety of this drug for use during pregnancy has not been established.

Therefore, the physician should consider carefully the benefits and risks of use of this drug during pregnancy.

Precautions: Since erythromycin is excreted principally by the liver, caution should be exercised in administering the antibiotic to patients with impaired hepatic function.

Surgical procedures should be performed when indicated.

Drug Interactions—The use of erythromycin in patients who are receiving high doses of theophylline may be associated with an increase in 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.

There have been reports of excessive prolongation of prothrombin times in patients receiving erythromycin concurrently with chronic warfarin therapy. Such patients, particularly the elderly who generally exhibit slower warfarin clearance, may be at risk for developing bleeding due to this interaction. In patients receiving erythromycin during chronic treatment with warfarin, prothrombin times should be monitored closely and warfarin dosage adjusted accordingly.

Adverse Reactions: The most frequent side effects of erythromycin preparations are gastrointestinal (e.g., 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 arise, the drug should be discontinued and appropriate therapy instituted.

Mild allergic reactions, such as urticaria and other skin rashes, have occurred. Serious allergic reactions, including anaphylaxis, have been reported.

There have been isolated reports of reversible hearing loss occurring chiefly in patients with renal insufficiency and in patients receiving high doses of erythromycin.

REFERENCES:

1. American Heart Association: Prevention of Bacterial Endocarditis, Circulation, *56*:139A, 1977.
2. Sexually Transmitted Diseases Treatment Guidelines 1982. Centers for Disease Control, Morbidity and Mortality Weekly Report, U.S. Department of Health and Human Services, Atlanta, *31*(Supplement):355, 1982.

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†Equivalent to erythromycin.

Hepatic dysfunction with or without jaundice has occurred, chiefly in adults, in association with erythromycin estolate administration.

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See adjoining column for summary of prescribing information.

PROTECTION AGAINST HAEMOPHILUS INFLUENZAE TYPE b (HIB) DISEASES

NEW *b*-CAPSA™ I VACCINE
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Clinical studies with a predecessor Haemophilus b Polysaccharide Vaccine demonstrated 90% protective efficacy in reducing bacteremic Hib disease in children 24 months to 6 years of age.[1]

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RECOMMENDED PROTECTION

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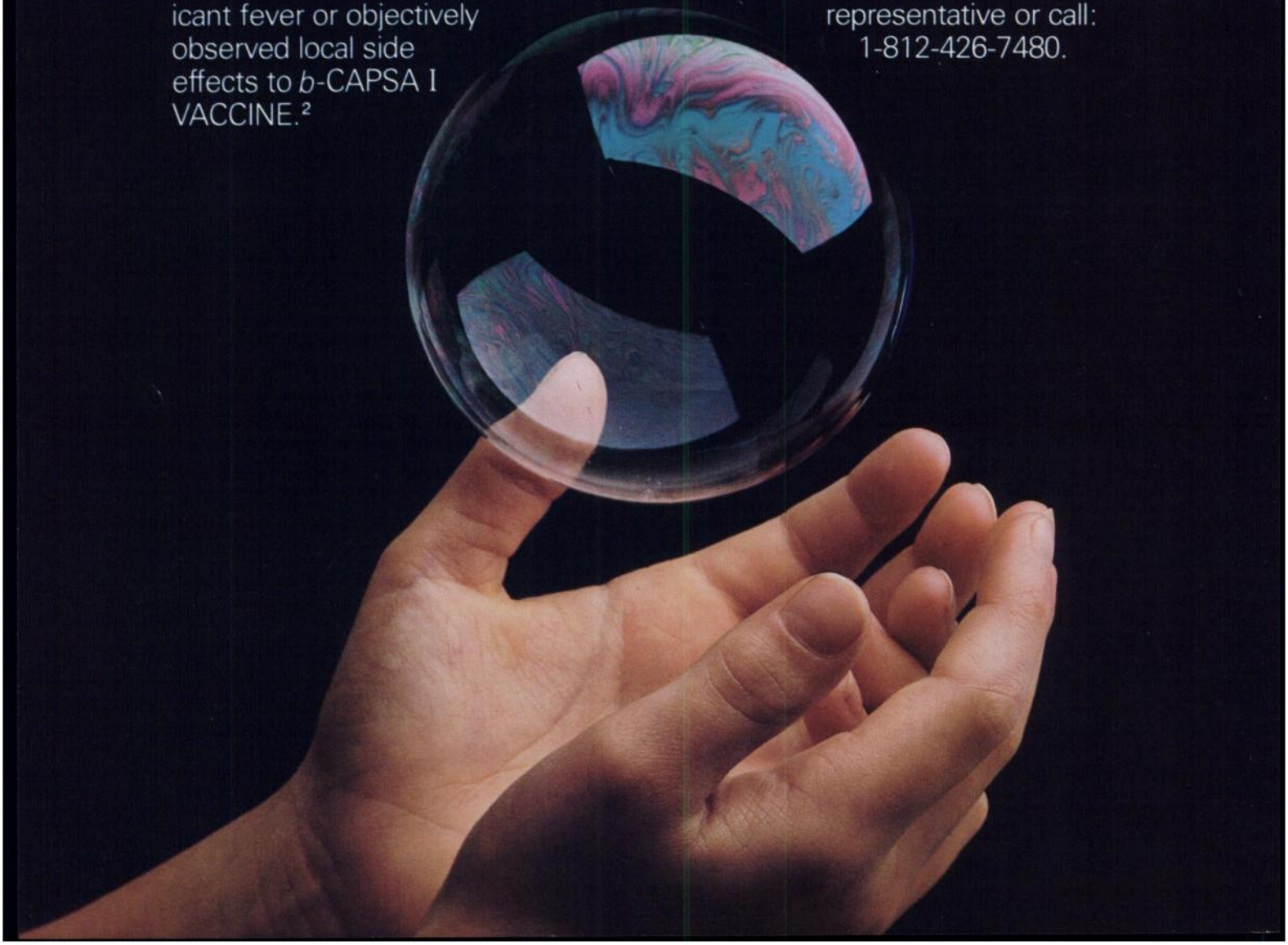
PROTECT NOW

For further information, contact your Mead Johnson Nutritional Division representative or call: 1-812-426-7480.



b-CAPSA™ I VACCINE

(Haemophilus b Polysaccharide Vaccine)

BRIEF SUMMARY

DESCRIPTION

b-CAPSA I VACCINE (Haemophilus b Polysaccharide Vaccine) is a sterile, lyophilized vaccine for subcutaneous administration. It is the capsular polysaccharide purified from the bacterium, *Haemophilus influenzae* type b, strain Eag and is a polymer of ribose, ribotol, and phosphate.[1]

Lactose is included in the vaccine at a concentration of 2.5 mg per 0.5 ml dose to improve product stability.[2] The lyophilized vaccine contains 25 μg of purified Haemophilus b polysaccharide per dose. The reconstituted vaccine contains thimerosal (mercurial derivative) 1:10,000 and sodium chloride for isotonicity. When reconstituted, *b*-CAPSA I VACCINE is a clear, colorless liquid.

CLINICAL PHARMACOLOGY

Haemophilus influenzae type b is the most common cause of bacterial meningitis and a leading cause of serious, systemic bacterial diseases in young children in the United States. This vaccine will not stimulate protection against other types of *Haemophilus influenzae* or other microorganisms that cause meningitis or septic disease.

Several population-based studies conducted within the last 10 years in the U.S. indicate that a child's cumulative risk of developing systemic *Haemophilus influenzae* b (Hib) disease at some time during the first 5 years of life is about 1 in 200.[3] About 60% of the children have meningitis and 40% other systemic diseases, such as cellulitis, epiglottitis, pericarditis, pneumonia, sepsis, or septic arthritis.[3] In these U.S. studies, about 35-40% of systemic Hib disease has occurred in children 18 months of age or older. In contrast, a recent prospective, five-year analysis of all children in Finland indicated that 60% of bacteremic Hib disease occurred in children 18 months of age or older and 45% in those 2 or more years of age.[4]

The incidence of systemic Hib disease is increased in certain children, e.g., Eskimo[5] and American Indian[6] children, patients with asplenia, sickle cell disease,[7] and antibody deficiency syndromes.[8] Recent studies also indicate that *Haemophilus influenzae* b can cause outbreaks of systemic disease among previously healthy children attending nursery school or day care, and that attendance at day care significantly increases the risk of developing systemic Hib disease.[9-11] Furthermore, the risk of acquiring systemic Hib disease for a child in intimate contact with one who has developed such a disease is up to 400 times that of a child in the general population.[9]

Hib diseases usually can be treated successfully. Even with appropriate antibiotic therapy, however, the mortality rate of Hib meningitis[12] and other bacteremic diseases can be 5%, and serious, long-term neurologic sequelae have been observed in 19-45% of survivors of meningitis.[3, 13] Up to 20% of *Haemophilus influenzae* b isolated in the USA from patients with systemic disease are resistant to ampicillin,[12, 14] and the mortality rate of meningitis is significantly greater when it is caused by ampicillin-resistant than by ampicillin-sensitive *Haemophilus influenzae* b.[12] Moreover, resistance to chloramphenicol and to multiple antibiotics has emerged.[14] When properly administered, rifampin can prevent bacteremic Hib disease among contacts at risk,[15] and its use for this purpose has been recommended by health authorities.[15, 16] Implementation of those recommendations can be difficult, however, especially in the setting of a large group. Thus, the strategy of controlling Hib disease by antibiotics has deficiencies.

The capsular polysaccharide of *Haemophilus influenzae* b (Haemophilus b polysaccharide) is its principal virulence factor. Anti-Haemophilus b polysaccharide antibody mediates complement-dependent bacteriolysis and opsonization *in vitro* and protects experimentally infected animals. Hyperimmune animal serum was used successfully to treat invasive human Hib diseases in the pre-antibiotic era, and antibody to the capsular polysaccharide was reported to be the protective component of that serum.[17]

For these reasons, Haemophilus b polysaccharide has been purified for use as a vaccine to prevent Hib diseases. More than 60,000 children and several hundred adults have been vaccinated with Haemophilus b polysaccharide in studies conducted in multiple centers.[4, 18-23] Adverse reactions have been mild and transient. Adults and older children uniformly produce a long-lived, non-boostable antibody response.[4, 18-20] Children respond variably according to their age: infants respond less frequently with less antibody.[4, 18-22] The percent of responding individuals increases significantly between 12 and 24 months of age.[4, 18, 20, 22] Approximately 90% of children 24 months of age or older produce a significant antibody response to Haemophilus b polysaccharide vaccination, and most of the non-responders have high pre-vaccination titers.[4] The amount of antibody produced by children is also affected by the molecular size of the vaccine: vaccines containing high molecular weight capsular polysaccharide generate more antibody than those with low molecular weight polysaccharide.[24]

The precise protective level of anti-Haemophilus b polysaccharide antibody has not been established. Titers associated with protection of agammaglobulinemic children[18, 20] and experimentally infected animals by passively administered gamma globulin suggest that 0.15 μg/ml is protective. In a controlled field trial, levels ≥1 μg/ml in 3 week post-vaccination serum were correlated with clinical protection[25]; approximately 75% of tested 18-23 month old and 85% of 24-29 month old children achieved that level following Haemophilus b polysaccharide vaccination.[23] These Finnish data can be compared to those obtained with *b*-CAPSA I (see Table 1).

The efficacy of Haemophilus b polysaccharide vaccine was evaluated in a double-blind, controlled field trial conducted in Finland in children 3 months to 5 years of age.[4, 23] Approximately 98,000 children, half of whom received Haemophilus b polysaccharide vaccine, were followed for 4 years. The Haemophilus b polysaccharide vaccine for that study was prepared by the scientific founders of Praxis Biologics. The results indicated that the vaccine was highly protective for children of 18 months to 5 years of age: a single dose reduced the overall attack rate of bacteremic Hib disease by 90%. Of more than 4,000 children who were 18-23 months old when vaccinated, *none* who received Haemophilus b polysaccharide developed bacteremic Hib disease during the four years of follow-up. However, the number of cases of bacteremic Hib disease in the control group was too small to permit a meaningful assessment of Haemophilus b polysaccharide vaccine efficacy in that age group. Children younger than 18 months of age had little immunologic response to the vaccine and were not protected.

Based on the results of their field trial, the Finnish investigators recommended universal vaccination with Haemophilus b polysaccharide for children of ≥18 months of age and suggested the potential need for a booster dose for children who received their primary Haemophilus b polysaccharide vaccination at 18-23 months of age.[4] An analysis of U.S. epidemiological data by clinical investigators at the USPHS Centers for Disease Control supported such use of Haemophilus b polysaccharide vaccine.[3]

Considerable evidence correlates the immunogenicity of bacterial polysaccharide vaccines with their physicochemical properties and the side effects with trace contaminants, especially endotoxin. The properties of *b*-CAPSA I VACCINE are equivalent to those of the Haemophilus b polysaccharide vaccine used in the Finnish field trial. The unique protein-free, chemically defined bacterial growth medium and purification procedures used in the preparation of *b*-CAPSA I VACCINE minimize the content of protein, nucleic acids, and endotoxin and guarantee a large molecular weight.

Table 1 summarizes the antibody responses to *b*-CAPSA I VACCINE.

