JULY 1979

VOLUME 64
NUMBER1

AMERICAN ACADEMY OF PEDIATRICS EVANSTON ILL

# Pediatrics





PEDIAU 64(1) pp 1–126 (1979)

# Her stuffy nose and ears are bad enough. Why make her drowsy, too?

Single-entity SUDAFED® (pseudoephedrine HCl) Syrup works without antihistamines—so it opens the nose without closing the eyes. Can't cause antihistamine "overdry" either.

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SIDE EFFECTS: While the great majority of patients will experience no side effects, those particularly sensitive to sympathomimetic drugs may note mild stimulation.

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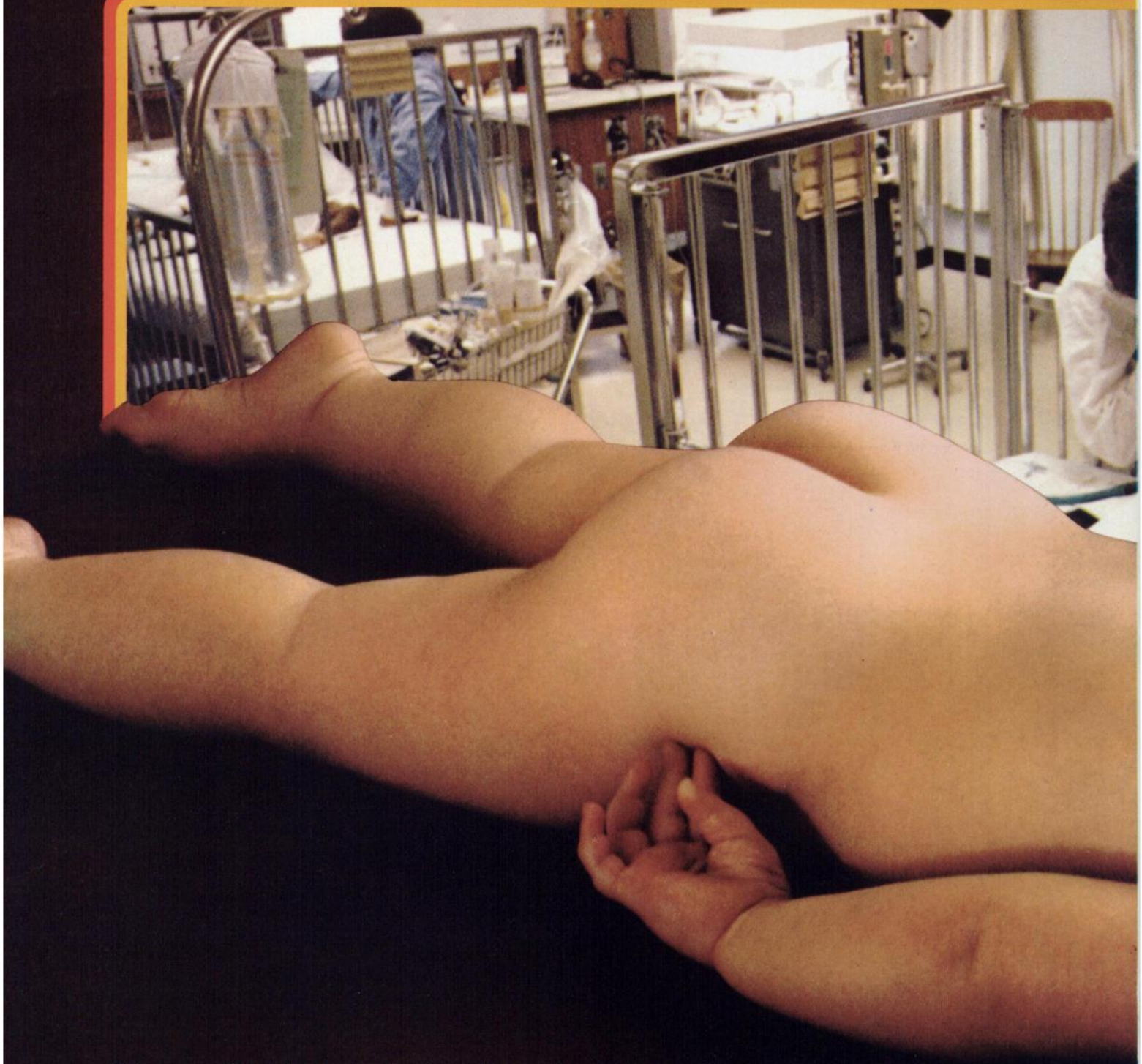
## (chloramphenicol) Sodium Succinate for injection

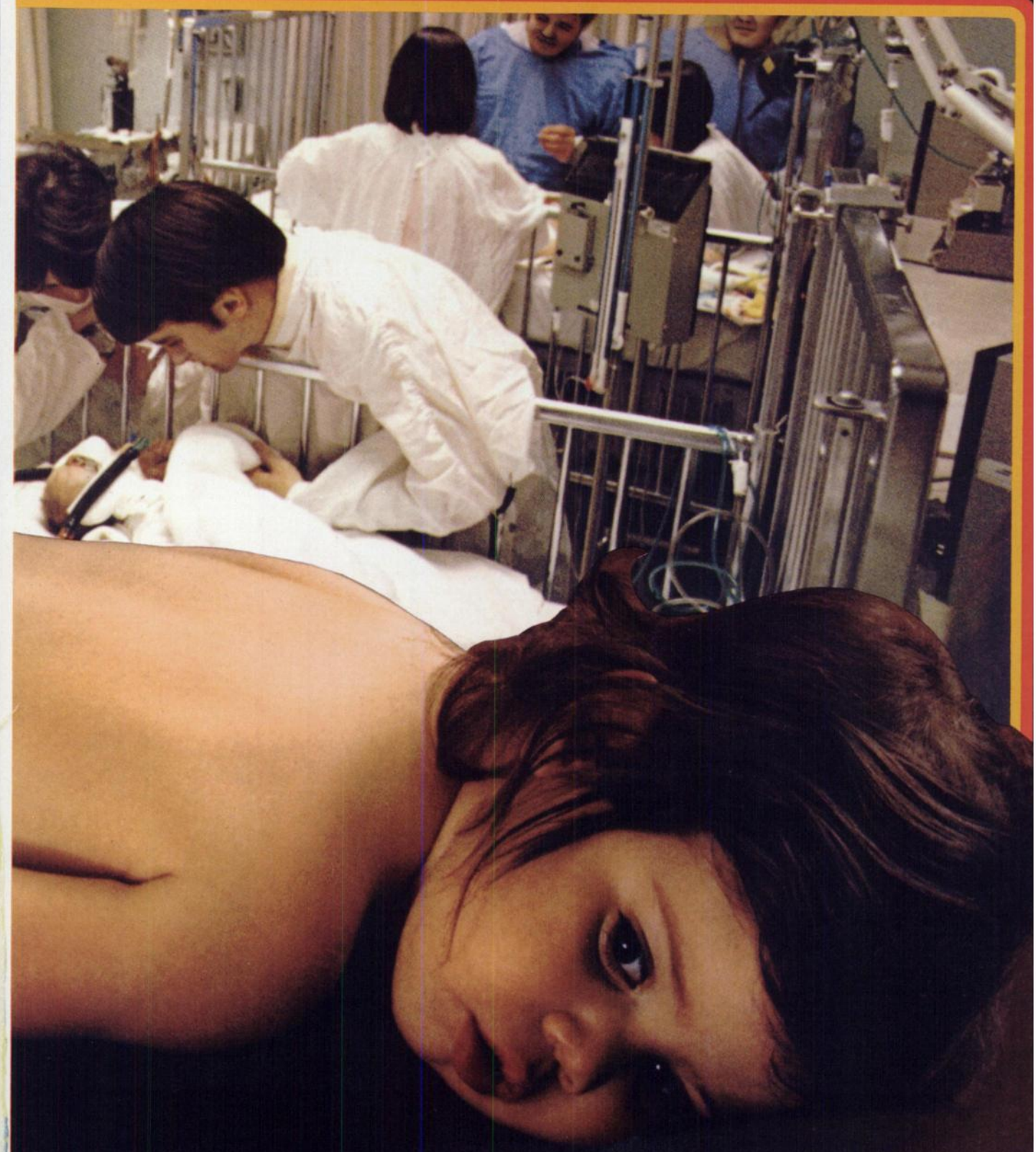


Chloromycetin (chloramphenicol) must be used only in those serious infections for which less potentially dangerous drugs are ineffective or contraindicated. However, Chloromycetin may be chosen to initiate antibiotic therapy on the clinical impression that *Hemophilus influenzae* meningitis is believed to be present.

Among diseases of the central nervous system, *H influenzae* meningitis is one of the most severely threatening. Chloromycetin can be particularly useful in this condition.

Chloromycetin may be used in the treatment of *H influenzae* meningitis when the patient has known—or suspected—allergy to penicillin.

# for H influenzae meningitis



Please see next page for complete prescribing information.

**PARKE-DAVIS**

**Prescribing Information**
**Chloromycetin Sodium Succinate**
**(chloramphenicol sodium succinate for injection, USP)**
**For intravenous administration**

**WARNING**

**Serious and fatal blood dyscrasias (aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia) are known to occur after the administration of chloramphenicol. In addition, there have been reports of aplastic anemia attributed to chloramphenicol which later terminated in leukemia. Blood dyscrasias have occurred after both short-term and prolonged therapy with this drug. Chloramphenicol must not be used when less potentially dangerous agents will be effective, as described in the Indications section. *It must not be used in the treatment of trivial infections or where it is not indicated, as in colds, influenza, infections of the throat; or as a prophylactic agent to prevent bacterial infections.***

**Precautions: It is essential that adequate blood studies be made during treatment with the drug. While blood studies may detect early peripheral blood changes, such as leukopenia, reticulocytopenia, or granulocytopenia, before they become irreversible, such studies cannot be relied on to detect bone marrow depression prior to development of aplastic anemia. To facilitate appropriate studies and observation during therapy, it is desirable that patients be hospitalized.**

## IMPORTANT CONSIDERATIONS IN PRESCRIBING INJECTABLE CHLORAMPHENICOL SODIUM SUCCINATE

**CHLORAMPHENICOL SODIUM SUCCINATE IS INTENDED FOR INTRAVENOUS USE ONLY. IT HAS BEEN DEMONSTRATED TO BE INEFFECTIVE WHEN GIVEN INTRAMUSCULARLY.**

1. Chloramphenicol sodium succinate must be hydrolyzed to its microbiologically active form and there is a lag in achieving adequate blood levels compared with the base given intravenously.
2. The oral form of chloramphenicol is readily absorbed and adequate blood levels are achieved and maintained on the recommended dosage.
3. Patients started on intravenous chloramphenicol sodium succinate should be changed to the oral form as soon as practicable.

## DESCRIPTION

Chloramphenicol is an antibiotic that is clinically useful for, *and should be reserved for,* serious infections caused by organisms susceptible to its antimicrobial effects when less potentially hazardous therapeutic agents are ineffective or contraindicated. Sensitivity testing is essential to determine its indicated use, but may be performed concurrently with therapy initiated on clinical impression that one of the indicated conditions exists (see Indications section).

Each gram (10 ml of a 10% solution) of chloramphenicol sodium succinate contains approximately 52 mg (2.25 mEq) of sodium.

## ACTIONS AND PHARMACOLOGY

*In vitro* chloramphenicol exerts mainly a bacteriostatic effect on a wide range of gram-negative and gram-positive bacteria and is active *in vitro* against rickettsias, the lymphogranuloma-psittacosis group, and *Vibrio cholerae.* It is particularly active against *Salmonella typhi* and *Hemophilus influenzae.* The mode of action is through interference or inhibition of protein synthesis in intact cells and in cell-free systems.

Chloramphenicol administered orally is absorbed rapidly from the intestinal tract. In controlled studies in adult volunteers using the recommended dosage of 50 mg/kg/day, a dosage of 1 g every six hours for eight doses was given. Using the microbiological assay method, the average peak serum level was 11.2 mcg/ml one hour after the first dose. A cumulative effect gave a peak rise to 18.4 mcg/ml after the fifth dose of 1 g. Mean serum levels ranged from 8 to 14 mcg/ml over the 48-hour period. Total urinary excretion of chloramphenicol in these studies ranged from a low of 68% to a high of 99% over a three-day period. From 8% to 12% of the antibiotic excreted is in the form of free chloramphenicol; the remainder consists of microbiologically inactive metabolites, principally the conjugate with glucuronic acid. Since the glucuronide is excreted rapidly, most chloramphenicol detected in the blood is in the microbiologically active free form. Despite the small proportion of unchanged drug excreted in the urine, the concentration of free chloramphenicol is relatively high, amounting to several hundred mcg/ml in patients receiving divided doses of 50 mg/kg/day. Small amounts of active drug are found in bile and feces. Chloramphenicol diffuses rapidly, but its distribution is not uniform. Highest concentrations are found in liver and kidney, and lowest concentrations are found in brain and cerebrospinal fluid. Chloramphenicol enters cerebrospinal fluid even in the absence of meningeal inflammation, appearing in concentrations about half of those found in the blood. Measurable levels are also detected in pleural and in ascitic fluids, saliva, milk, and in the aqueous and vitreous humors. Transport across the placental barrier occurs with somewhat lower concentration in cord blood of newborn infants than in maternal blood.