TABLE 1
ANTIBODY RESPONSES TO VACCINATION WITH *b*-CAPSA I VACCINE

Age (mos.)	No. of Children	Geometric Mean Titer (μg/ml) Pre	Post*	Percent of Children with Post-Vaccination Titers ≥1 μg/ml
18-20	34	0.63	1.88	76
24-29	161	0.37	4.30	96
≥30	72	0.24	12.11	100
ALL	267	0.35	5.06	95

**Approximately 3 weeks post-vaccination.*

A limited number of children have been reported to have received DTP and Haemophilus b polysaccharide vaccines at the same time.[22, 24, 26, 27] No impairment of the immune response to individual antigens occurred. The incidence and type of associated reactions[22, 24, 26, 27] approximated those reported for DTP vaccine.[28]

INDICATIONS AND USAGE

b-CAPSA I VACCINE is indicated for immunization of children of 24 months to six years of age against diseases caused by *Haemophilus influenzae* b.

Children of 24 months of age and older have a high rate of seroconversion, and clinical studies indicate that they will be protected against bacteremic Hib diseases following a single vaccination with *b*-CAPSA I VACCINE.

b-CAPSA I VACCINE may be given to children 18-23 months of age known to be at high-risk of systemic Hib disease, e.g., children who attend day care. A controlled field trial suggested that many children in this age group will be protected by a single vaccination, although the rate of seroconversion is not as high as with older children. Parents should be informed that the vaccine is not likely to be completely effective in this age group.

Studies are ongoing to determine the need and timing for revaccination, particularly for children vaccinated at 18-23 months of age.

b-CAPSA I VACCINE *will not protect children younger than 18 months of age and will not protect against* Haemophilus influenzae *other than type b or other microorganisms that cause meningitis or septic disease.*

Manufactured by:

PRAXIS
BIOLOGICS, INC.
Rochester, NY

Distributed by:

Mead Johnson
NUTRITIONAL DIVISION

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine, including thimerosal.

WARNINGS

If the vaccine is used in persons deficient in producing antibody, whether due to genetic defect or to immunosuppressive therapy, the expected immune response may not be obtained.

PRECAUTIONS

General

As with the injection of any biological material, epinephrine injection (1:1000) should be available for immediate use should an anaphylactoid reaction occur.

Any febrile illness or active infection is reason for delaying use of *b*-CAPSA I VACCINE.

The vaccine should not be injected intradermally or intravenously, since the safety and efficacy of these routes of administration have not been evaluated. The vaccine should be given *subcutaneously*.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of hepatitis viruses and other infectious agents from one person to another.

Pregnancy

Pregnancy Category C

Animal reproductive studies have not been conducted with *b*-CAPSA I VACCINE. It is not known whether *b*-CAPSA I VACCINE can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Data are not available to support the use of this product during pregnancy at this time, regardless of benefits.

Nursing Mothers

There is no indication for using this product in nursing mothers.

Pediatric Use

b-CAPSA I VACCINE is not recommended for infants younger than 18 months of age. See comments above about vaccine use in children older than 18 months of age.

ADVERSE REACTIONS

Different preparations of Haemophilus b polysaccharide produced by different procedures and administered at different doses have been evaluated in several field studies. Objectively observed side effects, e.g., erythema and induration at the injection site and fever, have generally been minor and lasted 24 hours or less.[18, 21-23] The incidence of local side effects reported in the Finnish field trial was 51%. In all other reported trials, the incidence of these reactions was 4-9%.[18, 21, 22] Temperatures >38.3°C (101°F) at 24 hours post-vaccination have occurred in up to 13% of vaccinated children. In the Finnish field trial, one child had a possible anaphylactoid reaction; following an injection of epinephrine, the child recovered rapidly and without complications.

The side effects associated with the use of *b*-CAPSA I VACCINE in children are summarized in Table 2. At 24 hours post-vaccination, local reactions were observed in 1.5% of vaccinated children, and temperature >38.3°C (101°F) in 0.75%.

TABLE 2
SIDE EFFECTS AT 24 HOURS ASSOCIATED WITH VACCINATION OF CHILDREN (18-60 MOS.) WITH *b*-CAPSA I VACCINE

No. of Children	Temperature >38.3°C (101°F)	Objective Local Reaction Swelling	Erythema
267*	2	4	4

**161 of these children were 24-29 months at vaccination.*

DO NOT INJECT INTRAVENOUSLY.

The immunizing dose is a single injection of 0.5 ml of reconstituted b-CAPSA I VACCINE given subcutaneously.

b-CAPSA I VACCINE is manufactured by Praxis Biologics, Inc., Rochester, New York 14623 and distributed by Mead Johnson Nutritional Division, Evansville, Indiana 47721.

For information contact: MEAD JOHNSON NUTRITIONAL DIVISION at (812) 426-7480.

Reference list will be supplied by Mead Johnson upon request.

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4. Hib Vaccine Introduced, Guidelines on Usage Given. AAP News 1985 (May); 1(5):3.

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First things first

Stop the pain of acute *otitis media*. While the ultimate aim of *otitis media* therapy is to eradicate the infection, your immediate concern is to ease the pain and pressure.

AURALGAN® Otic Solution promptly relieves the pain and reduces the pressure while your antibiotic begins to clear the infection. So when the pain of *otitis media* demands your attention, treat first things first: Stop pain fast with AURALGAN. Available on your prescription only.

OTIC SOLUTION
Auralgan®
Stops pain fast as your antibiotic goes to work.

BRIEF SUMMARY
(For full prescribing information, see package circular.)
AURALGAN® Otic Solution
Each ml contains:

Antipyrine	54.0 mg
Benzocaine	14.0 mg
Glycerin dehydrated q.s. to	1.0 ml

(contains not more than 0.6% moisture)
(also contains oxyquinoline sulfate)
INDICATIONS. *Acute otitis media of various etiologies*
—prompt relief of pain and reduction of inflammation in the congestive and serous stages
—adjuvant therapy during systemic antibiotic administration for resolution of the infection.
CONTRAINDICATIONS. Hypersensitivity to any of the components or substances related to them. In the presence of spontaneous perforation or discharge.
DOSAGE AND ADMINISTRATION. *Acute otitis media:* Instill AURALGAN, permitting the solution to run along the wall of the canal until it is filled. Avoid touching the ear with dropper. Then moisten a cotton pledget with AURALGAN and insert into meatus. Repeat every one to two hours until pain and congestion are relieved.
HOW SUPPLIED. No. 1000—AURALGAN® Otic Solution, in package containing 15 ml (½ fl oz) bottle with separate dropper-screw cap attachment.

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New York, NY 10017

LIQUID ASSETS

BOTH AVAILABLE OTC

— For decades pediatricians have relied on BENADRYL ELIXIR to effectively and safely treat a variety of allergy problems. Now you can recommend BENADRYL ELIXIR to your patients as over-the-counter therapy.

— Indicated for the temporary relief of runny noses, sneezing, itching of the nose or throat...itchy, watery eyes due to hay fever or other upper respiratory allergies...and runny nose and sneezing of the common cold.

— And now, when patients need temporary relief of nasal congestion, you can recommend new BENADRYL DECONGESTANT ELIXIR, with the added benefit of the professionally preferred nasal decongestant, pseudoephedrine hydrochloride.

— Usual starting dosage for children (6 to under 12 years): BENADRYL ELIXIR—12.5 to 25 mg (1 to 2 teaspoonfuls) every 4 to 6 hours, not to exceed 12 teaspoonfuls in 24 hours. BENADRYL DECONGESTANT ELIXIR—1 teaspoonful every 4 to 6 hours, not to exceed 4 teaspoonfuls in 24 hours.

Recommend each of these products when appropriate and give patients the benefit of your professional experience and knowledge of BENADRYL, the most prescribed allergy medication ever.

PARKE-DAVIS
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Benadryl®
Elixir
(diphenhydramine hydrochloride elixir, USP)
12.5 mg/5 mL

NEW Benadryl®
Decongestant Elixir
Each 5-mL teaspoonful contains
12.5 mg diphenhydramine hydrochloride,
30 mg pseudoephedrine hydrochloride,
and alcohol 5%.

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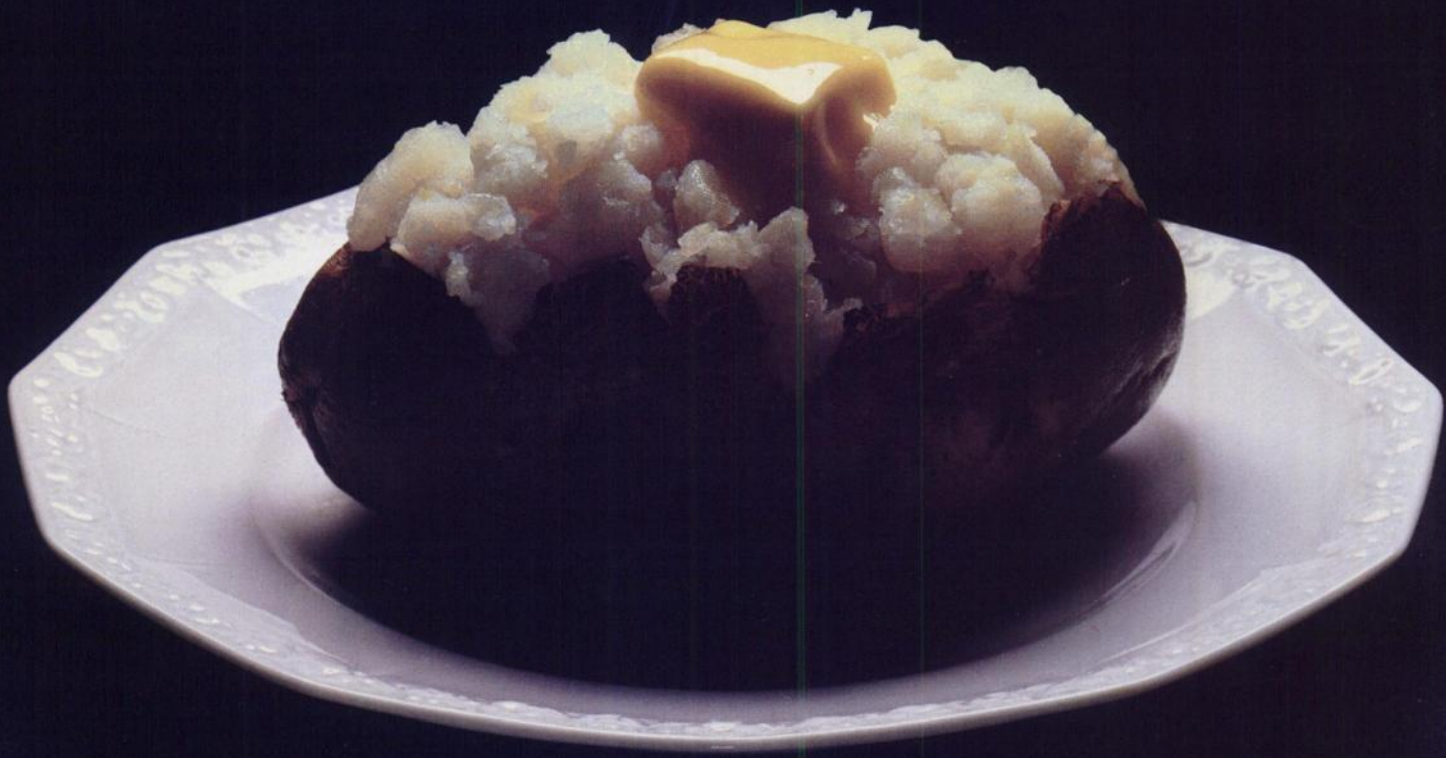
A potato has nutritional value.



No matter how you slice it.

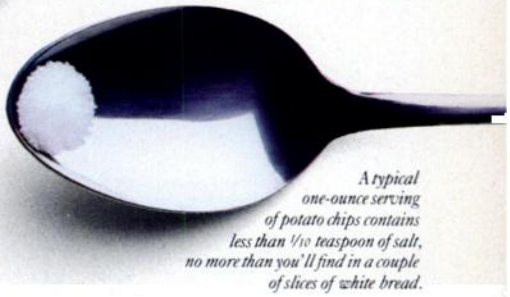
A potato is a potato is a potato. You can bake it. Boil it. Mash it. Or slice it up and quick-fry it into chips. It's still going to provide many of the same nutrients. As a matter of fact, a one-ounce serving of potato chips contains at least 15 essential nutrients. That includes about 10% of the U.S. RDA of Vitamin C and 8% of the U.S. RDA of Vitamin B_6.

A one-ounce bag of chips also contains 1.3 grams of dietary fiber. That's about how much you'll find in ½ cup of celery or cabbage. Which helps explain why potato chips are listed under the "vegetable" heading in USDA Handbook#8. Of course, potato chips aren't a basic source of nutrients. But they do have more nutrients than most people realize. And fewer calories. Only 150 in a one-ounce bag.

It may also surprise people to know that a typical bag of chips has less than 1/10 of a teaspoon of salt* and 2¼ teaspoons of oil. A lot of people put more salt and butter on a baked potato. And, according to the Health and Nutrition Examination Study (HANES II)**, the fat in potato chips accounts for less than 1% of the daily calories in the average American diet.

As for cholesterol, most potato chips don't have any. That's because most chips are cooked only in vegetable oils.*** And contrary to popular belief, most chips contain no preservatives.

A one-ounce serving of potato chips contains the same level of most nutrients you'll find in an average-sized baked potato.



A typical one-ounce serving of potato chips contains less than 1/10 teaspoon of salt, no more than you'll find in a couple of slices of white bread.

Potato Chips
NUTRITION INFORMATION
(Per Serving) Serving Size 1 ounce

Calories	150
Protein	2 grams
Carbohydrate	14 grams
Fat	10 grams
Cholesterol** (0 mg/100 g)	0 milligrams
Sodium	175 milligrams
Potassium	205 milligrams
Dietary Fiber	1.3 grams
Percentage of U.S. Recommended Daily Allowance (U.S. RDA)	
Protein	2
Vitamin A	*
Vitamin C	10
Thiamine	2
Riboflavin	*
Niacin	4
Calcium	*
Iron	2
Vitamin B_6	8
Phosphorus	4
Magnesium	4
Copper	6

*Contains less than 2% U.S. RDA for this nutrient
**Information on cholesterol content is provided for individuals who, on the advice of a physician are modifying their total dietary intake of cholesterol

Nutrition label developed according to the FDA guidelines found in Title 21 of the Federal Code of Regulations.

All this isn't to say that potato chips are for everyone. It's just a reminder that potato chips do come from potatoes. And, once a potato, always a potato.

The Potato Chip Information Bureau

*National industry assays indicate that the typical one-ounce bag of potato chips (15 to 20 large chips) contains an average of 175 milligrams of sodium. The range for the samples tested was from 100 to 260 milligrams per ounce.

**HANES II was conducted by the United States Department of Health and Human Services from 1976 to 1980.

***Typical P to S Ratio is 1.2 to 1.

For more information, write The Potato Chip Information Bureau, 1711 King Street, Alexandria, VA 22314.

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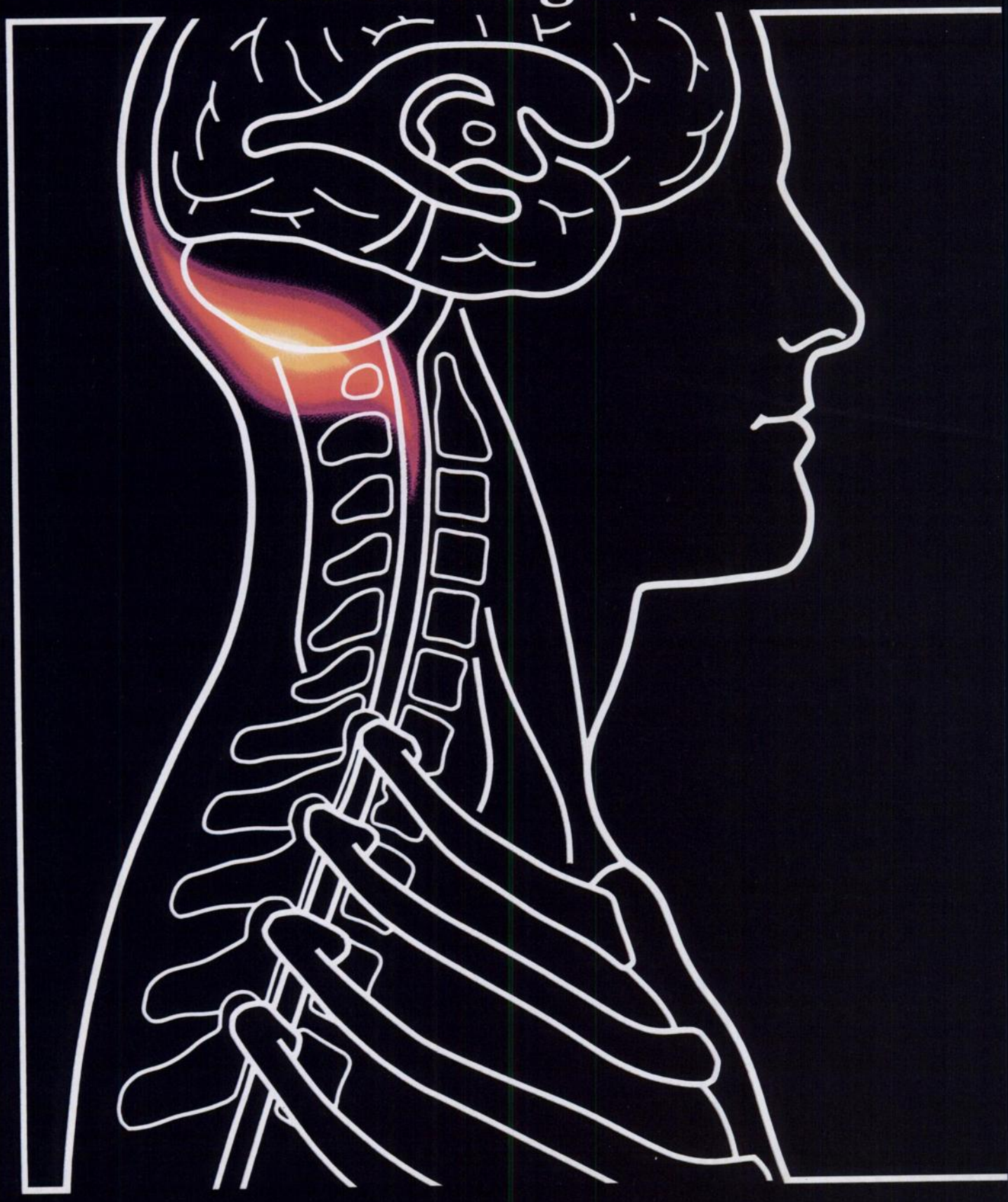
The Clear Choice for meningitis



Claforan®
(cefotaxime sodium)* STERILE IM/IV

In infants, children, and adults.

...the clear choice, because of its expanded-spectrum coverage, in vitro synergy† with its bactericidal metabolite, outstanding efficacy, uncompromised safety, convenient dosing, and economy.

A broader spectrum of indicated meningeal pathogens than ceftizoxime or ceftriaxone

Unlike ceftizoxime or ceftriaxone, Claforan* (cefotaxime sodium) is indicated for all five major Gram-negative and Gram-positive meningeal pathogens: *Neisseria meningitidis, Haemophilus influenzae, Klebsiella pneumoniae, Escherichia coli,* and *Streptococcus pneumoniae.*

Outstanding in vitro potency† against Gram-negative and Gram-positive organisms

The Claforan* parent compound alone is as or more potent than other advanced-generation cephalosporins against *Klebsiella pneumoniae, Escherichia coli, Neisseria meningitidis, Haemophilus influenzae,* and *Streptococcus pneumoniae.*[1]

Synergy between the Claforan* parent compound and its bactericidal metabolite potentiates its in vitro activity† against *Klebsiella pneumoniae* and *Escherichia coli*[2]—frequently encountered causative pathogens in Gram-negative bacillary meningitis.[3] These interactions are highly reproducible for aerobes and anaerobes.[2,4] Synergy has been demonstrated against 75.8% of aerobes and 80% of anaerobes tested.[2,5] Claforan* is also highly effective against *Neisseria meningitidis, Haemophilus influenzae,* and *Streptococcus pneumoniae,* with activity comparable to or greater than ceftriaxone or moxalactam.[1]

Bactericidal levels readily achieved in the CSF

Unlike chloramphenicol and aminoglycosides, which are not bactericidal against enteric pathogens at achievable CSF levels, Claforan* achieves tissue levels in excess of $MIC_{s_{90}}$ in Gram-negative bacillary meningitis comparable to those achieved when penicillin is used to treat pneumococcal meningitis.[6] CSF levels of both the parent compound and the metabolite have been maintained or even increased over the course of therapy.[7]

As safe as first-generation cephalosporins

Unlike aminoglycosides, Claforan* has not been shown to cause nephrotoxicity or ototoxicity.

In contrast to certain newer cephalosporins, Claforan* has not been shown to cause coagulation abnormalities, and there have been no reports of a disulfiram-like reaction following alcohol ingestion, including the ingestion of alcohol-containing medications.

There is no need to reduce Claforan* dosage except in severe renal impairment.‡ And enterococcal superinfection is very rare in Claforan*-treated patients.[8] This excellent safety profile has been maintained over 4 years and 1,000,000 courses of therapy.

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*U.S. Patent No. 4,152,432
Claforan* Registered trademark of ROUSSEL UCLAF

†Although a useful guide, in vitro activity does not necessarily imply in vivo effectiveness. Also, although in vitro synergy is a useful guide, it does not necessarily imply improved clinical effectiveness.

‡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.

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Please see full prescribing information, a brief summary of which appears on the following page.

...at the lowest price per gram of any advanced cephalosporin.[9]

Claforan®

The first of its generation—and still one step ahead

Claforan® STERILE IM/IV
(cefotaxime sodium)*

Brief Summary
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 non-penicillinase-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*.

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.

Prevention
The administration of Claforan preoperatively may reduce the incidence of certain infections in patients undergoing elective surgical procedures (e.g., abdominal or vaginal hysterectomy, gastrointestinal and genitourinary tract surgery) that may be classified as contaminated or potentially contaminated.

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

Effective use for elective surgery depends on the time of administration. To achieve effective tissue levels, Claforan should be given ½ to 1½ hours before surgery. See **DOSAGE AND ADMINISTRATION** section.

For patients undergoing gastrointestinal surgery, preoperative bowel preparation by mechanical cleansing as well as with a nonabsorbable antibiotic (e.g., neomycin) is recommended.

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* (cefotaxime sodium) 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[2] (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.

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

$$\text{Females:}\quad 0.85 \times \text{above value}$$

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 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 IM or IV 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, and 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.

DOSAGE AND ADMINISTRATION
Adults
Dosage and route of administration should be determined by susceptibility of the causative organisms, severity of the infection, and the condition of the patient (see table for dosage guideline). Claforan may be administered IM or IV after reconstitution. The maximum daily dosage should not exceed 12 grams.

GUIDELINES FOR DOSAGE OF CLAFORAN

Type of Infection	Daily Dose (grams)	Frequency and Route
Gonorrhea	1	1 gram IM (single dose)
Uncomplicated infections	2	1 gram every 12 hours IM or IV
Moderate to severe infections	3-6	1-2 grams every 8 hours IM or IV
Infections commonly needing antibiotics in higher dosage (e.g., septicemia)	6-8	2 grams every 6-8 hours IV
Life-threatening infections	up to 12	2 grams every 4 hours IV

To prevent postoperative infection in contaminated or potentially contaminated surgery, the recommended dose is a single 1 gram IM or IV administered 30 to 90 minutes prior to start of surgery.

Cesarean Section Patients
The first dose of 1 gram is administered intravenously as soon as the umbilical cord is clamped. The second and third doses should be given as 1 gram intravenously or intramuscularly at 6 and 12 hours after the first dose.

Neonates, Infants, and Children
The following dosage schedule is recommended:

Neonates (birth to 1 month):
- 0-1 week of age: 50 mg/kg IV q12h
- 1-4 weeks of age: 50 mg/kg IV q8h

It is not necessary to differentiate between premature and normal gestational age infants.

Infants and children (1 month to 12 years): For body weights less than 50 kg, the recommended daily dose is 50 to 180 mg/kg IM or IV of body weight divided into four to six equal doses. The higher dosages should be used for more severe or serious infections, including meningitis. For body weights 50 kg or more, the usual adult dosage should be used; the maximum daily dosage should not exceed 12 grams.

Impaired Renal Function—see **PRECAUTIONS** section.

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.

U.S. Patent No. 4,152,432 Claforan Registered trademark of ROUSSEL UCLAF.

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Somerville, New Jersey 08876

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The single active ingredient—7.5 mg pseudoephedrine HCl per 0.8 ml dropperful—is uniquely formulated to provide greater accuracy in measuring the precise amount of medicine based on age and weight. In fact, new PediaCare Infants' Drops offers dosing similar to the familiar schedule of Infants' TYLENOL® acetaminophen Drops.

A calibrated dropper is enclosed in each package, enabling parents to easily measure and administer the dose you recommend.

Next time you're treating an infant's stuffy nose, customize therapy with new PediaCare Infants' Cold Relief.

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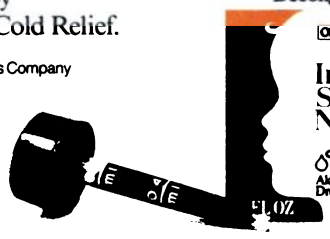

New Pedia Care™ Infants' Cold Relief

Customized for easier, more accurate cold relief

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Customized relief for any size cold

PediaCare™ Children's Cold Relief is the line of cold medications that lets you easily and more accurately customize treatment of any child's cold. Here's why...

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- New PediaCare Infants' Drops contains pseudoephedrine HCl (7.5 mg/0.8 ml) for infants' nasal congestion

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Unlike adult cold medications, PediaCare is formulated in pediatric concentrations, to allow more accurate measurement of medication based on age and weight (similar to the dosing of Children's TYLENOL® acetaminophen). A calibrated dosage cup or dropper is enclosed with each package to enable parents to easily measure the correct dose. And PediaCare is pleasant tasting to encourage patient compliance.

Next time you're treating a child's or infant's cold, customize therapy with PediaCare.