## INDICATIONS

**In accord with the concepts in the Warning Box and this Indications section, chloramphenicol must be used only in those serious infections for which less potentially dangerous drugs are ineffective or contraindicated. However, chloramphenicol may be chosen to initiate antibiotic therapy on the clinical impression that one of the conditions below is believed to be present; *in vitro* sensitivity tests should be performed concurrently so that the drug may be discontinued as soon as possible if less potentially dangerous agents are indicated by such tests. The decision to continue use of chloramphenicol rather than another antibiotic when both are suggested by *in vitro* studies to be effective against a specific pathogen should be based upon severity of the infection, susceptibility of the pathogen to the various antimicrobial drugs, efficacy of the various drugs in the infection, and the important additional concepts contained in the Warning Box above.**

1. Acute infections caused by *S typhi**
   It is not recommended for the routine treatment of the typhoid carrier state.
2. Serious infections caused by susceptible strains in accordance with the concepts expressed above.
   a) *Salmonella* species
   b) *H influenzae,* specifically meningeal infections
   c) Rickettsia
   d) Lymphogranuloma-psittacosis group
   e) Various gram-negative bacteria causing bacteremia, meningitis, or other serious gram-negative infections
   f) Other susceptible organisms which have been demonstrated to be resistant to all other appropriate antimicrobial agents
3. Cystic fibrosis regimens

*In the treatment of typhoid fever, some authorities recommend that chloramphenicol be administered at therapeutic levels for 8 to 10 days after the patient has become afebrile to lessen the possibility of relapse.

## CONTRAINDICATIONS

Chloramphenicol is contraindicated in individuals with a history of previous hypersensitivity and/or toxic reaction to it. *It must not be used in the treatment of trivial infections or where it is not indicated, as in colds, influenza, infections of the throat; or as a prophylactic agent to prevent bacterial infection.*

## PRECAUTIONS

1. Base line blood studies should be followed by periodic blood studies approximately every two days during therapy. The drug should be discontinued upon appearance of reticulocytopenia, leukopenia, thrombocytopenia, anemia, or any other blood study findings attributable to chloramphenicol. However, it should be noted that such studies do not exclude the possible later appearance of the irreversible type of bone marrow depression.
2. Repeated courses of the drug should be avoided if at all possible. Treatment should not be continued longer than required to produce a cure with little or no risk of relapse of the disease.
3. Concurrent therapy with other drugs that may cause bone marrow depression should be avoided.
4. Excessive blood levels may result from administration of the recommended dose to patients with impaired liver or kidney function, including that due to immature metabolic processes in the infant. The dosage should be adjusted accordingly or, preferably, the blood concentration should be determined at appropriate intervals.
5. There are no studies to establish the safety of this drug in pregnancy.
6. Since chloramphenicol readily crosses the placental barrier, caution in use of the drug is particularly important during pregnancy at term or during labor because of potential toxic effects on the fetus (gray syndrome).
7. Precaution should be used in therapy of premature and full-term infants to avoid gray syndrome toxicity. (See Adverse Reactions.) Serum drug levels should be carefully followed during therapy of the newborn infant.
8. Precaution should be used in therapy during lactation because of the possibility of toxic effects on the nursing infant.
9. The use of this antibiotic, as with other antibiotics, may result in an overgrowth of nonsusceptible organisms, including fungi. If infections caused by nonsusceptible organisms appear during therapy, appropriate measures should be taken.

## ADVERSE REACTIONS

**1. Blood Dyscrasias**

The most serious adverse effect of chloramphenicol is bone marrow depression. Serious and fatal blood dyscrasias (aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia) are known to occur after the administration of chloramphenicol. An irreversible type of marrow depression leading to aplastic anemia with a high rate of mortality is characterized by the appearance weeks or months after therapy of bone marrow aplasia or hypoplasia. Peripherally, pancytopenia is most often observed, but in a small number of cases only one or two of the three major cell types (erythrocytes, leukocytes, platelets) may be depressed.

A reversible type of bone marrow depression, which is dose-related, may occur. This type of marrow depression is characterized by vacuolization of the erythroid cells, reduction of reticulocytes, and leukopenia, and responds promptly to the withdrawal of chloramphenicol.

An exact determination of the risk of serious and fatal blood dyscrasias is not possible because of lack of accurate information regarding (1) the size of the population at risk, (2) the total number of drug-associated dyscrasias, and (3) the total number of nondrug-associated dyscrasias.

In a report to the California State Assembly by the California Medical Association and the State Department of Public Health in January 1967, the risk of fatal aplastic anemia was estimated at 1:24,200 to 1:40,500 based on two dosage levels.

There have been reports of aplastic anemia attributed to chloramphenicol which later terminated in leukemia.

Paroxysmal nocturnal hemoglobinuria has also been reported.

**2. Gastrointestinal Reactions**

Nausea, vomiting, glossitis and stomatitis, diarrhea and enterocolitis may occur in low incidence.

**3. Neurotoxic Reactions**

Headache, mild depression, mental confusion, and delirium have been described in patients receiving chloramphenicol. Optic and peripheral neuritis have been reported, usually following long-term therapy. If this occurs, the drug should be promptly withdrawn.

**4. Hypersensitivity Reactions**

Fever, macular and vesicular rashes, angioedema, urticaria, and anaphylaxis may occur. Herxheimer reactions have occurred during therapy for typhoid fever.

**5. "Gray Syndrome"**

Toxic reactions including fatalities have occurred in the premature and newborn; the signs and symptoms associated with these reactions have been referred to as the gray syndrome. One case of gray syndrome has been reported in an infant born to a mother having received chloramphenicol during labor. One case has been reported in a 3-month-old infant. The following summarizes the clinical and laboratory studies that have been made on these patients:

a) In most cases, therapy with chloramphenicol had been instituted within the first 48 hours of life.
b) Symptoms first appeared after three to four days of continued treatment with high doses of chloramphenicol.
c) The symptoms appeared in the following order:
   (1) abdominal distention with or without emesis;
   (2) progressive pallid cyanosis;
   (3) vasomotor collapse, frequently accompanied by irregular respiration;
   (4) death within a few hours of onset of these symptoms.
d) The progression of symptoms from onset to exitus was accelerated with higher dose schedules.
e) Preliminary blood serum level studies revealed unusually high concentrations of chloramphenicol (over 90 mcg/ml after repeated doses).
f) Termination of therapy upon early evidence of the associated symptomatology frequently reversed the process with complete recovery.

## ADMINISTRATION

Chloramphenicol, like other potent drugs, should be prescribed at recommended doses known to have therapeutic activity. Administration of 50 mg/kg/day in divided doses will produce blood levels of the magnitude to which the majority of susceptible microorganisms will respond.

**As soon as feasible, an oral dosage form of chloramphenicol should be substituted for the intravenous form because adequate blood levels are achieved with chloramphenicol by mouth.**

The following method of administration is recommended:

Intravenously as a 10% (100 mg/ml) solution to be injected over at least a one-minute interval. This is prepared by the addition of 10 ml of an aqueous diluent such as water for injection or 5% dextrose injection.

## DOSAGE

**Adults**

Adults should receive 50 mg/kg/day in divided doses at six-hour intervals. In exceptional cases, patients with infections due to moderately resistant organisms may require increased dosage up to 100 mg/kg/day to achieve blood levels inhibiting the pathogen, but these high doses should be decreased as soon as possible. Adults with impairment of hepatic or renal function or both may have reduced ability to metabolize and excrete the drug. In instances of impaired metabolic processes, dosages should be adjusted accordingly. (See discussion under Newborn Infants.) Precise control of concentration of the drug in the blood should be carefully followed in patients with impaired metabolic processes by the available microtechniques (information available on request).

**Children**

Dosage of 50 mg/kg/day divided into four doses at six-hour intervals yields blood levels in the range effective against most susceptible organisms. Severe infections (eg, bacteremia or meningitis), especially when adequate cerebrospinal fluid concentrations are desired, may require dosage up to 100 mg/kg/day; however, it is recommended that dosage be reduced to 50 mg/kg/day as soon as possible. Children with impaired liver or kidney function may retain excessive amounts of the drug.

**Newborn Infants**
***(See section titled Gray Syndrome under Adverse Reactions.)***

A total of 25 mg/kg/day in four equal doses at six-hour intervals usually produces and maintains concentrations in blood and tissues adequate to control most infections for which the drug is indicated. Increased dosage in these individuals, demanded by severe infections, should be given only to maintain the blood concentration within a therapeutically effective range. After the first two weeks of life, full-term infants ordinarily may receive up to a total of 50 mg/kg/day equally divided into four doses at six-hour intervals. *These dosage recommendations are extremely important because blood concentration in all premature infants and full-term infants under two weeks of age differs from that of other infants.* This difference is due to variations in the maturity of the metabolic functions of the liver and the kidneys.

When these functions are immature (or seriously impaired in adults), high concentrations of the drug are found which tend to increase with succeeding doses.

**Infants and Children with Immature Metabolic Processes**

In young infants and other children in whom immature metabolic functions are suspected, a dose of 25 mg/kg/day will usually produce therapeutic concentrations of the drug in the blood. In this group particularly, the concentration of the drug in the blood should be carefully followed by microtechniques. (Information available on request.)

## HOW SUPPLIED

N 0071-4057-3 (Steri-Vial® No. 57)
Chloromycetin Sodium Succinate (chloramphenicol sodium succinate for injection, USP) is supplied as a dried powder in Steri-Vials (rubber-diaphragm-capped vials). When reconstituted as directed, each vial contains a sterile solution equivalent to 100 mg of chloramphenicol per milliliter (1 g/10 ml). Available in packages of 10 vials.

CHLOROMYCETIN, brand of chloramphenicol. Reg US Pat Off RJ

PD-JA-1281-2-P(12-77)

*PARKE-DAVIS, Division of Warner-Lambert Company, Morris Plains, NJ 07950*

# PREPARATION OF MANUSCRIPTS

A CURRENT issue of PEDIATRICS should be consulted for general style. Three complete copies of the manuscript (including tables and illustrations) must be supplied. ALL material (including tables and references) should be double-spaced and typed on white 8½ × 11-inch bond paper with margins at least 1½ inches wide. Single-spaced material will be returned for retyping. Number pages consecutively.

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

**In view of the Copyright Revision Act of 1976, effective January 1, 1978, transmittal letters to the editor should contain the following language: "In consideration of the American Academy of Pediatrics taking action in reviewing and editing my submission entitled _____, also known as _____, the author(s) undersigned hereby transfers, assigns, or otherwise conveys all copyright ownership to the AAP in the event that such work is published by the AAP." We regret that transmittal letters not containing the foregoing language signed by all authors of the submission will delay review of the manuscripts.**

**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.

**The author's style** will be respected; however, writing should conform to acceptable English usage and syntax. 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.

References must be numbered consecutively according to order of appearance in the text. They must conform to the style employed in PEDIATRICS and be keyed in the text. Abbreviations for journals should be those listed in *Index Medicus*. References to books should contain the authors' names, title of book, volume, edition, city and state, name of publisher, year of publication, and page numbers.

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**Illustrations**—Photographs of line drawings and any other figure which is not composed simply of letters, numerals, and routine symbols must be furnished. Do not send original artwork or printed forms. A reasonable number of black-and-white illustrations will be printed from black-and-white glossies or film without cost, but the cost of color illustrations and other special processing is usually borne by the author. Manuscripts containing such materials will not be processed until arrangements for payment, on the basis of estimated prices, are made. Color work requires one month longer for production and authors will be expected to pay for the extra expenses involved.

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**Tables** must be comprehensible to the reader without reference to the text, typed (double-spaced) rather than photographed, and accompanied by headings. Care should be taken to make tables as concise and brief as possible.

Revised, December 1974

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(polymyxin B—bacitracin—neomycin)

Each gram contains: Aerosporin® brand Polymyxin B Sulfate 5,000 units; zinc bacitracin 400 units; neomycin sulfate 5 mg (equivalent to 3.5 mg neomycin base); special white petrolatum qs. In tubes of 1 oz and 1/2 oz and 1/32 oz (approx.) foil packets.

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

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

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

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

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

Wellcome

**Burroughs Wellcome Co.**
Research Triangle Park
North Carolina 27709

JULY 1979 VOL. 64 NO. 1

# Pediatrics

OFFICIAL PUBLICATION OF THE AMERICAN ACADEMY OF PEDIATRICS



PUBLISHER
American Academy of Pediatrics
Lucy Ranes Maloney, Publication Manager
Hugh Morgan, Advertising Manager
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PEDIATRICS (ISSN 0031 4005) is owned and controlled by the American Academy of Pediatrics. It is published monthly by the American Academy of Pediatrics, P.O. Box 1034, Evanston, IL 60204.

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- Pleasant tasting to encourage patient acceptance and compliance in the young asthmatic.
- Controlled theophylline content for effective round-the-clock therapy.
- Contains glyceryl guaiacolate, a beneficial ingredient lacking in many other theophylline bronchodilators.

**Indications:** For the symptomatic relief of bronchospastic conditions such as bronchial asthma, chronic bronchitis, and pulmonary emphysema.
**Dosage:** Treatment should be initiated at 150 mg theophylline every 6 hours for adults and 4 mg/kg every 6 hours for children. The usual recommended dosages are *Adults:* 1-2 capsules or 1-2 tablespoons (15 ml) liquid every 6-8 hours. *Children 9 to 12:* 4-5 mg theophylline/kg bodyweight every 6-8 hours. *Children under 9:* 4-6 mg theophylline/kg bodyweight every 6-8 hours. When necessary, to achieve greater efficacy theophylline dosage may be cautiously adjusted upward. Serum theophylline determinations are helpful in monitoring therapeutic progress. When dosages exceed the usual recommended ranges serum determinations are essential. In the absence of side effects, the dosage may be titrated upward cautiously by increments of no more than 25% of previous dose, increasing the dose no more than every third day until the desired clinical response is obtained. If nausea, vomiting or other evidence of toxicity occurs, omit one dose and resume treatment at a lower dose.
**Warnings:** Do not administer more frequently than every 6 hours, or within 12 hours after rectal dose of any preparation containing theophylline or aminophylline. Do not give other compounds containing xanthine derivatives concurrently.

**Precautions:** Use with caution in patients with cardiac disease, hepatic or renal impairment. Concurrent administration with certain antibiotics, i.e., clindamycin, erythromycin, troleandomycin, may result in higher serum levels of theophylline. Plasma prothrombin and factor V may increase, but any clinical effect is likely to be small. Metabolites of guaifenesin may contribute to increased urinary 5-hydroxyindoleacetic acid readings, when determined with nitrosonaphthol reagent. Safe use in pregnancy has not been established. Use in case of pregnancy only when clearly needed.
**Adverse Reactions:** Theophylline may exert some stimulating effect on the central nervous system. Its administration may cause local irritation of the gastric mucosa, with possible gastric discomfort, nausea, and vomiting. The frequency of adverse reactions is related to the serum theophylline level and is not usually a problem at serum theophylline levels below 20 mcg/ml.
**How Supplied:** Capsules in bottles of 100 and 1000 and unit-dose packs of 100; Liquid in bottles of 1 pint and 1 gallon.
*See package insert for complete prescribing information.*

**Mead Johnson** PHARMACEUTICAL DIVISION

**AMERICAN ACADEMY OF PEDIATRICS**

1801 Hinman Avenue
Evanston, IL 60204

# SCHEDULE OF MEETINGS

## ANNUAL MEETINGS

**1979**
San Francisco Hilton
St. Francis Hotel
San Francisco
October 13 to 18

**1980**
Detroit Plaza Hotel
Detroit
October 25 to 30

**1981**
New Orleans
Oct 31 to Nov 5

**1982**
New York Hilton
Americana Hotel
New York City
October 23 to 28

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October 22 to 27

**Note:** All Annual Meetings start on Saturday

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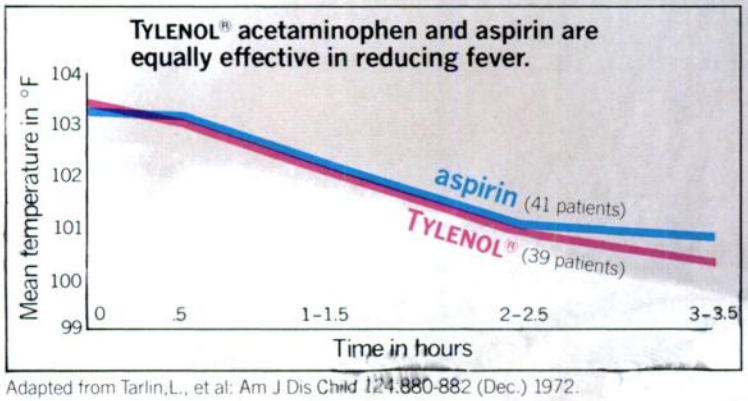
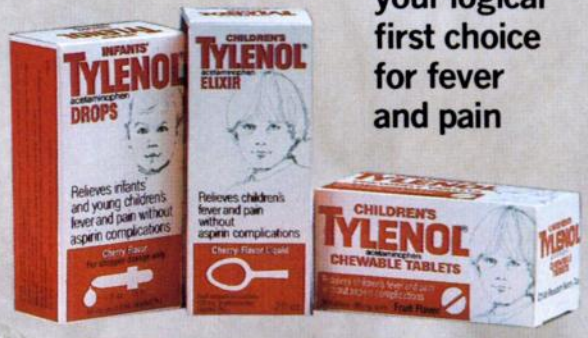
## Clinical evidence:




Adapted from Tarlin,L., et al: Am J Dis Child 124:880-882 (Dec.) 1972.




**your logical first choice for fever and pain**

McNEIL

McNeil Consumer Products Company
Fort Washington, Pa. 19034

# PEDICULOSIS.

## THE ONLY DISEASE YOU CAN CURE IN FOUR MINUTES.

A single, four-minute lathering with Kwell Shampoo is generally all it takes to eliminate head and pubic lice fast–and completely![1] Just about 100% effective,[2] nonsensitizing and nonirritating to the skin, it's as easy to use as any ordinary shampoo.[1,2] For lice on less hirsute areas of the body, and for scabies, Kwell is also available in lotion form.

Available on prescription as Kwell Shampoo and Lotion in 2 and 16 fl. oz. bottles, and as Kwell Cream in 2 oz. and 1 lb. jars. Patient instruction pads in English and Spanish are available on request. See package insert for complete prescribing information.

REFERENCES: 1. Wexler, L.: Am. J. Nurs. 69:3, March, 1969. 2. Patient Care 7:94, Nov. 1, 1973.

WARNING: KWELL SHOULD BE USED WITH CAUTION ESPECIALLY IN INFANTS, CHILDREN AND IN PREGNANCY. GAMMA BENZENE HEXACHLORIDE PENETRATES HUMAN SKIN AND HAS THE POTENTIAL FOR CNS TOXICITY. STUDIES INDICATE THAT POTENTIAL TOXIC EFFECTS OF TOPICALLY APPLIED LINDANE ARE GREATER IN THE YOUNG. Seizures have been reported after the use of gamma benzene hexachloride but a cause and effect relationship has not been established. Simultaneous application of creams, ointments or oils may enhance the percutaneous absorption of gamma benzene hexachloride.

PRECAUTIONS: If accidental ingestion occurs, prompt institution of gastric lavage will rid the body of large amounts of the toxicant. However, since oils favor absorption, saline cathartics for intestinal evacuation should be given rather than oil laxatives. If central nervous system manifestations occur, they can be antagonized by the administration of pentobarbital, or phenobarbital.

If accidental contact with the eyes occurs flush with water. If irritation or sensitization occurs discontinue this product and consult a physician.

ADVERSE REACTIONS: Eczematous eruptions due to irritation from this product have been reported.

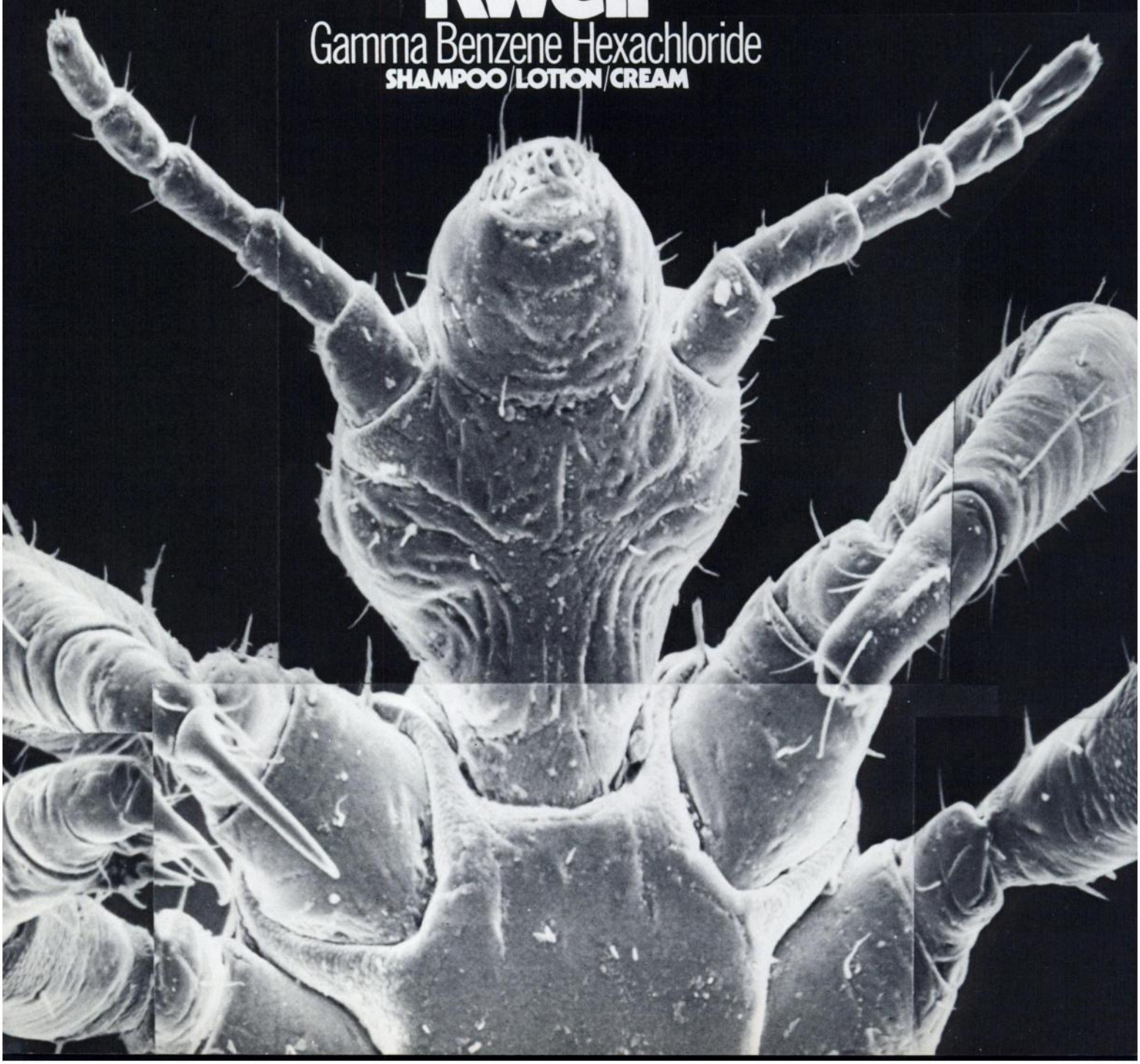
**The unsurpassed standard for the treatment of pediculosis and scabies.**

# Kwell®

## Gamma Benzene Hexachloride

**SHAMPOO/LOTION/CREAM**

Reed & Carnrick/Kenilworth, New Jersey 07033



## AMERICAN ACADEMY OF PEDIATRICS

1801 Hinman Avenue
Evanston, Illinois 60204

# SCHEDULE OF MEETINGS

### SPRING SESSIONS

**1980**
Las Vegas Hilton
Las Vegas
April 19 to 24

**1981**
Washington, DC
April 4 to 9

**1982**
Honolulu
March 20 to 25

**Note:** All Spring Sessions start on Saturday

In pediatric infections

# Septra®

Each teaspoonful (5 ml) contains:
40 mg trimethoprim and 200 mg sulfamethoxazole

# Suspension B.I.D.®

Acute
Otitis
Media

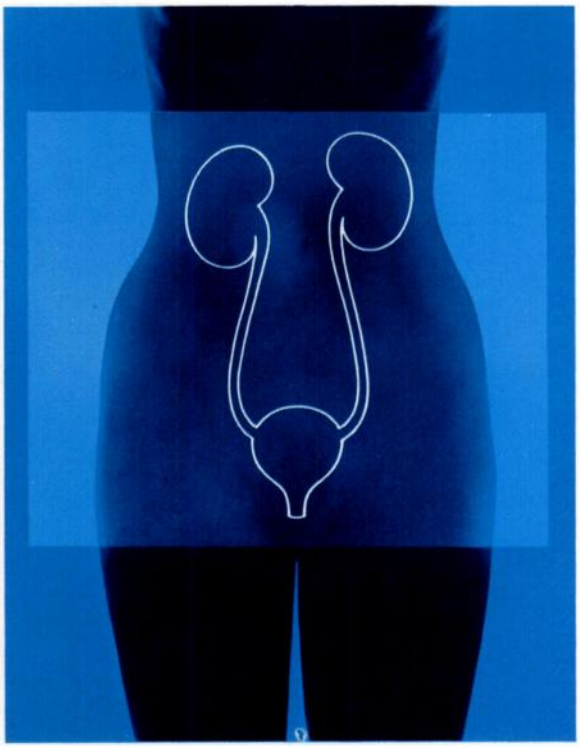
# where the action is.

# In acute otitis media

Septra Suspension provides effective antibacterial action against susceptible strains of H influenzae and S pneumoniae (D pneumoniae), the pathogens most likely to cause acute otitis media in children.

Septra Suspension is useful in many patients, but especially in those with penicillin allergy or with infections caused by ampicillin-resistant H influenzae. Limited clinical data are presently available on the effectiveness of treatment of acute otitis media with Septra when the infection is due to H influenzae resistant to ampicillin. However, in vitro data is highly favorable; when over 200 strains of ampicillin-resistant H influenzae were tested, all proved susceptible to TMP/SMX.*

And unlike most other antibacterials for the treatment of acute otitis media, Septra Suspension is administered on a convenient b.i.d. dosage schedule. The cherry-flavored suspension is well accepted by children.



# In recurrent urinary tract infections

Septra Suspension provides effective antibacterial action in urine and blood against susceptible strains of E coli, Klebsiella-Enterobacter and Proteus. Whether the infection centers in the kidneys or bladder, Septra Suspension maintains effective levels at the site of the infection with just two doses a day.