Pedia Care™

Children's Cold Relief

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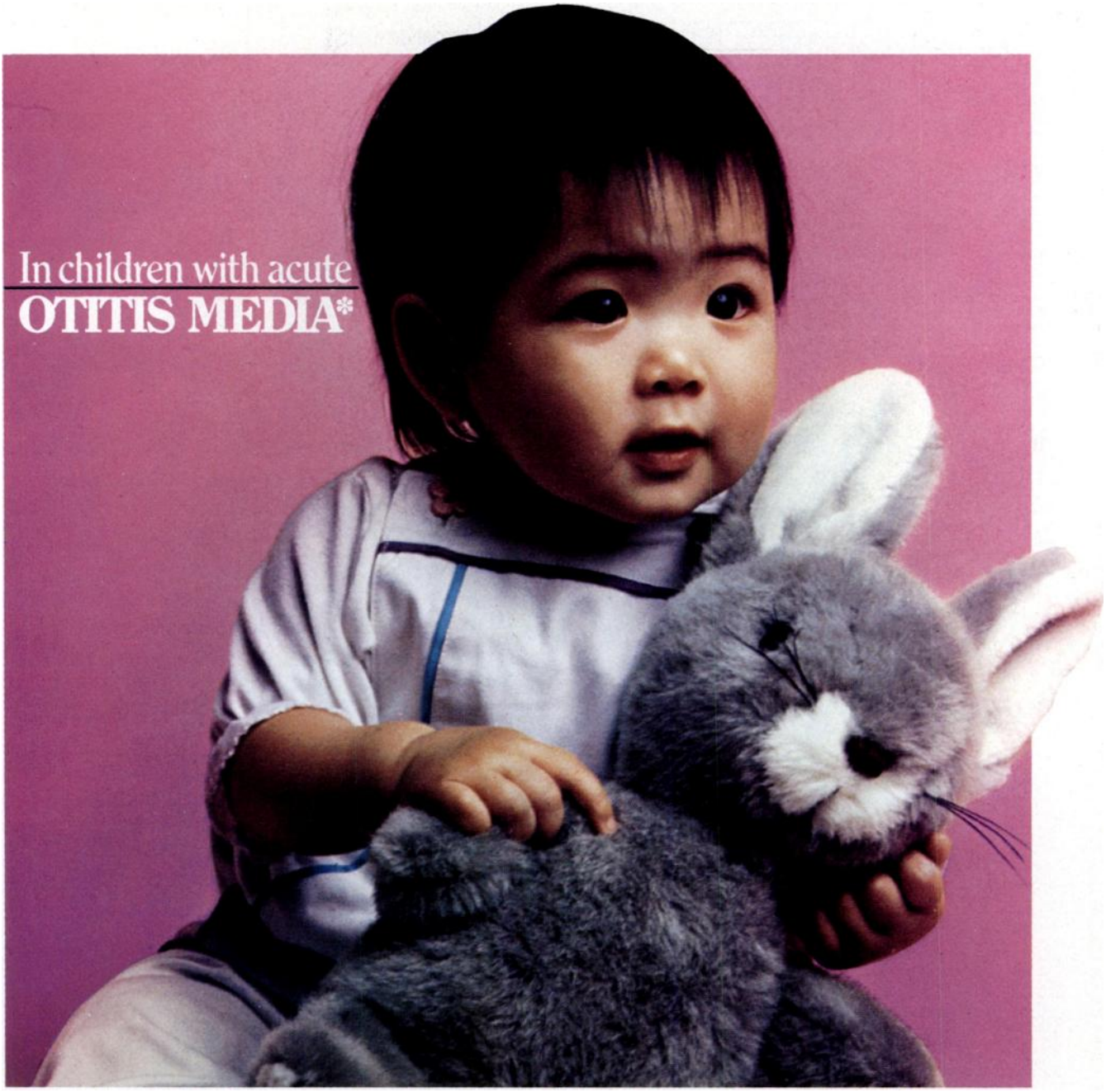
Customized for easier, more accurate cold relief



Initiate therapy with

SEPTRA®
trimethoprim and sulfamethoxazole
SUSPENSION

Gentle enough to be well tolerated...

In a study comparing SEPTRA and ampicillin it was reported that there was "an acceptably low frequency" of side effects in both treatment groups, with no "clinically significant toxicity" or hematological abnormalities observed.[1] Since severe adverse reactions, although rare, have been reported, physicians should review full prescribing information.

Yet strong enough for consistent results

SEPTRA is effective against the most common causative pathogens in otitis media: *Streptococcus pneumoniae* and *Haemophilus influenzae* including strains of *H influenzae* resistant to ampicillin/amoxicillin. And SEPTRA penetrates serum and middle ear fluid with antibacterial concentrations well above the MICs required for *S pneumoniae* and *H influenzae*. Convenient b.i.d. dosage helps promote compliance, too.

*Due to susceptible strains of *S pneumoniae* and *H influenzae*.

Please see brief summary of prescribing information on next page.

Burroughs Wellcome Co.
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84-SEP-12

In acute otitis media initiate therapy with

SEPTRA® SUSPENSION

trimethoprim and sulfamethoxazole

Indications and Usage: For the treatment of urinary tract infections due to susceptible strains of the following organisms: *Escherichia coli, Klebsiella-Enterobacter, Proteus mirabilis, Proteus vulgaris, Proteus morganii.* It is recommended that initial episodes of uncomplicated urinary tract infections be treated with a single effective antibacterial agent rather than the combination. *Note:* The increasing frequency of resistant organisms limits the usefulness of all antibacterials, especially in these urinary tract infections.
For acute otitis media in children due to susceptible strains of *Haemophilus influenzae* or *Streptococcus pneumoniae* when in physician's judgment it offers an advantage over other antimicrobials. To date, there are limited data on the safety of repeated use of Septra in children under two years of age. Septra is not indicated for prophylactic or prolonged administration in otitis media at any age. For acute exacerbations of chronic bronchitis in adults due to susceptible strains of *Haemophilus influenzae* or *Streptococcus pneumoniae* when in physician's judgment it offers an advantage over a single antimicrobial agent. For enteritis due to susceptible strains of *Shigella flexneri* and *Shigella sonnei* when antibacterial therapy is indicated.
Also for the treatment of documented *Pneumocystis carinii* pneumonitis.
Contraindications: Hypersensitivity to trimethoprim or sulfonamides; patients with documented megaloblastic anemia due to folate deficiency; pregnancy at term; nursing mothers because sulfonamides are excreted in human milk and may cause kernicterus; infants less than 2 months of age.
Warnings: SEPTRA SHOULD NOT BE USED TO TREAT STREPTOCOCCAL PHARYNGITIS. Clinical studies show that patients with group A β-hemolytic streptococcal tonsillopharyngitis have higher incidence of bacteriologic failure when treated with Septra than do those treated with penicillin. Deaths from hypersensitivity reactions, agranulocytosis, aplastic anemia and other blood dyscrasias have been associated with sulfonamides. Experience with trimethoprim is much more limited but occasional interference with hematopoiesis has been reported as well as an increased incidence of thrombopenia with purpura in elderly patients on certain diuretics, primarily thiazides. Sore throat, fever, pallor, purpura or jaundice may be early signs of serious blood disorders. Frequent CBC's are recommended; therapy should be discontinued if a significantly reduced count of any formed blood element is noted.
Precautions: *General:* Use cautiously in patients with impaired renal or hepatic function, possible folate deficiency, severe allergy or bronchial asthma. In patients with glucose-6-phosphate dehydrogenase deficiency, hemolysis, frequently dose-related, may occur. During therapy, maintain adequate fluid intake and perform frequent urinalyses, with careful microscopic examination, and renal function tests, particularly where there is impaired renal function. Septra may prolong prothrombin time in those receiving warfarin; reassess coagulation time when administering Septra to these patients. *Pregnancy:* Teratogenic Effects: Pregnancy Category C. Because trimethoprim and sulfamethoxazole may interfere with folic acid metabolism, use during pregnancy only if potential benefits justify the potential risk to the fetus.
Adverse Reactions: All major reactions to sulfonamides and trimethoprim are included, even if not reported with Septra. *Blood dyscrasias:* Agranulocytosis, aplastic anemia, megaloblastic anemia, thrombopenia, 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:* Glossitis, stomatitis, nausea, emesis, abdominal pains, hepatitis, diarrhea, pseudomembranous colitis and pancreatitis. *CNS reactions:* Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo, insomnia, apathy, fatigue, muscle weakness and nervousness. *Miscellaneous reactions:* Drug fever, chills, toxic nephrosis with oliguria and anuria, periarteritis nodosa and L.E. phenomenon. Due to certain chemical similarities to some goitrogens, diuretics (acetazolamide, thiazides) and oral hypoglycemic agents, sulfonamides have caused rare instances of goiter production, diuresis and hypoglycemia in patients; cross-sensitivity with these agents may exist. In rats, long-term therapy with sulfonamides produced thyroid malignancies.
Dosage: Not recommended for infants less than two months of age.
URINARY TRACT INFECTIONS AND SHIGELLOSIS IN ADULTS AND CHILDREN, AND ACUTE OTITIS MEDIA IN CHILDREN:
Adults: Usual adult dosage for urinary tract infections: 2 tablets (single strength) or 4 teasp. (20 ml) b.i.d. for 10-14 days. Use identical daily dosage for 5 days for shigellosis.
Children: Recommended dosage for children with urinary tract infections or acute otitis media — 8 mg/kg trimethoprim and 40 mg/kg sulfamethoxazole per 24 hours, in two divided doses for 10 days. Use identical daily dosage for 5 days for shigellosis.
For patients with renal impairment: Use recommended dosage regimen when creatinine clearance is above 30 ml/min. If creatinine clearance is between 15 and 30 ml/min, use one-half the usual regimen. Septra is not recommended if creatinine clearance is below 15 ml/min.
ACUTE EXACERBATIONS OF CHRONIC BRONCHITIS IN ADULTS:
Usual adult dosage: 2 tablets (single strength) or 4 teasp. (20 ml) b.i.d. for 14 days.
PNEUMOCYSTIS CARINII PNEUMONITIS:
Recommended dosage: 20 mg/kg trimethoprim and 100 mg/kg sulfamethoxazole per 24 hours in equal doses every 6 hours for 14 days. See complete product information for suggested children's dosage table.
How Supplied: TABLETS, containing 80 mg trimethoprim and 400 mg sulfamethoxazole — bottles of 100 and 500 tablets; unit dose pack of 100.
ORAL SUSPENSION, containing the equivalent of 40 mg trimethoprim and 200 mg sulfamethoxazole in each teaspoonful (5 ml), cherry flavored — bottle of 1 pint (473 ml).
Unit of Use: bottle of 100 ml with child resistant cap.
Also available in double strength, oval-shaped, pink, scored tablets containing 160 mg trimethoprim and 800 mg sulfamethoxazole — bottles of 100 and 250, unit dose pack of 100 and COMPLIANCE™ Pak of 20.

Reference: 1. Shurin PA, Pelton SI, Donner A, et al: Trimethoprim-sulfamethoxazole compared with ampicillin in the treatment of acute otitis media. *J Pediatr* 1980; 96:1081-1087.

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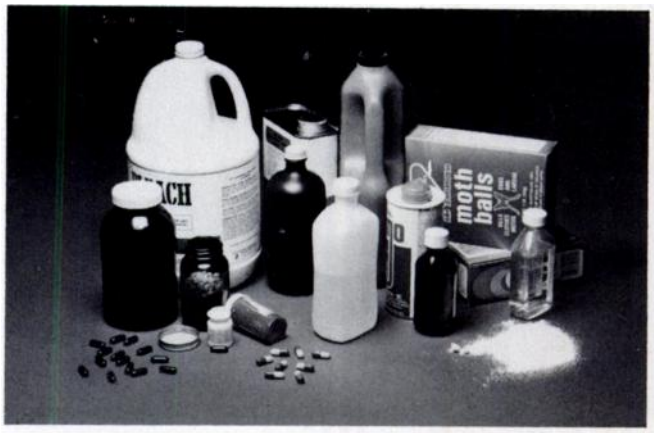
Some practical reasons for a guide on common childhood poisonings.



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Now, the only major Rx brands with an antitussive/expectorant combination

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Please see the following page for a brief summary of prescribing information.

TUSSI-ORGANIDIN® with Ⓥ Codeine
TUSSI-ORGANIDIN® DM

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

Indications and Usage: For the symptomatic relief of irritating, nonproductive cough associated with respiratory tract conditions such as chronic bronchitis, bronchial asthma, tracheobronchitis, and the common cold; also for the symptomatic relief of cough accompanying other respiratory tract conditions such as laryngitis, pharyngitis, croup, pertussis and emphysema. Appropriate therapy should be provided for the primary disease.

Contraindications: History of marked sensitivity to inorganic iodides; hypersensitivity to any of the ingredients or related compounds; pregnancy; newborns; and nursing mothers.

Warnings: Discontinue use if rash or other evidence of hypersensitivity appears. Use with caution or avoid use in patients with history or evidence of thyroid disease.

Precautions: *General*—Iodides have been reported to cause a flare-up of adolescent acne. Children with cystic fibrosis appear to have an exaggerated susceptibility to the goitrogenic effects of iodides.

Dermatitis and other reversible manifestations of iodism have been reported with chronic use of inorganic iodides. Keep these in mind in patients receiving these preparations for prolonged periods.

Drug Interactions—Iodides may potentiate the hypothyroid effect of lithium and other antithyroid drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility—No long-term animal studies have been performed.

Pregnancy—Teratogenic effects. Pregnancy Category X (see CONTRAINDICATIONS).

Nursing Mothers—Do not administer to a nursing woman.

Adverse Reactions: Side effects have been rare, including those which may occur with the individual ingredients and which may be modified as a result of their combination.
Organidin—Gastrointestinal irritation, rash, hypersensitivity, thyroid gland enlargement, and acute parotitis.
Codeine—(Tussi-Organidin only). Nausea, vomiting, constipation, drowsiness, dizziness, and miosis.
Dextromethorphan—(Tussi-Organidin DM only): Drowsiness or gastrointestinal disturbances.

Drug Abuse and Dependence (Tussi-Organidin only):
Controlled Substance—Schedule V.
Dependence—Codeine may be habit-forming.

Overdosage: No reports of any serious problems.

Dosage and Administration: *Adults*: 1 to 2 teaspoonfuls every 4 hours.

Children: ½ to 1 teaspoonful every 4 hours.

How Supplied: *Tussi-Organidin Liquid*—clear red liquid, in bottles of one pint (NDC 0037-4812-10) and one gallon (NDC 0037-4812-20).

Tussi-Organidin DM Liquid—clear yellow liquid, in bottles of one pint (NDC 0037-4712-10) and one gallon (NDC 0037-4712-20).