Adequate fluid intake should be maintained and frequent urinalyses with careful microscopic examination performed during Septra therapy. Septra is contraindicated in infants under two months of age.

*In vitro data do not necessarily correlate with clinical results. Data on file, Burroughs Wellcome Co.
NOTE: Septra should not be used in the treatment of streptococcal pharyngitis.

*Please see prescribing information on next page.*

Wellcome | **Burroughs Wellcome Co.**
Research Triangle Park
North Carolina 27709

# Septra® Suspension B.I.D.

Each teaspoonful (5 ml) contains: 40 mg trimethoprim and 200 mg sulfamethoxazole

# Septra® DS B.I.D.

Each tablet contains: 160 mg trimethoprim and 800 mg sulfamethoxazole

**Septra® DS Tablets Double Strength**
**Septra® Tablets**
**Septra® Suspension**

**INDICATIONS AND USAGE:**
*URINARY TRACT INFECTIONS:* **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: Currently, the increasing frequency of resistant organisms is a limitation of the usefulness of all antibacterial agents, especially in the treatment of these urinary tract infections.

*ACUTE OTITIS MEDIA:* **For the treatment of acute otitis media in children due to susceptible strains of** *Haemophilus influenzae* **or** *Streptococcus pneumoniae* **when in the judgment of the physician Septra offers some advantage over the use of other antimicrobial agents. Limited clinical information is presently available on the effectiveness of treatment of otitis media with Septra when the infection is due to** *Haemophilus influenzae* **resistant to ampicillin. 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.**

*SHIGELLOSIS:* **For the treatment of enteritis caused by susceptible strains of** *Shigella flexneri* **and** *Shigella sonnei* **when antibacterial therapy is indicated.**

*PNEUMOCYSTIS CARINII* **PNEUMONITIS: For the treatment of documented** *Pneumocystis carinii* **pneumonitis. To date, this drug has been tested only in patients 9 months to 16 years of age who were immunosuppressed by cancer therapy.**

**CONTRAINDICATIONS:** Hypersensitivity to trimethoprim or sulfonamides. Pregnancy and during the nursing period. Infants less than two months of age.

**WARNINGS: SEPTRA SHOULD NOT BE USED IN THE TREATMENT OF STREPTOCOCCAL PHARYNGITIS.**

Clinical studies have documented that patients with Group A $\beta$-hemolytic streptococcal tonsillopharyngitis have a greater incidence of bacteriologic failure when treated with Septra than do those patients treated with penicillin as evidenced by failure to eradicate this organism from the tonsillopharyngeal area.

Deaths associated with administration of sulfonamides have been reported from hypersensitivity reactions, agranulocytosis, aplastic anemia and other blood dyscrasias. Experience with trimethoprim alone 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 CBCs are recommended; therapy should be discontinued if a significant reduction in the count of any formed blood element is noted.

**PRECAUTIONS:** Use with caution in patients with impaired renal or hepatic function, possible folate deficiency, severe allergy or bronchial asthma. In glucose-6-phosphate dehydrogenase-deficient individuals, hemolysis may occur (frequently dose-related). 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.

Since Septra may prolong prothrombin time in patients on warfarin, coagulation time should be reassessed when Septra is given.

**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 and pancreatitis. *C.N.S. Reactions:* Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo, insomnia, apathy, fatigue, muscle weakness and nervousness. *Miscellaneous Reactions:* Drug fever, chills, and toxic nephrosis with oliguria and anuria. Periarteritis nodosa and L. E. phenomenon have occurred.

Due to certain chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents, sulfonamides have caused rare instances of goiter production, diuresis and hypoglycemia; cross-sensitivity may exist with these agents. In rats, long-term administration of sulfonamides has produced thyroid malignancies.

**DOSAGE AND ADMINISTRATION: Not recommended for use in infants less than two months of age.**

*URINARY TRACT INFECTIONS AND SHIGELLOSIS IN ADULTS AND CHILDREN AND ACUTE OTITIS MEDIA IN CHILDREN:*

*Adults:* The usual adult dosage for the treatment of urinary tract infections is two tablets or four teaspoonfuls (20 ml) every 12 hours for 10 to 14 days. An identical daily dosage is used for 5 days in the treatment of shigellosis.

*Children:* The recommended dose for children with urinary tract infections or acute otitis media is 8 mg/kg trimethoprim and 40 mg/kg sulfamethoxazole per 24 hours, given in two divided doses every 12 hours for 10 days. An identical daily dosage is used for 5 days in the treatment of shigellosis. The following table is a guideline for the attainment of this dosage using Septra Tablets or Suspension.

Children: Two months of age or older:

| Weight | | Dose —every 12 hours | |
|---|---|---|---|
| lb | kg | Teaspoonfuls | Tablets |
| 22 | 10 | 1 ( 5 ml) | ½ |
| 44 | 20 | 2 (10 ml) | 1 |
| 66 | 30 | 3 (15 ml) | 1½ |
| 88 | 40 | 4 (20 ml) | 2 (or 1 DS tablet) |

For patients with renal impairment:

| Creatinine Clearance (ml/min) | Recommended Dosage Regimen |
|---|---|
| Above 30 | Usual Standard Regimen |
| 15-30 | Half of the usual dosage regimen |
| Below 15 | Use Not Recommended |

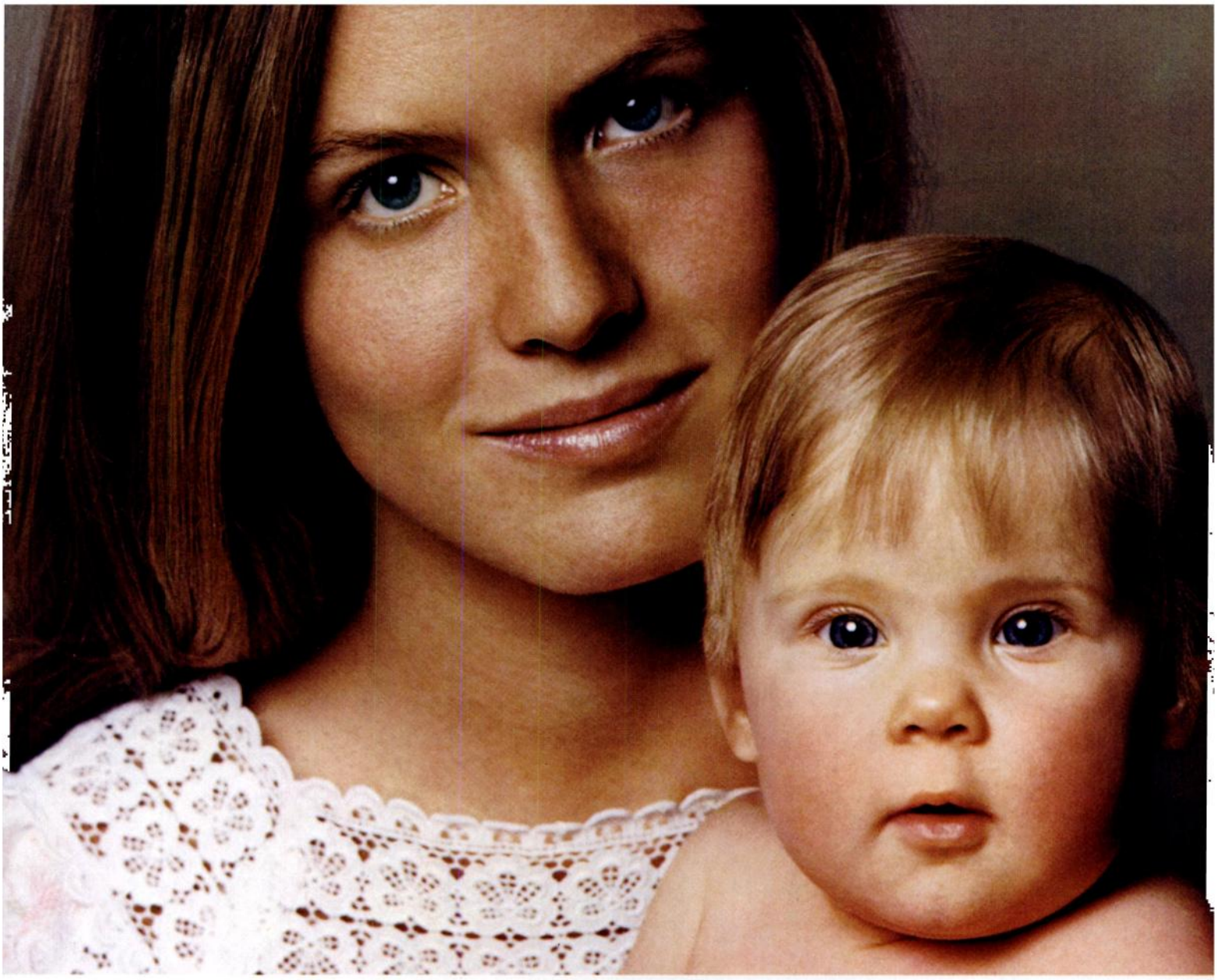
*PNEUMOCYSTIS CARINII* **PNEUMONITIS:**
The recommended dosage for patients with documented *Pneumocystis carinii* pneumonitis is 20 mg/kg trimethoprim and 100 mg/kg sulfamethoxazole per 24 hours given in equally divided doses every 6 hours for 14 days. The following table is a guideline for the attainment of this dosage in children.

| Weight | | Dose —every 6 hours | |
|---|---|---|---|
| lb | kg | Teaspoonfuls | Tablets |
| 18 | 8 | 1 ( 5 ml) | ½ |
| 35 | 16 | 2 (10 ml) | 1 |
| 53 | 24 | 3 (15 ml) | 1½ |
| 70 | 32 | 4 (20 ml) | 2 (or 1 DS tablet) |

**HOW SUPPLIED:** TABLETS, containing 80 mg trimethoprim and 400 mg sulfamethoxazole—bottles of 40, 100, 500 and 1000 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 450 ml. Also available in double strength, oval-shaped, pink, scored tablets containing 160 mg trimethoprim and 800 mg sulfamethoxazole—Compliance™ Pak of 20, bottle of 60 and unit dose pack of 100.

Wellcome | **Burroughs Wellcome Co.**
Research Triangle Park
North Carolina 27709



# Infant Formula for 12 Months? Think of it as Nutritional Insurance

That's why you should specify that new mothers keep their babies on breast milk or infant formula for a full 12 months.

Switching to cow's milk in the first year is not advisable. The high sodium content and the high protein content of cow's milk may increase the risk of dehydration and hypernatremia when diarrhea or other conditions increase the demand for water. Cow's milk feedings may place infants at risk for developing iron deficiency. And cow's milk is a poor source of copper and Vitamin C.[1]

**Enfamil Provides Balanced Nutrition**
ENFAMIL infant formula is patterned after breast milk and is a good source of digestible heat-treated protein, polyunsaturated fat, vitamins and minerals.

Recommend ENFAMIL until the end of the first year for infants who aren't breast feeding or who stop breast feeding.

For a more in-depth discussion of this subject, as well as other aspects of infant nutrition, an educational newsletter series entitled "Dialogues in Infant Nutrition" is available. This is part of a continuing education program on infant nutrition. For copies of the newsletter, contact your Mead Johnson Representative or Health Learning Systems, 1455 Broad Street, Bloomfield, New Jersey 07003.

[1] Material presented at March 23, 1977, symposium, Infant Nutrition: A Foundation for Lasting Health?


**ENFAMIL®**
**ENFAMIL® WITH IRON**
INFANT FORMULA

Mead Johnson NUTRITIONAL DIVISION

L-K6

# Itching* a problem? Rest easy.

**Before prescribing, see complete prescribing information in SK&F literature or *PDR*. The following is a brief summary.**

* **Indications**

Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications as follows:

Effective: For symptomatic relief of pruritic symptoms in urticaria.

Possibly effective: For relief of pruritic symptoms in neurodermatitis, allergic dermatitis, contact dermatitis, atopic dermatitis, chickenpox, pruritus ani and vulvae.

Final classification of the less-than-effective indications requires further investigation.

**Contraindications:** Comatose patients; presence of large amounts of C.N.S. depressants; bone marrow depression; idiosyncrasy or hypersensitivity to this drug or other phenothiazines; in newborn or premature children; in nursing mothers; in acutely ill and/or dehydrated children.

**Warnings:** May impair mental and/or physical ability required for potentially hazardous tasks (driving vehicles, operating machinery); may impair mental alertness in children. Concomitant use with alcohol or other C.N.S. depressants may have additive effect. Warn patients accordingly

Use with extreme caution in patients with asthmatic attack, narrow-angle glaucoma, prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstruction, bladder neck obstruction, patients receiving MAO inhibitors.

Do not use in women of childbearing potential. There are reported instances of jaundice and prolonged extrapyramidal symptoms in infants whose mothers received phenothiazines during pregnancy.

Use with caution in children, as administration may result in excitation; overdosage may produce hallucinations, convulsions, sudden death.

Elderly patients (60 or older) are more prone to develop the following phenothiazine side effects: hypotension, syncope, toxic confusional states, extrapyramidal symptoms (especially parkinsonism), excessive sedation.

**Precautions:** May increase, prolong or intensify sedative action of C.N.S. depressants (when administered concomitantly, narcotic or barbiturate dosage should be reduced to ¼ or ½); lead to restlessness and motor hyperactivity in patients with pain being treated with narcotics; block or reverse the pressor effect of epinephrine. Use cautiously in persons (particularly children) with acute or chronic respiratory impairment, as it may suppress cough reflex; in persons with cardiovascular disease, liver function impairment, or history of ulcer disease. The drug's slight antiemetic action may obscure signs of intestinal obstruction, brain tumor, toxic drug overdose.

**Adverse Reactions:** (Note: May produce adverse reactions attributable

# The oral antipruritic that controls itching*... while you treat the cause.


Each 5 ml. teaspoonful contains trimeprazine tartrate equivalent to 2.5 mg. of trimeprazine, and alcohol, 5.7%.

# TEMARIL®

brand of

## trimeprazine tartrate syrup

**Use lowest effective dose. Do not use in children acutely ill and/or dehydrated.**

to both phenothiazines and antihistamines, although not all the following have been reported with 'Temaril'. There have been occasional reports of sudden death in patients receiving phenothiazine derivatives chronically.) Drowsiness, extrapyramidal reactions (opisthotonos, dystonia, akathisia, dyskinesia, parkinsonism), particularly with high doses, hyperreflexia in newborn (when used during pregnancy), dizziness, headache, lassitude, tinnitus, incoordination, fatigue, blurred vision, euphoria, diplopia, nervousness, insomnia, tremors and grand mal seizures, excitation, catatonic-like states, neuritis and hysteria, oculogyric crises, disturbing dreams/nightmares, pseudoschizophrenia, intensification and prolongation of action of C.N.S. depressants, atropine, heat, organophosphorus insecticides.

Also postural hypotension, reflex tachycardia, bradycardia, faintness, cardiac arrest, ECG changes, anorexia, nausea, vomiting, epigastric distress, diarrhea, constipation, dry mouth, increased appetite and weight gain, urinary frequency and dysuria, urinary retention, early menses, induced lactation, gynecomastia, decreased libido, inhibition of ejaculation, false positive pregnancy tests, thickening of bronchial secretions, tightness of chest, wheezing, nasal stuffiness, urticaria, dermatitis, asthma, laryngeal edema, angioneurotic edema, photosensitivity, lupus erythematosus-like syndrome, anaphylactoid reactions, leukopenia, agranulocytosis, pancytopenia, hemolytic anemia, elevation of plasma cholesterol levels, thrombocytopenic purpura, jaundice, erythema, peripheral edema, stomatitis, high or prolonged glucose tolerance curves, glycosuria, elevated spinal fluid proteins, reversed epinephrine effects.

After prolonged phenothiazine administration at high dosage, the following have occurred: skin pigmentation, ocular changes (the appearance of lenticular and corneal opacities, epithelial keratopathies, pigmentary retinopathy). Vision may be impaired.

**Drug Interactions:** MAO inhibitors and thiazide diuretics prolong and intensify anticholinergic effects. Combined use of MAO inhibitors and phenothiazines may result in hypertension and extrapyramidal reactions. Phenothiazines potentiate C.N.S. depressant and analgesic effects of narcotics. Phenothiazine effects may be potentiated by oral contraceptives, progesterone, reserpine, nylidrin HCl.

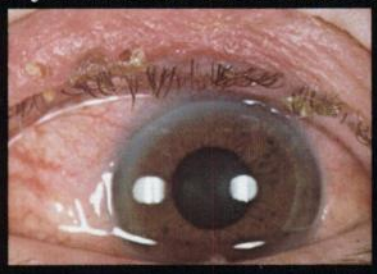
**Supplied:** Syrup—in 4 fl. oz. bottles. Spansule® capsules (not for use in children 6 and under)—Each capsule contains trimeprazine tartrate equivalent to 5 mg. of trimeprazine, in bottles of 50. Tablets—Each tablet contains trimeprazine tartrate equivalent to 2.5 mg. of trimeprazine, in bottles of 100 and 1000. Tablets and 'Spansule' capsules also available in Single Unit Packages (SUP) of 100, intended for institutional use only.

**Smith Kline & French Laboratories**
Division of SmithKline Corp., Phila., Pa.

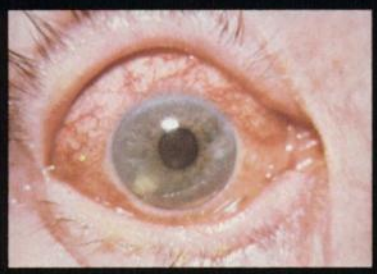
SK&F
a SmithKline company

# The infected eye–

**If you trace it to one of these common problems...**



*Acute bacterial conjunctivitis**
Marked by itching or burning, hyperemia, lid edema and lacrimation or purulent discharge. Second only to refractive errors in frequency among ocular complaints.



*Bacterial corneal ulcer**
Pain, photophobia, lacrimation and blepharospasm are usual presenting symptoms. Prompt institution of therapy is vital to avoid possible visual difficulty.

*When due to susceptible microorganisms.

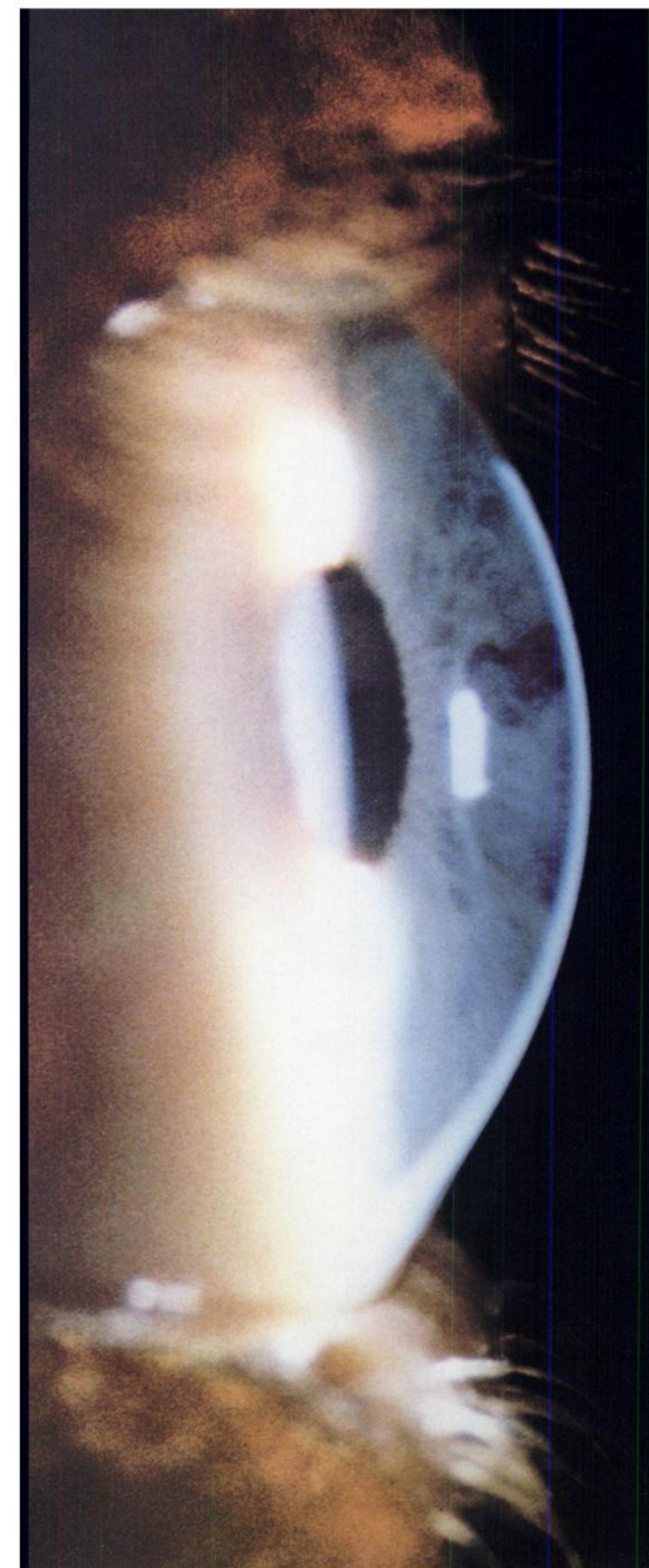
**Gantrisin®** **sulfisoxazole diolamine/Roche**
**Ophthalmic Solution, Ophthalmic Ointment**

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

**Indications:** Conjunctivitis, corneal ulcer, other superficial ocular infections due to susceptible microorganisms; as adjunct in systemic sulfonamide therapy of trachoma.

**Contraindications:** Hypersensitivity.

**Precautions:** Incompatible with silver preparations; inactivated by para-aminobenzoic acid in purulent exudates; may increase growth of nonsusceptible organisms, including fungi. Ointment may retard corneal healing. Discontinue use if undesirable reactions occur.



watch it respond to

# Gantrisin®

## sulfisoxazole diolamine

### Ophthalmic Solution and Ophthalmic Ointment

**Effective treatment** for conjunctivitis, corneal ulcer and other infections due to susceptible microorganisms, such as *Staphylococcus aureus*

**Ophthalmic Solution**—a sterile, isotonic preparation containing 4% (40 mg/ml) sulfisoxazole diolamine—generally avoids significant stinging or burning

**Ophthalmic Ointment**—also containing 4% sulfisoxazole diolamine—provides more sustained contact with the ocular infection and is particularly appropriate for nighttime therapy

**A Brief Summary** of the product information, below, provides precautions and contraindications

Main photo taken with the Carl Zeiss photo slit lamp.

**Dosage and Administration:** Solution: 2-3 drops in eye 3 or more times daily. Take care not to contaminate dropper. Ointment: small amount in lower conjunctival sac 1-3 times daily and at bedtime.

**How Supplied:**
Solution, ½-oz bottles with dropper. Ointment, ⅛-oz tubes.

ROCHE

Roche Laboratories
Division of Hoffmann-La Roche Inc.
Nutley, New Jersey 07110


Pinworm:
simply
awful
© Ortho Pharmaceutical Corporation 1979

# Vermox: awfully simple

## No dosage calculation

**one dose** single VERMOX 100 mg tablet is the treatment for pinworm in both adults and children* of all body weights; no dosage calculations or confusion

**one time** the VERMOX tablet may be taken any time that is convenient, so that normal routines won't be interrupted; convenient schedule encourages compliance

**one tablet** chewable, orange-flavored VERMOX tablet may also be crushed and mixed or simply swallowed; no messy liquid to spill and no dye to stain

**95% cure** mean cure rate in clinical studies was 95% (range: 90%-100%) after treatment with one VERMOX tablet; in cases of reinfection, a second tablet is advised

* Because Vermox has not been extensively studied in children under two years of age, the relative benefit/risk should be considered before treating these children. Vermox is contraindicated in pregnancy (see: Pregnancy Precautions) and in persons who have shown hypersensitivity to the drug.

# Vermox TRADEMARK chewable tablets (mebendazole)

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

**Actions** VERMOX exerts its anthelmintic effect by blocking glucose uptake by the susceptible helminths, thereby depleting the energy level until it becomes inadequate for survival.

In man, approximately 2% of administered mebendazole is excreted in urine as unchanged drug or a primary metabolite. Following administration of 100 mg of mebendazole twice daily for three consecutive days, plasma levels of mebendazole and its primary metabolite, the 2-amine, never exceeded 0.03 μg/ml and 0.09 μg/ml, respectively.

**Indications** VERMOX is indicated for the treatment of *Trichuris trichiura* (whipworm), *Enterobius vermicularis* (pinworm), *Ascaris lumbricoides* (roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm) in single or mixed infections. Efficacy varies in function of such factors as pre-existing diarrhea and gastrointestinal transit time, degree of infection and helminth strains.

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

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

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

**Adverse reactions** Transient symptoms of abdominal pain and diarrhea have occurred in cases of massive infection and expulsion of worms.

**Dosage and administration** The same dosage schedule applies to children and adults. The tablet may be chewed, swallowed or crushed and mixed with food.

For the control of pinworm (enterobiasis), a single tablet is administered orally, one time.

For the control of roundworm (ascariasis), whipworm (trichuriasis), and hookworm infection, one tablet of VERMOX is administered, orally, morning and evening, on three consecutive days.

If the patient is not cured three weeks after treatment, a second course of treatment is advised. No special procedures, such as fasting or purging, are required.

**How supplied** VERMOX is available as chewable tablets, each containing 100 mg of mebendazole, and is supplied in boxes of twelve tablets.

VERMOX (mebendazole) is an original product of Janssen Pharmaceutica, Belgium, and co-developed by Ortho Pharmaceutical Corporation.