Storage: Store at room temperature, avoid excessive heat. Keep bottle tightly closed.

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The Pediatrics Insurance Consultants Advisor can answer any questions you might have . . . and, if you want, can give you rate quotations on coverages you're interested in. There is no obligation for this service.

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- ☐ DISABILITY INCOME PROTECTION
- ☐ OFFICE OVERHEAD EXPENSE/up to $7,500
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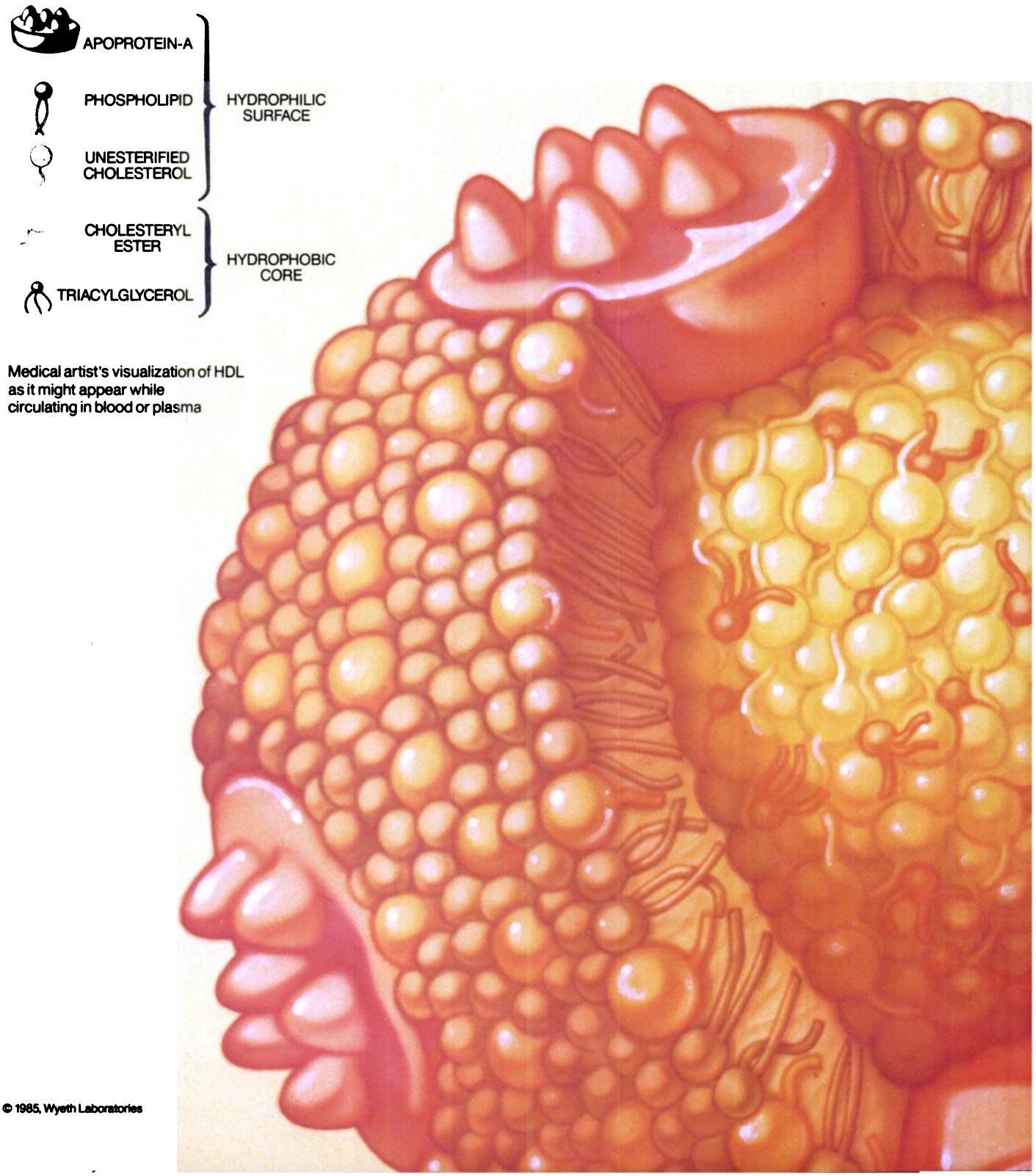
P-1285

HDL: the protective lipoprotein

HDL (high-density lipoprotein) has been called the "good" lipoprotein because, unlike LDL (low-density lipoprotein) which promotes fatty deposits in the blood vessels, HDL helps eliminate cholesterol from the body. Because of this, researchers have noted that persons with higher levels of HDL have a lower rate of heart disease.



Medical artist's visualization of HDL as it might appear while circulating in blood or plasma

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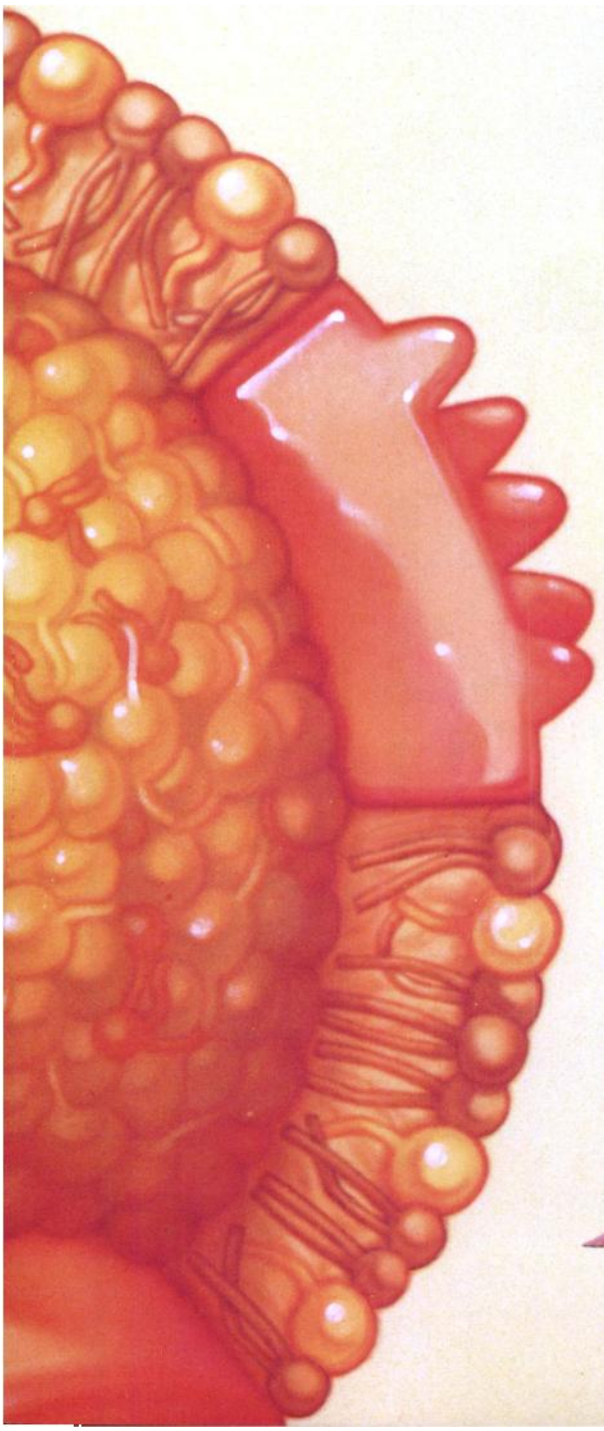
Clinical study:

SMA® produces high HDL levels virtually identical to breast milk.



- The effects of different polyunsaturated to saturated (P/S) fat ratios on circulating HDL were compared in infants fed infant formulas or human milk.[1]
- Human milk, with a low P/S ratio, provided high levels of protective HDL cholesterol.
- SMA, with a P/S ratio virtually identical to breast milk, maintained the high level of HDL cholesterol closest to that of human milk.
- Infant formula with a high P/S ratio significantly lowered the level of HDL cholesterol compared with human milk and SMA.

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1. Carlson SE, DeVoe PW, Barness LA: Effect of infant diets with different polyunsaturated to saturated fat ratios on circulating high-density lipoproteins. J Pediatr Gastroenterol Nutr 1:303-309, 1982.

Important Notice. Breast milk is best for babies. Infant formula is intended to replace or supplement breast milk when breast-feeding is not possible or is insufficient, or when mothers elect not to breast-feed.

Good maternal nutrition is important for the preparation and maintenance of breast-feeding. Extensive or prolonged use of partial bottle-feeding, before breast-feeding has been well established, could make breast-feeding difficult to maintain. A decision not to breast-feed could be difficult to reverse.

Professional advice should be followed on the need for and proper method of use of infant formula and on all matters of infant feeding. Infant formula should always be prepared and used as directed. Unnecessary or improper use of infant formula could present a health hazard. Social and financial implications should be considered when selecting the method of infant feeding.

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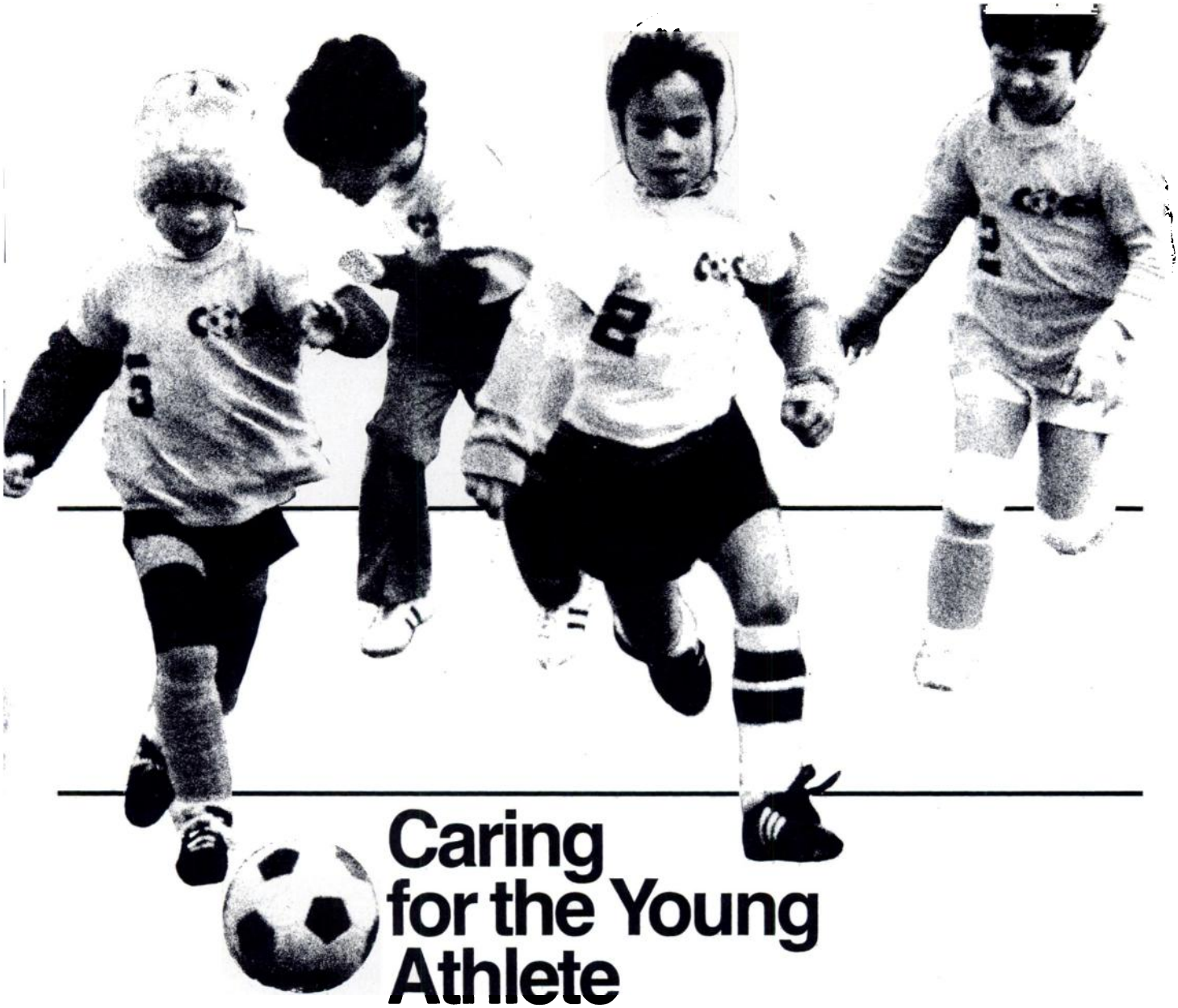

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As children and adolescents become more active in sports, you need more hard information to provide the best medical care.

The American Academy of Pediatrics' new book, *Sports Medicine: Health Care for Young Athletes,* provides this information—with important guidelines.

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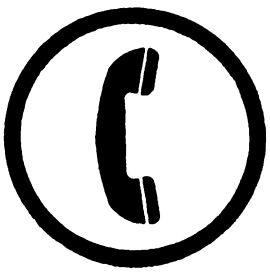

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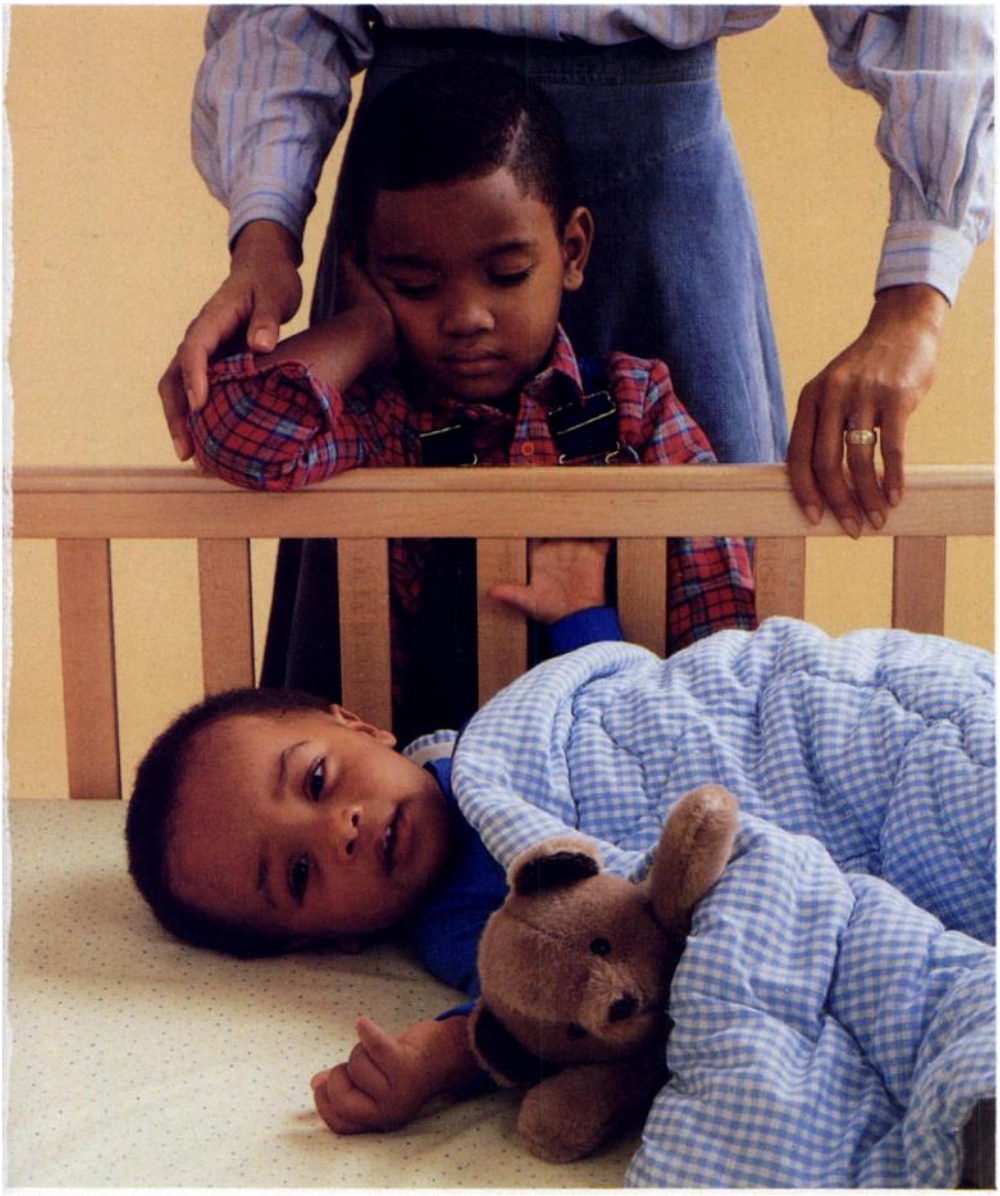
Gary was worried about the baby's fever...



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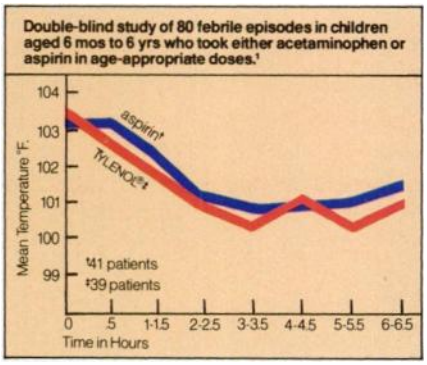
until the pediatrician recommended liquids, rest and Children's TYLENOL® acetaminophen.

The family pediatrician believes that TYLENOL is a superior product for fever relief. That's because, milligram for milligram, it's as effective an antipyretic as aspirin.[1]



And, with TYLENOL, there are few aspirin complications, such as frequent GI upset or allergic reactions.[2]

Next time a family in your practice is worried, and it's right to treat a fever, recommend TYLENOL.

Available in alcohol-free Drops and Elixir, as well as Chewable or Swallowable Tablets.

References: 1. Tarlin L, et al: *Am J Dis Child* 124:880, 1972.
2. Aspirin or paracetamol? *Lancet* II:287, 1981.

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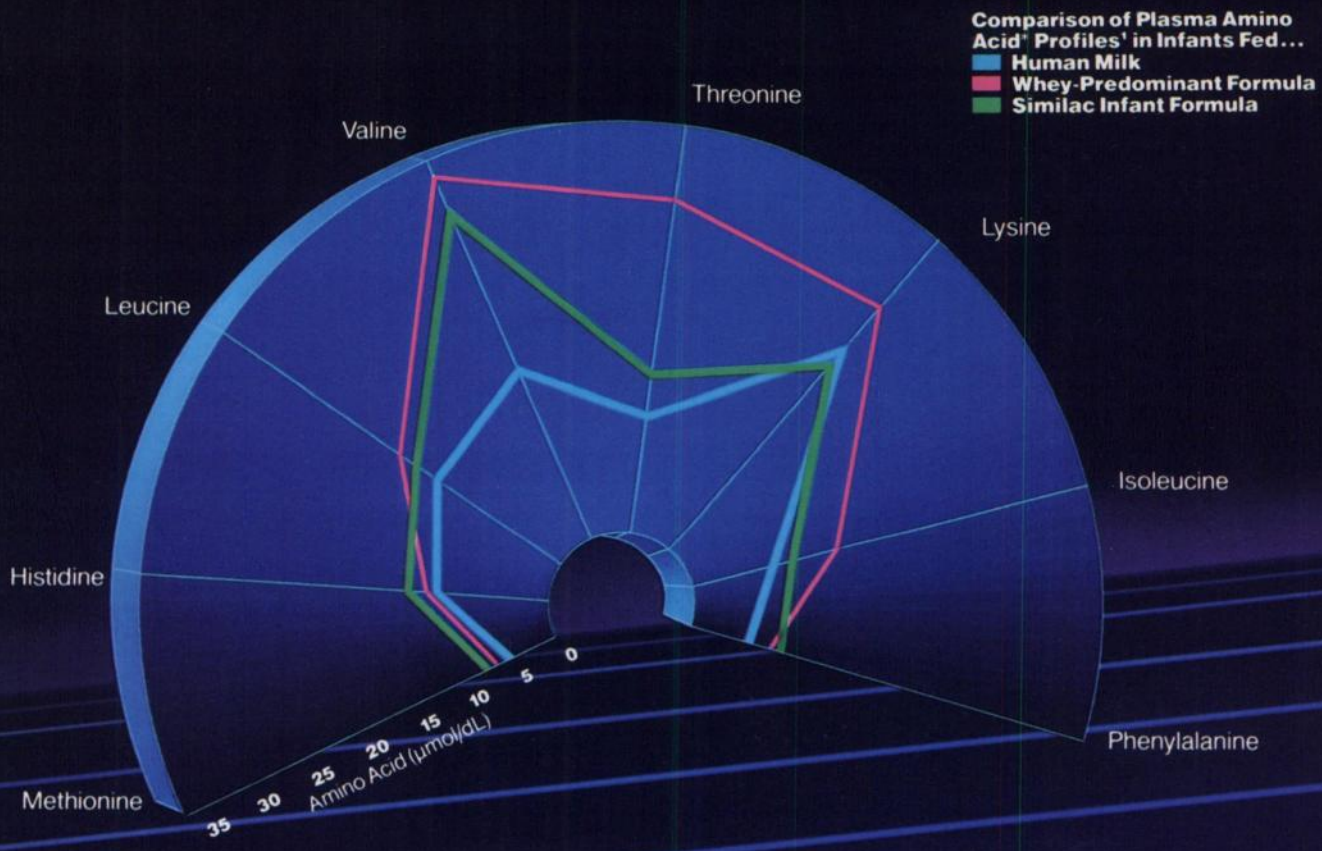

***Essential amino acids**

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Plasma taurine concentration– equivalent to mother's milk.

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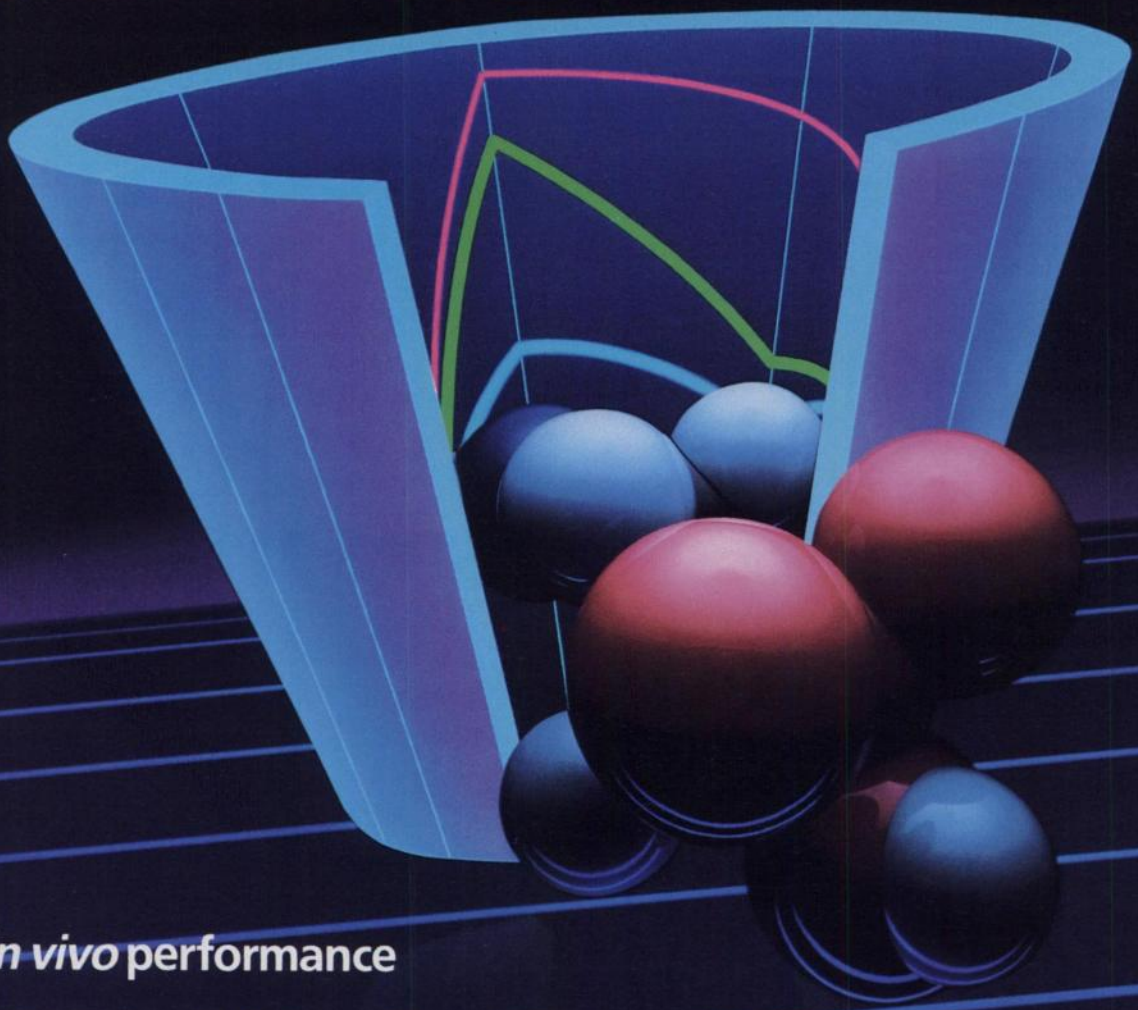