ORTHO PHARMACEUTICAL CORPORATION
Raritan, New Jersey 08869

OJ-1511

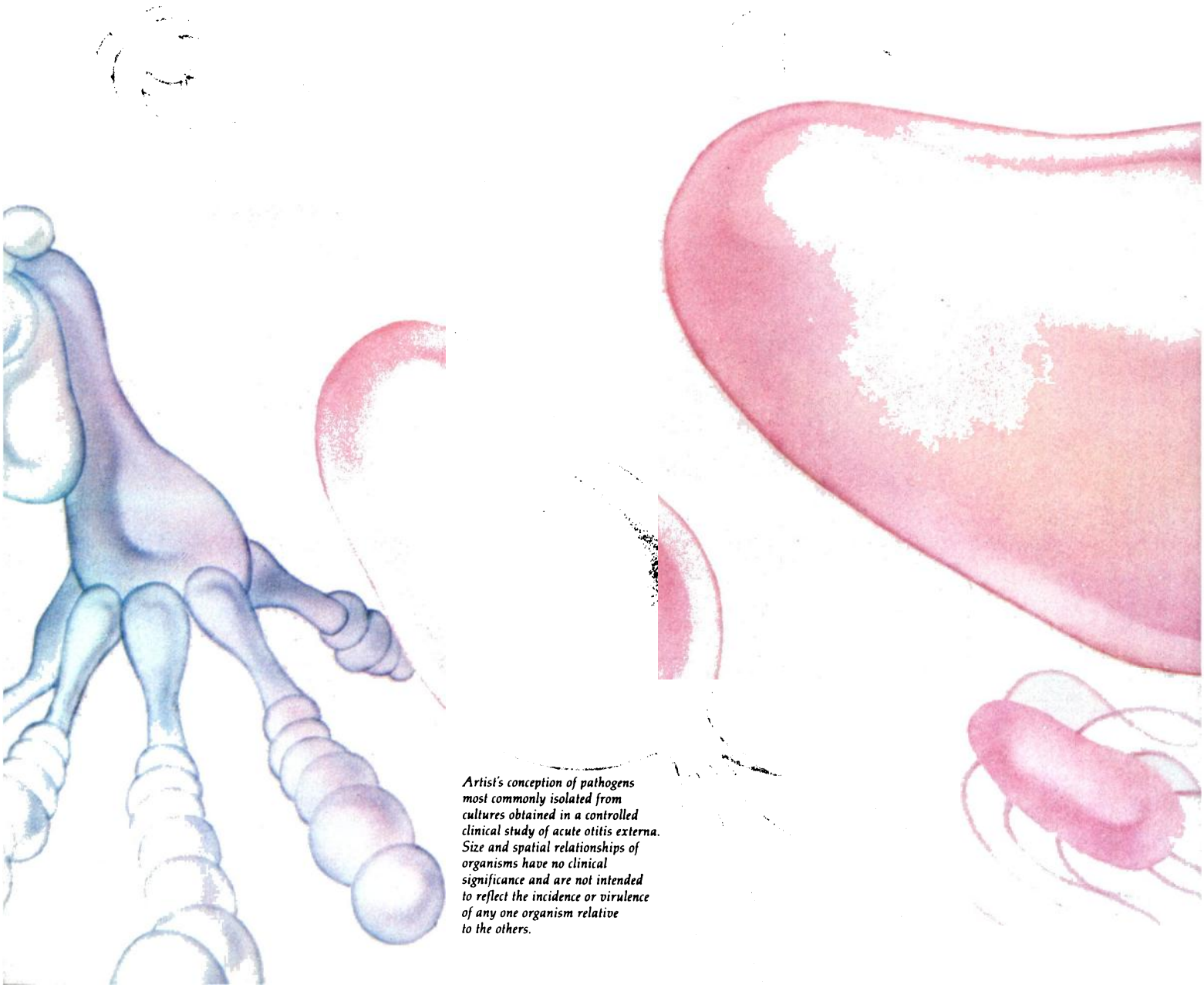
ORTHO

Examination of clinical specimens proves:

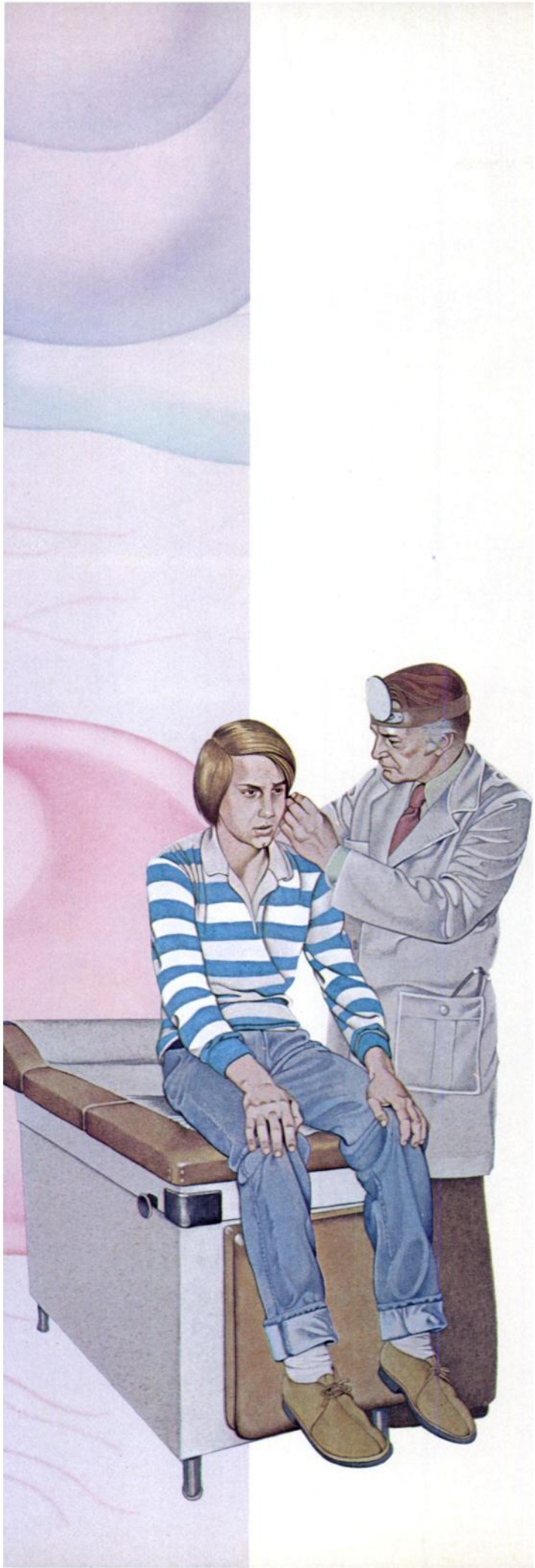
# Nonantibiotic VōSoL® HC Otic Solution

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

# eliminates Pseudomonas* in otitis externa**



*Artist's conception of pathogens most commonly isolated from cultures obtained in a controlled clinical study of acute otitis externa. Size and spatial relationships of organisms have no clinical significance and are not intended to reflect the incidence or virulence of any one organism relative to the others.*



# A frequent problem in children

"The warm, damp environment of this area (the child's external auditory canal) is conducive to the growth of *Pseudomonas aeruginosa* and other gram-negative bacteria."†

# VōSoL HC as effective as Cortisporin*‡ Otic Solution

In a multicenter double-blind randomized study, VōSoL HC and Cortisporin Otic Solution achieved equivalent overall microbial cure rates* and equivalent overall clinical cure rates when *Pseudomonas aeruginosa*, other susceptible bacterial pathogens, *Candida* or *Aspergillus* were initially present, alone or in combination.**

# VōSoL HC avoids the potential risks of neomycin and other antibiotics

There have been no reports of allergic cross-reactions with other anti-infective agents... no reports of overgrowth of nonsusceptible bacteria and fungi.

**antibacterial/antifungal/anti-inflammatory**

# VōSoL® HC

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

# Otic Solution

*Based on absence of pathogens on repeat cultures, the overall microbial cure rates were 78.9% with VōSoL HC and 81.4% with Cortisporin Otic Solution. Usual duration of treatment was 10 days, but varied from 8 to 14 days.

†Reichelderfer, T.E., and Ziai, M.: The ears, in *Pediatrics*, ed. 2. (Ziai, M., Janeway, C.A., and Cooke, R.E. eds.): Boston, Little, Brown and Company, 1975, pp. 254-259.

‡Registered trademark of Burroughs Wellcome Co.; a combination of polymyxin B, neomycin and hydrocortisone.

**Data on file, Medical Department, Wallace Laboratories, Cranbury, New Jersey 08512.

**VōSoL HC Otic Solution** is a nonaqueous solution containing hydrocortisone (1%) and acetic acid (2%), in a propylene glycol vehicle containing propylene glycol diacetate (3%), benzethonium chloride (0.02%), sodium acetate (0.015%) and citric acid (0.2%).

**Actions:** VōSoL HC is antibacterial, antifungal, hydrophilic, has an acid pH and a low surface tension. VōSoL HC is, in addition, anti-inflammatory and antipruritic.

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

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

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

**How Supplied:** VōSoL HC, in 10 ml measured-drop, safety-tip plastic bottle.

Issued 5/78

WALLACE LABORATORIES
Division of Carter-Wallace, Inc., Cranbury, New Jersey 08512 WJ 1679

# *Send pollen packing...*

# *with effective relief from the symptoms of allergic rhinitis.*

- tearing and weeping eyes
- uncomfortable itching around the eyes and nose
- uncontrolled sneezing and runny nose

There's hardly any symptom of allergic rhinitis that can't be helped significantly with Benadryl.

**BENADRYL®**
(diphenhydramine hydrochloride, USP)

**Brief Summary of Prescribing Information**

**BENADRYL® (diphenhydramine hydrochloride)**
**INDICATIONS.** Benadryl in the oral form is effective for the following indications

**Antihistaminic:** For perennial and seasonal (hay fever) allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, mild, uncomplicated allergic skin manifestations of urticaria and angioedema, amelioration of allergic reactions to blood or plasma, dermatographism, as therapy for anaphylactic reactions *adjunctive* to epinephrine and other standard measures after the acute manifestations have been controlled

**Motion sickness:** For active and prophylactic treatment of motion sickness

**Antiparkinsonism:** For parkinsonism (including drug-induced extrapyramidal reactions) in the elderly unable to tolerate more potent agents; mild cases of parkinsonism (including drug-induced) in other age groups; in other cases of parkinsonism (including drug-induced) in combination with centrally acting anticholinergic agents

**CONTRAINDICATIONS. Use in Newborn or Premature Infants:** This drug should *not* be used in newborn or premature infants.

**Use in Nursing Mothers:** Because of the higher risk of antihistamines for infants generally, and for newborns and prematures in particular, antihistamine therapy is contraindicated in nursing mothers.

**Use in Lower Respiratory Disease:** Antihistamines *should NOT* be used to treat lower respiratory tract symptoms, including asthma.

Antihistamines are also contraindicated in the following conditions:

Hypersensitivity to diphenhydramine hydrochloride and other antihistamines of similar chemical structure.

Monoamine oxidase inhibitor therapy (See Drug Interactions section)

**WARNINGS.** Antihistamines should be used with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, bladder-neck obstruction.

**Use in Children:** In infants and children, especially, antihistamines in *overdosage* may cause hallucinations, convulsions, or death.

As in adults, antihistamines may diminish mental alertness in children. In the young child, particularly, they may produce excitation.

**Use in Pregnancy:** Experience with this drug in pregnant women is inadequate to determine whether there exists a potential for harm to the developing fetus.

**Use with CNS Depressants:** Diphenhydramine hydrochloride has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.)

**Use in Activities Requiring Mental Alertness:** Patients should be warned about engaging in activities requiring mental alertness, such as driving a car or operating appliances, machinery, etc.

**Use in the Elderly (approximately 60 years or older):** Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients.

**PRECAUTIONS.** Diphenhydramine hydrochloride has an atropine-like action and, therefore, should be used with caution in patients with a history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease, or hypertension.

**DRUG INTERACTIONS.** MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

**ADVERSE REACTIONS.** The most frequent adverse reactions are underscored.

1. *General*: Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose, and throat.
2. *Cardiovascular System*: Hypotension, headache, palpitations, tachycardia, extrasystoles.
3. *Hematologic System*: Hemolytic anemia, thrombocytopenia, agranulocytosis.
4. *Nervous System*: Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions.
5. *GI System*: Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
6. *GU System*: Urinary frequency, difficult urination, urinary retention, early menses.
7. *Respiratory System*: Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

**OVERDOSAGE.** Antihistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Atropine-like signs and symptoms, dry mouth, fixed, dilated pupils, flushing, and gastrointestinal symptoms may also occur.

*If vomiting has not occurred spontaneously*, the patient should be induced to vomit. This is best done by having him drink a glass of water or milk after which he should be made to gag. Precautions against aspiration must be taken, especially in infants and children.

*If vomiting is unsuccessful*, gastric lavage is indicated within 3 hours after ingestion and even later if large amounts of milk or cream were given beforehand. Isotonic or 1/2 isotonic saline is the lavage solution of choice.

*Saline cathartics*, as milk of magnesia, by osmosis draw water into the bowel and, therefore, are valuable for their action in rapid dilution of bowel content.

*Stimulants* should *not* be used.

Vasopressors may be used to treat hypotension.