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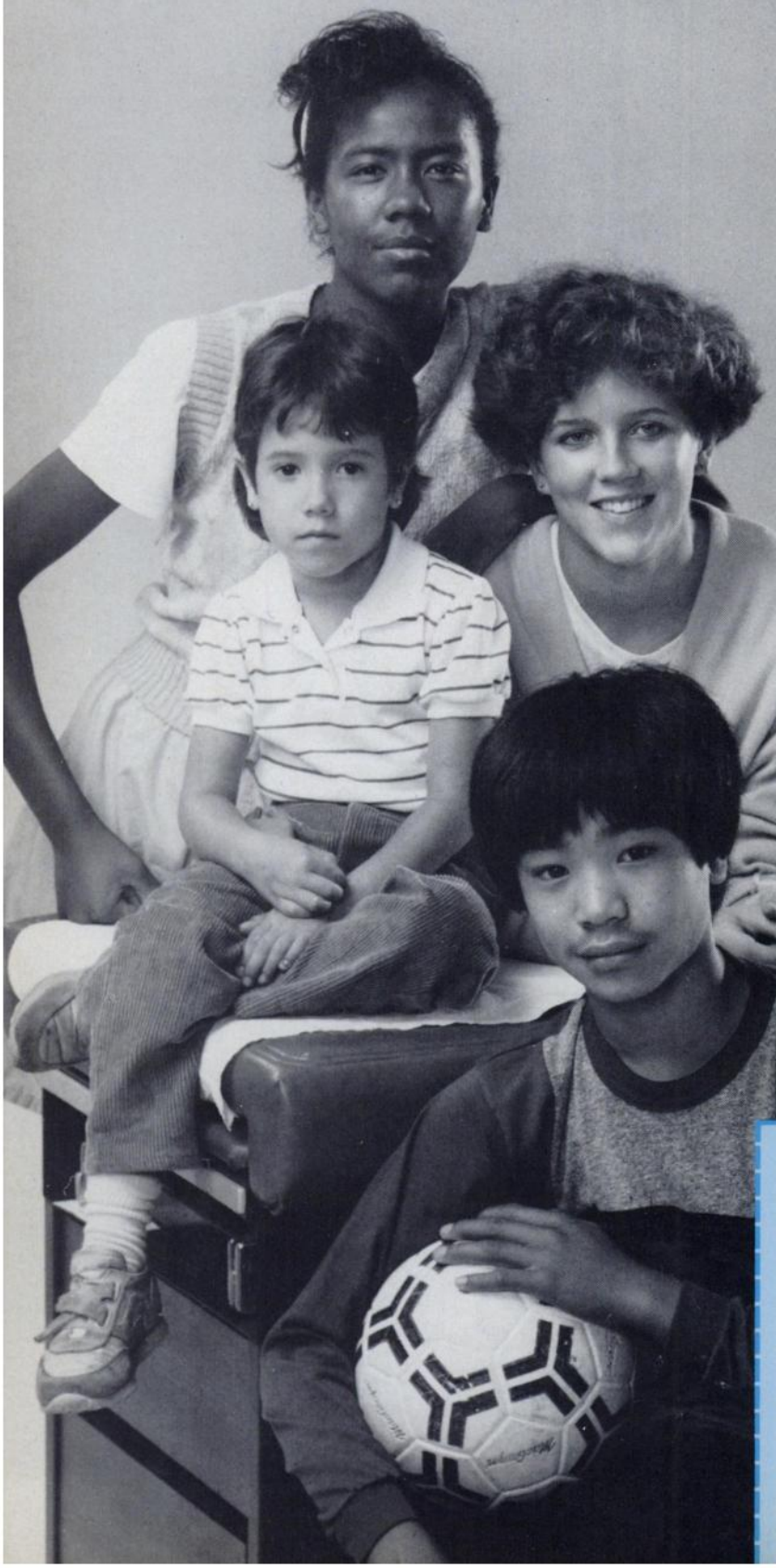

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That's why, for so many kids, itch ends with ATARAX Syrup.

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10 mg per 5 ml, ethyl alcohol 0.5% v/v

Contraindications: Hypersensitivity to hydroxyzine. Hydroxyzine, when administered to the pregnant mouse, rat, and rabbit, induced fetal abnormalities in the rat and mouse at doses substantially above the human therapeutic range. Safety in human pregnancy has not been established. Until such data are available, hydroxyzine is contraindicated in early pregnancy.
Warnings: *Nursing Mothers*—It is not known whether hydroxyzine is excreted in human milk. Since many drugs are so excreted, hydroxyzine should not be given to nursing mothers.
Precautions: THE POTENTIATING ACTION OF HYDROXYZINE MUST BE CONSIDERED WHEN THE DRUG IS USED IN CONJUNCTION WITH CENTRAL NERVOUS SYSTEM DEPRESSANTS SUCH AS NARCOTICS, NON-NARCOTIC ANALGESICS AND BARBITURATES. Therefore, when central nervous system depressants are administered concomitantly with hydroxyzine, their dosage should be reduced. Since drowsiness may occur, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery. Patients should be advised against the simultaneous use of other CNS depressant drugs and cautioned that the effect of alcohol may be increased.

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Adverse Reactions: Side effects reported are usually mild and transitory in nature. *Anticholinergic*—Dry mouth. *Central Nervous System*—Drowsiness is usually transitory and may disappear in a few days of continued therapy or upon reduction of the dose. Involuntary motor activity, including rare instances of tremor and convulsions, has been reported, usually with doses considerably higher than those recommended.
Supply: Tablets, containing 10 mg hydroxyzine hydrochloride, in 100's, 500's, Unit Dose (10 × 10's), and Unit of Use 40's; Tablets, containing 25 mg, in 100's, 500's, Unit Dose (10 × 10's), and Unit of Use 40's; Tablets, containing 50 mg, in 100's, 500's, and Unit Dose (10 × 10's); Tablets, containing 100 mg, in 100's and Unit Dose (10 × 10's); Syrup, containing 10 mg per teaspoonful (5 ml) and ethyl alcohol 0.5% v/v, in pint bottles.

Before prescribing or administering, see package insert.

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Phenergan® VC for prompt relief of cold symptoms

Each teaspoonful (5 ml) contains promethazine HCl 6.25 mg and phenylephrine HCl 5 mg in a flavored syrup base. Alcohol 7%.

Phenergan® with Codeine ℞ for unsurpassed cough relief

Each teaspoonful (5 ml) contains codeine phosphate 10 mg (⅙ gr) (Warning—may be habit-forming) and promethazine HCl 6.25 mg in a flavored syrup base. Alcohol 7%.

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Each teaspoonful (5 ml) contains codeine phosphate 10 mg (⅙ gr) (Warning—may be habit-forming), promethazine HCl 6.25 mg and phenylephrine HCl 5 mg in a flavored syrup base. Alcohol 7%.

Phenergan® with Dextromethorphan for non-narcotic cough suppression; now with 15 mg dextromethorphan, twice as much as the previous formulation

Each teaspoonful (5 ml) contains promethazine HCl 6.25 mg and dextromethorphan hydrobromide 15 mg in a flavored syrup base. Alcohol 7%.

Phenergan® Syrup Plain for the relief of allergy-related upper respiratory symptoms

Each teaspoonful (5 ml) contains promethazine HCl 6.25 mg in a flavored syrup base. Alcohol 7%.

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The leading prescription cough/cold/allergy products, now better than ever

Reformulated Phenergan* Syrups treat cough, cold and allergy symptoms more specifically, control them effectively. Each contains ingredients with specific pharmacological activity—with no expectorants and an increase in antihistamine—to give kids effective relief.

Effective, great-tasting relief for kids

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Available by prescription only, with a 4-6h dosage schedule for most indications, reformulated Phenergan* Syrups help keep you in control of your patients' medication.

Reformulated Cough/Cold/Allergy Syrups

PHENERGAN®

(promethazine HCl)

A better way for kids to feel better.

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See important information on following page.

PHENERGAN® (Promethazine HCl) SYRUPS IN BRIEF:

Indications and Usage:

Temporary relief of coughs and/or upper respiratory symptoms associated with allergy or the common cold

Contraindications:

Contraindicated in patients with hypersensitivity to any component. Promethazine is contraindicated in individuals hypersensitive or who have had an idiosyncratic reaction to it or to other phenothiazines.

Phenylephrine is contraindicated in patients with hypertension or with peripheral vascular insufficiency (ischemia may result with risk of gangrene or thrombosis of compromised vascular beds).

Avoid phenylephrine in patients hypersensitive to it or on a monoamine oxidase inhibitor (MAOI).

Antihistamines and codeine are both contraindicated in those with lower respiratory tract symptoms, including asthma.

Withhold dextromethorphan from patients on a MAOI.

Warnings

CODEINE: Dosage SHOULD NOT BE INCREASED if cough fails to respond; reevaluate unresponsive cough in 5 days or sooner for possible underlying pathology, e.g. foreign body or lower respiratory tract disease.

Codeine may cause or aggravate constipation.

Respiratory depression leading to arrest, coma, and death occurred with codeine antitussives in young children, particularly in the under-one-year infants whose ability to deactivate the drug is not fully developed.

Codeine may be accompanied by histamine release; use with caution in atopic children.

Head Injury and Increased Intracranial Pressure—The respiratory-depressant effects of narcotic analgesics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, intracranial lesions, or preexisting increase in intracranial pressure. Narcotics may produce adverse reactions which may obscure the clinical course of patients with head injuries.

Asthma and Other Respiratory Conditions—Narcotic analgesics or cough suppressants, including codeine, should not be used in asthmatic patients (see "Contraindications"), nor in acute febrile illness with productive cough or in chronic respiratory disease where interference with ability to clear the tracheobronchial tree of secretions would have a deleterious effect on respiratory function.

Hypotensive Effect—Codeine may produce orthostatic hypotension in ambulatory patients.

PROMETHAZINE: May cause marked drowsiness. Caution ambulatory patients against driving or operating machinery until it is known that they do not become drowsy or dizzy from promethazine therapy.

The sedative action of promethazine is additive to the sedative effects of CNS depressants; therefore, agents such as alcohol, narcotic analgesics, sedatives, hypnotics, and tranquilizers should either be eliminated or given in reduced dosage in presence of promethazine. When given concomitantly with promethazine, reduce dose of barbiturates by at least ½, and the dose of analgesic depressants, e.g. morphine or meperidine, by ¼ to ½.

Promethazine may lower seizure threshold. Consider this when giving to persons with known seizure disorders or in combination with narcotics or local anesthetics which may also affect seizure threshold.

Avoid sedative drugs or CNS depressants in patients with history of sleep apnea. Use antihistamines with caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, and urinary bladder obstruction due to symptomatic prostatic hypertrophy and narrowing of bladder neck.

Promethazine has been associated with cholestatic jaundice.

PHENYLEPHRINE: Because phenylephrine is adrenergic, give with caution to patients with thyroid diseases, diabetes mellitus, and heart diseases or those on tricyclic antidepressants.

Men with symptomatic, benign prostatic hypertrophy can experience urinary retention when given oral nasal decongestants.

Phenylephrine can decrease cardiac output. Use extreme caution when giving the drug, parenterally or orally, to patients with arteriosclerosis, to elderly individuals, and/or to patients with initially poor cerebral or coronary circulation.

Use with caution in patients on diet preparations, such as amphetamines or phenylpropanolamine, because synergistic adrenergic effects could result in serious hypertensive response and possible stroke.

DEXTROMETHORPHAN: May be accompanied by histamine release; use with caution in atopic children.

Precautions

Animal reproduction studies have not been conducted with these drug combinations. It is not known if they can cause fetal harm when given to pregnant women, or affect reproduction capacity. Give to pregnant women only if clearly needed.

GENERAL

Give narcotic analgesics, e.g. codeine, with caution and reduce initial dose in patients with acute abdominal conditions, convulsive disorders, significant hepatic or renal impairment, fever, hypothyroidism, Addison's disease, ulcerative colitis, prostatic hypertrophy, in patients with recent gastrointestinal or urinary tract surgery, and in the very young or elderly or debilitated.

Use promethazine cautiously in persons with cardiovascular disease or with impairment of liver function.

Use phenylephrine with caution in patients with cardiovascular disease, particularly hypertension.

Use dextromethorphan with caution in sedated patients, in the debilitated, and in patients confined to supine position.

INFORMATION FOR PATIENTS

All Phenergan Syrups may cause marked drowsiness or impair mental and/or physical abilities required for hazardous tasks, e.g. driving or operating machinery. Tell ambulatory patients to avoid such activities until it is known that they do not become drowsy or dizzy from Phenergan. Supervise children to avoid harm in bike riding or other hazardous activities. Concomitant use of alcohol or other CNS depressants, including narcotic analgesics, sedatives, hypnotics, and tranquilizers, may have an additive effect and should be avoided or their dosage reduced.

Advise patients to report any involuntary muscle movements or unusual sensitivity to sunlight.

Codeine may produce orthostatic hypotension in ambulatory patients; caution patients.

DRUG INTERACTIONS

CODEINE: In patients receiving MAOIs, an initial small test dose is advisable to allow observation of any excessive narcotic effects or MAOI interaction.

PROMETHAZINE: The sedative action is additive to sedative effects of other CNS depressants, e.g. alcohol, narcotic analgesics, sedatives, hypnotics, tricyclic antidepressants, and tranquilizers; therefore, these agents should be avoided or given in reduced dosage.

PHENYLEPHRINE

Drug	Effect
Phenylephrine with prior administration of MAOIs	Cardiac pressor response potentiated. May cause acute hypertensive crisis
Phenylephrine with tricyclic antidepressants	Pressor response increased
Phenylephrine with ergot alkaloids	Excessive rise in blood pressure
Phenylephrine with bronchodilator sympathomimetic agents and with epinephrine or other sympathomimetics	Tachycardia or other arrhythmias may occur
Phenylephrine with prior administration of propranolol or other β-adrenergic blockers	Cardiostimulating effects blocked
Phenylephrine with atropine sulfate	Reflex bradycardia blocked; pressor response enhanced
Phenylephrine with prior administration of phentolamine or other α-adrenergic blockers	Pressor response decreased
Phenylephrine with diet preparations, e.g. amphetamines or phenylpropanolamine	Synergistic adrenergic response

DRUG/LABORATORY TEST INTERACTIONS

Because narcotic analgesics may increase biliary tract pressure, with resultant increases in plasma amylase or lipase levels, determination of these enzyme levels may be unreliable for 24 hours after a narcotic analgesic has been given. These tests may be affected in patients on promethazine.

Pregnancy Tests

Diagnostic pregnancy tests based on immunological reactions between HCG and anti-HCG may result in false-negative or false-positive interpretations.

Glucose Tolerance Test

Increase in blood glucose has been reported in patients on promethazine.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

CODEINE, PROMETHAZINE, AND DEXTROMETHORPHAN

Long-term animal studies have not been performed to assess the carcinogenic potential of codeine or of promethazine or of dextromethorphan, nor are there other animal or human data concerning carcinogenicity, mutagenicity, or impairment of fertility with these agents. Codeine has been reported to show no evidence of carcinogenicity or mutagenicity in a variety of test systems, including the micronucleus and sperm abnormality assays and the *Salmonella* assay. Promethazine was nonmutagenic in the *Salmonella* test system of Ames.

PHENYLEPHRINE

A study which followed the development of cancer in 143,574 patients over a 4-year period indicated that in 11,981 patients who received phenylephrine (systemic or topical), there was no statistically significant association between the drug and cancer at any or all sites.

Long-term animal studies have not been performed to assess carcinogenic potential of phenylephrine, nor are there other animal or human data on mutagenicity.

A study of the effects of adrenergic drugs on ovum transport in rabbits indicated that treatment with phenylephrine did not alter incidence of pregnancy, the number of implantations was significantly reduced when high doses were used.

PREGNANCY

Teratogenic Effects—Pregnancy Category C

CODEINE: A study in rats and rabbits reported no teratogenic effect of codeine given in the period of organogenesis in doses ranging from 5 to 120 mg/kg. In the rat, doses at the 120-mg/kg level, in the toxic range for the adult animal, were associated with increase in embryo resorption at implantation. In another study a single 100-mg/kg dose in pregnant mice resulted in delayed ossification in offspring. There are no studies in humans; significance of these findings to humans, if any, is not known.

PROMETHAZINE: Teratogenic effects have not been demonstrated in rat-feeding studies at doses of 6.25 and 12.5 mg/kg of promethazine. These doses are 6 and 16.7 times the maximum recommended total daily dose of promethazine for a 50-kg subject depending on the indication for which the drug is prescribed. Specific studies to test the action of the drug on parturition, lactation, and development of the animal neonate were not done, but a general preliminary study in rats indicated no effect on these parameters. Although antihistamines, including promethazine, have been found to produce fetal mortality in rodents, the pharmacological effects of histamine in the rodent do not parallel those in man. There are no adequate and well-controlled studies of promethazine in pregnant women.

PHENYLEPHRINE: A study in rabbits indicated continued moderate overexposure to phenylephrine (3 mg/day) during the second half of pregnancy (22nd day of gestation to delivery) may contribute to perinatal wastage, prematurity, premature labor, and possibly fetal anomalies; when phenylephrine (3 mg/day) was given to rabbits during first half of pregnancy (3rd day after mating for 7 days), a significant number gave birth to litters of low birth weight. Another study showed that phenylephrine was associated with anomalies of aortic arch and with ventricular septal defect in the chick embryo. Phenergan® (promethazine HCl) Syrups should be used during pregnancy only if potential benefit justifies potential risk to the fetus.

Nonteratogenic Effects

Dependence has been reported in newborns whose mothers took opiates regularly during pregnancy. Withdrawal signs include irritability, excessive crying, tremors, hyperreflexia, fever, vomiting, and diarrhea. Signs usually appear during the first few days of life.

Promethazine taken within two weeks of delivery may inhibit platelet aggregation in newborn.

LABOR AND DELIVERY

Narcotic analgesics cross the placental barrier. The closer to delivery and the larger the dose used, the greater the possibility of respiratory depression in the newborn. Narcotic analgesics should be avoided during labor if delivery of a premature infant is anticipated. If the mother has received narcotic analgesics during labor, newborn infants should be observed closely for signs of respiratory depression. Resuscitation may be required (see "Overdosage"). The effect of codeine, if any, on the later growth, development, and functional maturation of the child is unknown. Administration of phenylephrine to patients in late pregnancy or labor may cause fetal anoxia or bradycardia by increasing contractility of the uterus and decreasing uterine blood flow.

NURSING MOTHERS

Some studies, but not others, have reported detectable amounts of codeine in breast milk. The levels are probably not clinically significant after usual therapeutic dosage. The possibility of clinically important amounts being excreted in breast milk in individuals abusing codeine should be considered. It is not known whether phenylephrine, promethazine or dextromethorphan is excreted in human milk. Caution should be exercised when any Phenergan Syrup is administered to a nursing woman.

PEDIATRIC USE

These products should not be used in children under 2 years of age because safety for such use has not been established.

Adverse Reactions

CODEINE

CNS—CNS depression, particularly respiratory depression, and to a lesser extent circulatory depression, light-headedness, dizziness, sedation, euphoria, dysphoria, headache, transient hallucination, disorientation, visual disturbances, and convulsions.

CV—Tachycardia, bradycardia, palpitation, faintness, syncope, orthostatic hypotension (common to narcotic analgesics).

GI—Nausea, vomiting, constipation, and biliary tract spasm. Patients with chronic ulcerative colitis may experience increased colonic motility, in patients with acute ulcerative colitis, toxic dilation has been reported.

GU—Oliguria, urinary retention, antidiuretic effect has been reported (common to narcotic analgesics).

Allergic—Infrequent pruritus, giant urticaria, angioneurotic edema, and laryngeal edema.

Other—Flushing of the face, sweating and pruritus (due to opiate-induced histamine release), weakness.

PROMETHAZINE

CNS—Sedation, sleepiness, occasional blurred vision, dryness of mouth, dizziness, rarely confusion, disorientation, and extrapyramidal symptoms such as oculogyric crisis, torticollis, and tongue protrusion (usually in association with parenteral injection or excessive dosage).

CV—Increased or decreased blood pressure.

Dermatologic—Rash, rarely photosensitivity.

Hematologic—Rarely leukopenia, thrombocytopenia, agranulocytosis (1 case).

GI—Nausea and vomiting.

PHENYLEPHRINE

CNS—Restlessness, anxiety, nervousness, and dizziness.

CV—Hypertension (see "Warnings").

Other—Precordial pain, respiratory distress, tremor, and weakness.

DEXTROMETHORPHAN

Occasionally causes slight drowsiness, dizziness, and GI disturbances.

Drug Abuse and Dependence

CONTROLLED SUBSTANCE

Phenergan with codeine and Phenergan VC with codeine are Schedule V Controlled Substances.

ABUSE

Codeine is known to be subject to abuse, however, abuse potential of oral codeine appears to be quite low. Even parenteral codeine does not appear to offer psychic effects sought by addicts to the same degree as heroin or morphine. However, codeine must be administered only under close supervision to patients with history of drug abuse or dependence.

DEPENDENCE

Psychological dependence, physical dependence, and tolerance are known to occur.

According to WHO Expert Committee on Drug Dependence, dextromethorphan could produce very slight psychic but no physical dependence.

Overdosage

CODEINE: Serious overdose with codeine is characterized by respiratory depression (decrease in respiratory rate and/or tidal volume; Cheyne-Stokes respiration; cyanosis); extreme somnolence progressing to stupor or coma; skeletal muscle flaccidity; cold and clammy skin; and sometimes bradycardia and hypotension. The triad of coma, pinpoint pupils, and respiratory depression is strongly suggestive of opiate poisoning. In severe overdosage, particularly by the IV route, apnea, circulatory collapse, cardiac arrest, and death may occur. Promethazine is additive to depressant effects of codeine.

It is difficult to determine what constitutes a standard toxic or lethal dose. However, lethal oral dose of codeine in adults is reported to be in range of 0.5 to 1.0 gram. Infants and children are believed to be relatively more sensitive to opiates on body-weight basis. Elderly patients are also comparatively intolerant to opiates.

PROMETHAZINE: Signs and symptoms of overdosage range from mild CNS and cardiovascular depression to profound hypotension, respiratory depression, and unconsciousness.

Stimulation may be evident, especially in children and geriatric patients. Convulsions may rarely occur. A paradoxical reaction has been reported in children receiving single doses of 75 mg to 125 mg orally, characterized by hyperexcitability and nightmares.

Atropine-like signs and symptoms—dry mouth, fixed, dilated pupils, flushing, as well as GI symptoms, may occur.

PHENYLEPHRINE: Signs and symptoms of overdosage include hypertension, headache, convulsions, cerebral hemorrhage, and vomiting. Ventricular premature beats and short paroxysms of ventricular tachycardia may also occur. Headache may be a symptom of hypertension. Bradycardia may also be seen early in phenylephrine overdosage through stimulation of baroreceptors.

DEXTROMETHORPHAN

May produce central excitement and mental confusion. Very high doses may produce respiratory depression. One case of toxic psychosis (hyperactivity, marked visual and auditory hallucinations) after single dose of 20 tablets (300 mg) of dextromethorphan was reported.

TREATMENT

Treatment of overdosage with Phenergan Syrups is essentially symptomatic and supportive. Only in cases of extreme overdosage or individual sensitivity do vital signs including respiration, pulse, blood pressure, temperature, and EKG need to be monitored. Activated charcoal orally or by lavage may be given; or sodium or magnesium sulfate orally as a cathartic. Attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation.

The narcotic antagonist, naloxone HCl, may be given when significant respiratory depression occurs with the codeine syrups; any depressant effects of promethazine are not reversed by naloxone. Diazepam may be used to control convulsions.

The antidotal efficacy of narcotic antagonists to dextromethorphan has not been established.

Avoid analeptics, which may cause convulsions. Acidosis and electrolyte losses should be corrected.

A rise in temperature or pulmonary complications may signal the need for institution of antibiotic therapy.

Severe hypotension usually responds to norepinephrine or phenylephrine. EPINEPHRINE SHOULD NOT BE USED, since in a patient with partial adrenergic blockade it may further lower blood pressure.

Limited experience with dialysis indicates that it is not helpful.

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3/14/84

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For the normal newborn, breast milk is the optimal source of nutrition. If an infant is not breast-fed, infant formulas are a safe, nutritionally adequate alternative.

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The right time for starting baby foods will depend on developmental criteria – rate of growth, activity level, and the need for additional calories, vitamins, minerals and protein. Practical parameters – like doubling of birthweight (approximately 13 pounds or 6-7 kilos), breast-feeding more than 8-10 times in a 24-hour period and/or consumption of more than 32 ounces of formula per day – help identify the most advantageous time for starting baby foods.

Iron-fortified infant cereal is one of the most frequently recommended first foods. When iron supplementation for the breast-fed baby is desirable, infant cereal can be mixed with vitamin C-fortified fruit juice.

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AN ACCOUNT OF FAMILIAL ICTERUS GRAVIS, REPORTED BY MICHAEL UNDERWOOD IN 1799

Michael Underwood (1737–1820), the most advanced writer on diseases of infants and children in the eighteenth century, included the following account of familial icterus gravis in the fourth edition of his superb pediatric textbook (1799).[1]

Mrs. J. had been the mother of eleven children; on nine of which the jaundice appeared a few days after they were born, and they all died within a period of a month after their birth. The tenth child lived six years, was then afflicted with the jaundice and died. In May, 1796, Mrs. J. was delivered of her eleventh child; on the third day after its birth, the skin became yellow, and the child was at the same time remarkably torpid and sleepy, and seemed to be slightly convulsed. On the following day, the colour of the skin often varied, being somewhat of a deeper yellow, and at other times nearly regaining its natural colour; the child continued, however, in the same languid and almost insensible state, but received nourishment, and sucked the breast of the mother, till within a few hours of its death, which took place on the ninth day.

Noted by T.E.C., Jr, MD

REFERENCE
1. Underwood M: *A Treatise on the Diseases of Children*, vol 1, ed 4. London, J. Callow, 1799, pp 31–32.

THE ANTI-CHILD TREND

According to the most recent survey of the National Center for Health Statistics, a division of the U.S. Department of Health and Human Services, the use of sterilization by married men and women has risen dramatically since 1965.

H. Theodore Groat, a sociology professor who studies fertility control at the Population and Society Research Center at Bowling Green State University in Ohio, said it was now common for newly married young couples to consider sterilization as a future option.

"The planning for their lives is such today that, unless they can plan their fertility as well, the plans for other aspects of their lives get knocked out of kilter," he said.

Professor Groat attributes this trend to "the devaluation of fertility, the devaluation of children as important in one's life."

"The whole fertility revolution," he said, "has to do with an almost anti-child posture."

Submitted by Student

From Shipp ER: Sterilization gains in popularity in U.S. *The New York Times*, July 6, 1985.

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The American Academy of Pediatrics recommends that children up to age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation for caries prophylaxis.

Warnings: As in the case of all medications, keep out of the reach of children.

Precautions: Before prescribing VI-FLOR® products the physician should determine the amount of fluoride which the child is receiving. The suggested dose should not be exceeded since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Adverse Reactions: Allergic rash and other idiosyncrasies have been rarely reported.

Dosage and Administration: As prescribed by the physician. VI-FLOR 0.25 mg drops provide fluoride in drop form for infants and young children from birth to 2 years of age in areas where the drinking water contains less than 0.3 ppm of fluoride and for children ages 2-3 years in areas where the drinking water contains 0.3 thru 0.7 ppm of fluoride. Each 1.0 ml supplies sodium fluoride (0.25 mg fluoride) plus certain essential vitamins. VI-FLOR 1.0 chewable tablets contain fluoride for children over 3 years of age in areas where water fluoride is less than 0.3 ppm. Each tablet supplies sodium fluoride (1.0 mg fluoride) plus certain essential vitamins.

How Supplied: VI-FLOR Drops are supplied in 50 ml bottles. VI-FLOR Chewable Tablets are supplied in bottles of 100.

References:

1. Heins M, et al: Attitudes of pediatricians toward maternal employment. *Pediatrics* 1983;72:283-290.
2. "Nutrition vs. Inflation: The Battle of the Eighties," 2nd *Woman's Day*/FMI Family Food Study, conducted by Yankelovich, Skelley and White, Inc., 1980, pp 39, 48.
3. Wurtmann JJ: What do children eat? Eating styles of the preschool, elementary school, and adolescent child, in Suskind RM (ed): *Textbook of Pediatric Nutrition*. New York, Raven Press, 1981, pp 598-599.
4. Source: Preliminary findings from USDA Nationwide Food Consumption Survey conducted 4/77-3/78 using 1980 Recommended Dietary Allowances.

For complete details, please consult full prescribing information.

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