**HOW SUPPLIED.** Supplied in (as) 50 and 25 mg capsules and Elixir 12.5 mg/5 ml. **WF**

PD JA-2303 2 P(1 79)

**PARKE-DAVIS**

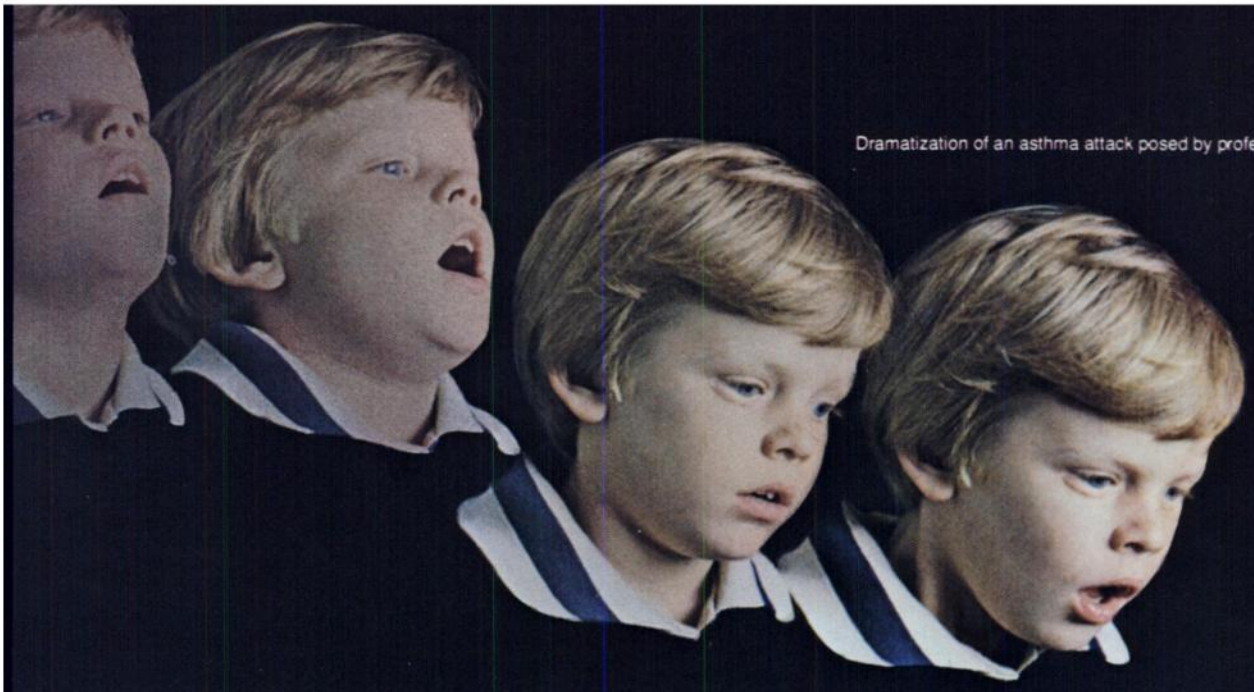
*PARKE-DAVIS*
*Division of Warner-Lambert Company,*
*Morris Plains, NJ 07950*

# THE ASTHMA ATTACK THAT NEVER HAPPENED

He is asthmatic. He was in contact with an allergen that has triggered his attacks in the past. But, this time—nothing. No wheeze. No cough. No mucus. Thanks to **INTAL**® (cromolyn sodium), he enjoyed a normal day of activity, attending school and playing with his friends afterwards.

**INTAL**® therapy stopped the attack before it happened. **INTAL**® suppresses release of pharmacologic mediators (such as histamine) from the mast cell and "short circuits" allergic response to trigger mechanisms. No other drug works quite like it. Result: no asthmatic attack.

The preventive action of **INTAL**® therapy works right at the site of the problem—the mast cell. Because of its unique preventive action, **INTAL**® is the logical first step in managing asthma patients who require daily symptomatic therapy. It's easier to prevent an attack than to treat it!



Dramatization of an asthma attack posed by professional model.

"Cromolyn sodium has proved most effective in preventing recurring attacks of bronchial asthma..."

Grollman AG: Status report no. 2. Drugs in bronchial asthma. *Consultant* 149-157 (July) 1977.

"In any discussion relative to the treatment of chronic bronchial asthma there can be no doubt that cromolyn sodium must be considered as an integral part of the comprehensive management program."

Feldman BR, Davis WJ: Treatment of asthma with cromolyn and corticosteroids. *Cutis* **17**:1103-1109 (June) 1976.

"Cromolyn sodium is dramatic, useful, and has a definite role in the treatment of asthma."

Kaiser HB, in: Asthma: Individualizing drug therapy, a roundtable. *Patient Care* 92-171 (Aug 15) 1977.

# INTAL® capsules 20 mg
# (cromolyn sodium)

## YOUR FIRST LINE OF DEFENSE IN TREATING THE ASTHMATIC PATIENT

INTAL® is indicated as an adjunct in the management of patients with severe bronchial asthma in whom the frequency, intensity and predictability of episodes indicate the use of a continuing program of symptomatic medication. Such patients must have a significant bronchodilator-reversible component to their airway obstruction as demonstrated by a generally accepted pulmonary function test of airway mechanics.

® FISONS

Fisons Corporation, Bedford, Massachusetts 01730



Please see following page for brief summary of prescribing information.

# INTAL® capsules 20 mg (cromolyn sodium)

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

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

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

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

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

permits a significant reduction in or elimination of steroids, or

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

**CONTRAINDICATIONS:** INTAL is contraindicated in those patients who have shown hypersensitivity to it.

**WARNINGS: INTAL® (cromolyn sodium) has no role in the treatment of an acute attack of asthma, especially status asthmaticus.**

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

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

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

**USE IN PREGNANCY:** Reproduction studies have been performed in rabbits, rats, and mice. Adverse fetal effects (increased resorptions, decreased fetal weight) were noticed only at very high parenteral doses that produced maternal toxicity. The relevance to the human is not known. Since there is no experience in pregnant women who have received this drug, safety in pregnancy has not been established and its use in pregnancy is not recommended.

**USE IN CHILDREN:** Clinical experience in children under 5 years of age is limited due to the necessity for administration by inhalation. Use of INTAL is not recommended for such children. Because of the possiblity that adverse effects of the drug could become apparent only after many years, a benefit-risk consideration of the long term use of INTAL is particularly important in pediatric patients.

**PRECAUTIONS:** Occasionally patients may experience cough and/or bronchospasm following INTAL inhalation. At times, patients with cromolyn sodium induced bronchospasm may not be able to continue its administration despite prior bronchodilator administration.

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

**ADVERSE REACTIONS:** The most frequently reported adverse reactions attributed to INTAL (on the basis of reoccurrence following readministration) involve the respiratory tract and include:

- Bronchospasm
- Cough
- Laryngeal Edema (rare)
- Nasal Congestion
- Pharyngeal Irritation
- Wheezing

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

- Angioedema
- Dizziness
- Dysuria and Urinary Frequency
- Joint Swelling and Pain
- Lacrimation
- Nausea and Headache
- Rash
- Swollen Parotid Gland
- Urticaria

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

- Anaphylaxis
- Anemia
- Exfoliative Dermatitis
- Hemoptysis
- Hoarseness
- Myalgia
- Nephrosis
- Periarteritic Vasculitis
- Pericarditis
- Peripheral Neuritis
- Photodermatitis
- Polymyositis
- Pulmonary Infiltrates with Eosinophilia
- Vertigo

The following adverse effects which have occurred are related to the cromolyn sodium delivery system:

- Inhalation of gelatin particles
- Inhalation of mouthpiece or propeller

**DOSAGE AND ADMINISTRATION:** The usual **Starting Dosage** for adults and children 5 years of age and over is the contents of one INTAL (cromolyn sodium) capsule inhaled four times daily at regular intervals using a SPINHALER turbo-inhaler. Because INTAL and the Spinhaler represent a different approach to the treatment of asthma, careful explanation and instruction in the use of the Spinhaler should be given to each patient. (Please see the instructions for the use of the Spinhaler included with the device.) **It should be emphasized to the patient that the drug is not absorbed when swallowed and is not effective by this route of administration.** Patients should be advised that the effect of INTAL therapy is dependent upon its administration at regular intervals, as directed. INTAL should be introduced into the patient's therapeutic regimen when the acute episode has been controlled, the airway cleared and the patient is able to inhale adequately. INTAL has no role in the treatment of an acute asthma attack especially status asthmaticus.

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

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

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

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

**HOW SUPPLIED:** INTAL capsules, each containing 20 mg. cromolyn sodium in strips of four capsules each, in trade packages of 60 and 120 capsules. SPINHALER® turbo-inhalers are supplied separately in individual containers.

**CAUTION:** Federal law prohibits dispensing without prescription.

October 1977

FISONS®

Fisons Corporation, Bedford, Massachusetts 01730

**COLY-MYCIN® S OTIC**
with Neomycin and Hydrocortisone
(colistin sulfate—neomycin sulfate—thonzonium bromide—hydrocortisone acetate otic suspension)

**Caution:** Federal law prohibits dispensing without prescription

**Description** Coly-Mycin S Otic with Neomycin and Hydrocortisone (colistin sulfate—neomycin sulfate—thonzonium bromide—hydrocortisone acetate otic suspension) is a sterile aqueous suspension containing in each ml: Colistin base activity, 3 mg (as the sulfate); Neomycin base activity, 3.3 mg (as the sulfate); Hydrocortisone acetate, 10 mg (1%); Thonzonium bromide, 0.5 mg (0.05%); Polysorbate 80, acetic acid, and sodium acetate in a buffered aqueous vehicle. Thimerosal, 0.002%, added as a preservative. It is a non-viscous liquid, buffered at pH 5, for instillation into the canal of the external ear or direct application to the affected aural skin.

**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.

**Contraindications** This product is contraindicated in those individuals who have shown hypersensitivity to any of its 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.

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.

**Precautions** If sensitization or irritation occurs, medication should be discontinued promptly.

This drug should be used with care in cases of perforated ear drum and in longstanding cases of chronic otitis media because of the possibility of ototoxicity caused by neomycin.

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.

**Dosage and Administration** The external auditory canal should be thoroughly cleansed and dried with a sterile cotton applicator.

For adults, 4 drops of the suspension should be instilled into the affected ear 3 or 4 times daily. For infants and children, 3 drops are suggested because of the smaller capacity of the ear canal.

The patient should lie with the affected ear upward and then the drops should be instilled. This position should be maintained for 5 minutes to facilitate penetration of the drops into the ear canal. Repeat, if necessary, for the opposite ear.

If preferred, a cotton wick may be inserted into the canal and then the cotton may be saturated with the solution. This wick should be kept moist by adding further solution every 4 hours. The wick should be replaced at least once every 24 hours.

**How Supplied** In bottles containing 5 ml (N 0047-0141-05) or 10 ml (N 0047-0141-10). Each package contains a sterile dropper calibrated at 4 drops.

Store at controlled room temperature (59°-86°F) (15°-30°C). Stable for 18 months at room temperature; prolonged exposure to higher temperatures should be avoided.

SHAKE WELL BEFORE USING

Full information is available on request.

**WARNER/CHILCOTT** CO-GP-81
Div. Warner-Lambert Company
Morris Plains, N.J. 07950

VOLUME 64 • JULY 1979 • NUMBER 1

Pediatrics

# Nonoperative Management of Distal Fingertip Amputations in Children

**Laurie J. Rosenthal, MD, Mark A. Reiner, MD, and Michael A. Bleicher, MD**

*From the Department of General Surgery, Division of Emergency Surgical Services and Division of Pediatric Surgery, The Mount Sinai Hospital and City Hospital Center at Elmhurst, New York*

Success with the uncommonly recognized technique of nonoperative management of fingertip amputations in children has prompted presentation of four cases so treated in our institution. Previously, fingertips amputated distal to the distal interphalangeal joint have been observed to regenerate in children under 12 years of age.[1,2]

## MATERIAL

Our patients were 1, 2, 4, and 9 years old. They had injured the thumb, middle, index, and small fingers, respectively. The levels of amputation are seen in Fig 1. Three injuries transsected the distal bone. All cases were evaluated for extent of injury and chosen for nonoperative therapy (Fig 2). The wounds were cleansed with antiseptic solution and dressed with fine mesh absorbent gauze impregnated with bismuth tribromophenate 3% in petrolatum blend (Xeroform) and sterile gauze bandage. To encourage mobility, no splints were used. Dressings were changed one week after injury and biweekly thereafter. All children were free of pain within 24 hours after treatment. Healing began at three weeks and was completed 12 weeks after injury. Good cosmetic and functional result with

Received for publication Oct 17, 1978; accepted Nov 10, 1978.
Reprint request to (M.A.B.) Chief, Division of Pediatric Surgery, Department of Surgery, The Mount Sinai Hospital, 100 St and Fifth Ave, New York, NY 10029.

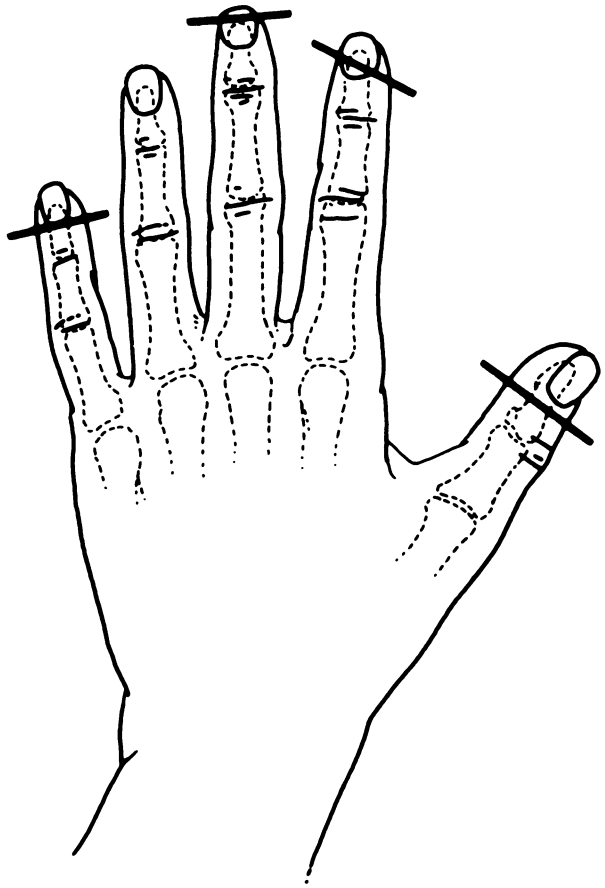


**Fig 1.** Composite of level of amputation in each case.

the morbidity attendant to this common childhood injury.

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## GUIDELINES FOR MEDICAL RESEARCH PAPERS

A. To improve the medical studies being done:
   1. Editors should give publication preference to well-documented reports of controlled clinical trials instead of reports of exciting data from poorly controlled studies.
   2. Statisticians should be involved at the very beginning of research projects.

B. To improve the documentation in medical research papers:
   1. Standards governing the content and format of statistical aspects should be developed to guide authors in the publication policy and should be enforced by reviewers and editorial boards.
   2. All raw data should be made available for examination by interested readers.
   3. In publishing reports of uncontrolled clinical observations, editorial boards should either print a warning section or insist that the author(s) explicitly spell out the limitations of the study.
   4. A system for classifying medical articles based on the quality of their scientific evidence should be developed. The classification criteria should be printed in the journals.
   5. Editors should refrain from cutting material which critical readers need to evaluate the paper, and editors should reproduce in great detail those papers which are concerned with areas of controversy or uncertainty.

C. To improve the editorial review process:
   1. Journals should recruit biometrically sophisticated people as manuscript reviewers and editorial board members. The Biometric Society should help identify such people.
   2. Authors should prepare a detailed exposition concerning methodology, which would not appear in print but would be available to the editor and referees when evaluating a manuscript.
   3. Editorial boards should carefully consider the quality of the study design, performance, presentations of results, and analysis when evaluating a manuscript.

D. To improve the critical reading abilities of medical journal readers:
   1. Statistics courses for medical students should place greater emphasis on critical thinking and logic in decision-making than on the technical aspects of statistics.

E. To improve the quality of mass media reports of medical research:
   1. The Biometric Society should sponsor a workshop for scientific reporters.

Submitted by Student


From Should there be statistical guidelines for medical research papers? (panel discussion). *Biometrics* 34: 687, 1978.

unacceptable rate of false negative values. Of children with fever 57% had a normal temperature on the Clinitemp. In only one case did the Clinitemp identify fever in a child found not to be febrile with the IVAC 821. The Clinitemp company indicates that the instrument can be used on adults. However, adults have a lower mean body temperature than children, and it is possible that an even smaller percentage of adults with fever would be identified.

There appears to be an appreciable risk that if this device is not improved or removed from the market that someone with a serious illness may delay seeking medical attention on the basis of a normal temperature as measured by the Clinitemp.

The company that manufactures Clinitemp also makes a thermometer that indicates bath water temperature ("the Frog Prince") and one that measures the temperature of wine. Wine drinking bathers beware, the Frog Prince may be slow to show!

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## A SICK CHILD AND A PROFESSIONAL TRICKSTER—AS VIEWED IN 1861

Professional tricksters, or quacks, have always been with us. The following example is a typical trickster's ploy (Editorial: Professional tricksters. *Am Med Times* 3:35, 1861).

In that well-furnished nursery lies a sick child, tended by its officious nurse, and watched by its sensitive mamma with continued and restless solicitude. The care bestowed upon the infant is out of all proportion to the exigency of the case. The child is ill and may possibly die, but will, under ordinary care and attention, in all probability recover. The medical man who has charge of the case is a well-informed and experienced practitioner, perfectly aware of the contingencies of the ailment, and calmly alive to the whims and fancies by which he is beset. His little patient lingers on; his credit is on the wane. Another practitioner is named of infallible skill, particularly in cases of this description; and he is called into consultation along with the family medical attendant. At the appointed hour, a carriage and pair drive up to the house, no knocker is raised, for fear of a noise; only the door-bell vibrates gently; and in walks the pattern M.D. He is a tall man with an obsequious stoop, and his knees slightly bent. His hair is brushed back; he wears gold spectacles, a white tie, and a black suit. There is no creaking of his shoes, and his manner is bland and soothing. He hangs over the crib of the dear sick child in a solemn attitude of observation; touches it lightly, listens to its breathing, feels its tiny pulse at the wrist, and then, quietly looking up, asks the old practitioner, who is standing by and looking on, whether he has given his little patient *Tous les mois*—a panacea at that time only just introduced. The answer is in the negative. Why?—Not!—replies the pattern with an affected look of surprise; not given *Tous les mois*? *Tous les mois*, nurse; *Tous les mois*, my lady—turning to the agonized mamma—*Tous les mois* will cure your child! The old practitioner is dismissed, on the score of ignorance, and under the judicious use of *Tous les mois* the child recovers.

There are tricks in every trade, but of all tricks, professional pedantry is the most detestable. It has it all its own way. The party duped can have no insight into the secrets by which he is guided in the management of his property, his soul, or his life. He must trust implicitly to the integrity and skill of his professional adviser, whom he flies to in moments of the last resort. It is in the embarrassment of such occasions that the trickster succeeds. There is the opportunity of putting himself forward, and he seizes it with adroit avidity.

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

answers to the question could have been written 20 years ago for 129 (68%) of the items. The fact that 78% of the correct answers were known 20 years ago and only 68% of the questions could have been written 20 years ago can be explained by the observation that portions of the question or answers contained more recent knowledge.

As can be noted in Table 2 the chief reasons that 61 questions could not be answered 20 years ago were that the correct answer was unknown (28 items) and that one of the distractors contained an unknown piece of information (24 items).

New facts were the leading cause of a question being unanswerable 20 years ago (Table 3) with new drugs and new diagnostic tests accounting for the majority of the remaining unanswerable questions.

The content areas of neonatal, toxic and traumatic, psychologic and psychosocial, infectious, gastrointestinal, and genetics and congenital accounted for approximately two-thirds of the questions that were unanswerable 20 years ago. No other content area accounted for more than three questions (Table 4).

## DISCUSSION

Analysis of the questions and answers of the 1977 edition of In-Training Examination of the American Board of Pediatrics indicates that close to 80% of the answers were known 20 years ago.

This statement is not judgmental but merely analytical. Since we who administer the test, or take the test, are unaware of the guidelines employed in test construction we cannot determine whether our findings reflect the intent of the examination or highlight a shortcoming of the testing instrument.

It is apparent that most of the questions and answers have withstood the test of time and thus are neither capricious or ambiguous. These findings also suggest that the test reflects an attempt to evaluate longstanding core knowledge of pediatrics.

Our own impression, gained from an analysis of the test, suggests that it is a useful tool for testing candidates on the fundamental aspects of pediatrics.


## ACKNOWLEDGMENTS

We wish to express our appreciation to the American Board of Pediatrics for permission to perform and publish this study.


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## NIGHT WAKING

An association was found in a sample of 59 healthy middle-class first-born babies between regular night-waking at 1 year old and pre- and perinatal events. The only measure of parental behaviour discriminating night wakers from regular sleepers was that mothers of wakers responded more rapidly to crying during daytime observations. However, this was shown to be a difference related to the child's obstetric history and the persistence of crying, and not directly to night waking. Rapid response to crying, and night waking itself, seem to be separate outcomes of a sub-optimal obstetric history. The evidence is that no aspect of parental behaviour yet examined produces night-waking children.

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## "INFECTIOUS DISEASE MAFIA?"

I am less than an admirer of what I call the "Infectious Disease Mafia."

The people who set the Rules. They are the ones who told us in medical school that if we prescribed antibiotics over the phone we would obscure endless cases of SBE. They were the ones who told us that treating an adult with a red-hot throat or a creamy urethral discharge without a bacteriologic diagnosis was sinful. They were the ones who told us that pneumococcal pneumonia is still a major problem. They were the ones who told us that if there wasn't bacterial growth in a sputum culture or if the cold agglutinins weren't positive, then we were dealing with a virus, and to prescribe antibiotics was evil.

One of the Tenets of the Infectious Disease Mafia, you see, is that it is near-immoral to treat without a specific diagnosis. The ID Mafia has an overwhelming tendency to see diagnosis as an end in itself—it offends their moral sensibility for physicians to cure infections through the use of "broad spectrum" or "shotgun" preparations. The fact is that there are no good controlled studies in adults to indicate that antibiotics might not be cost-effective in some upper and lower respiratory infections.

I would like to declare a truce between the university- or hospital-based infectious disease specialist and the rest of us. As my part of the bargain, I promise not to emphasize that much of their data about the dangers of superinfection is derived from immunosuppressed or alcoholic or otherwise compromised patients, and has little relevance to community practice. I will not remind them of their failure to investigate the long-term use of tetracycline in patients with acne or their belated (and somewhat paradoxical) acceptance of prophylactic antibiotics in patients with chronic lung disease. I will not speculate on the disappearance of chronic running ears, mastoid infections, bronchiectasis, rheumatic fever, and acute nephritis—except to remind the Mafia that by chance alone a lot of those "unnecessary" antibiotics must have wiped out a lot of strep. I will not speculate on what has happened to pneumococcal pneumonia, except to say that it rarely occurs in the middle-class ambulatory community anymore. I will not dwell on the fact that ID specialists want us to be more precise in our diagnosis, yet at the same time bemoan the deficiencies in bacteriology labs and the inexactitude of nonbacteriologists in interpreting cultures and Gram stains. I'll hold off on all of this, if only the bastards would stop treating me as though I were retarded or venal or both.

We are not stupid or brainwashed, oh professors of infectious disease!

From Halberstam MJ: *Modern Medicine*: February 15–28, 1979

*Class C: Discontinuance of Life-Sustaining Therapy.* Most of these patients are dying and usually can be made comfortable. In keeping with the highest principles of caring for persons in ways that they and their families desire, the child, family, responsible physician, and others will work out patient by patient how they will proceed. Recognizing this terminal phase of life, their primary aim is to ease dying as conscience, prudence, and kindness dictate.

The Committee on Guidelines consisted of 12 physicians: R. Duff (Chairman), I. Gross, J. Leventhal, R. J. Levine, M. Lewis, L. Margolis, G. Seashore, B. Shaywitz, C. Stashwick, R. Touloukian, M. Wessel, and one who chose not to be named; four nurses: K. Fallon, P. Johnson, R. O'Grady, and B. Smith; three social workers: R. Breslin, C. Cooper, and J. London; Chaplain D. Duncombe; Attorney A. Holder; and an administrator *(ex officio).*


### ACKNOWLEDGMENT

The author wishes to thank members of the committee and numerous others who have commented on this manuscript.


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## CONGENITAL CYTOMEGALOVIRUS INFECTION

Congenital cytomegalovirus (CMV) infection, as judged by virus excretion from neonates, occurred in 1.7 per 1000 "normal" babies, 5.5 per 1000 babies in special care units, and 8.8 per 1000 in a separate group of babies of unmarried mothers. Eighty-four cases were identified as having CMV and 43 were followed for over five years. The different patterns of illness and defects and their subsequent development are described. Twelve children suffered from deafness, five having severe sensorineural deafness (in three cases with late onset) and seven having persisent conductive deafness. Of 27 infected babies who were found in the Manchester routine surveys of neonates, one died, 11 were handicapped, and 15 developed normally. The complement fixing antibody titre to cytomegalovirus in congenitally infected babies ranged from less than 10 to 160 or more, and half of them had CMV-specific $I_gM$ when tested by indirect immunofluorescence in the early weeks of life. Two-thirds of those children who were $I_gM$-positive were handicapped.

From MacDonald, Tobin: *Dev Med Child Neurol* 20:471, 1978.

efficacy in steroid rosacea. Tetracycline obviously must be avoided in the pediatric age group.

Nonfluorinated steroids such as low potency hydrocortisone cream or desonide in selected cases can be implemented to blunt the rebound phenomenon seen after discontinuing the fluorinated steroids.[4,5] However, this may reinforce the practice of indiscriminate use of topical steroids by these patients. Hydrocortisone butyrate, a high potency, nonfluorinated steroid has been shown to be at least as efficacious in steroid rosacea as hydrocortisone cream;[5] however, treatment of steroid rosacea with this agent is not recommended at this time. Antiacne agents such as BPO in our experience have also been valuable in treating steroid rosacea as well as acne rosacea. Once fluorinated steroids are discontinued and specific therapy begun, the usual course is for the steroid rosacea to subside slowly over a few months, often interrupted by an initial flare or rebound consisting of increase in the number of pustular lesions. This usually occurs the first week after discontinuing the topical fluorinated steroids and can be minimized by therapy as previously outlined.

Erythematous papules and pustules grouped on the eyelids, cheeks, and chin associated with telangiectasia should bring to mind steroid rosacea. A careful history for the use of topical fluorinated glucocorticosteroids should be obtained. When advising about the process, it should be emphasized to patient and parent that the process is likely to worsen over the two weeks following the cessation of topical fluorinated glucocorticosteroids.

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## ASBETOS EXPOSURES AT SCHOOL

The news media have reflected the great concern about exposures to asbestos from school ceilings that were sprayed with asbestos, a common practice in schools built or renovated between 1950 and 1973. The material, now friable, is constantly polluting the school rooms with lint-like fibers. Doses may be higher than those permitted in industry. Inhalation can lead to mesothelioma decades hence, or, among future cigarette smokers, to a markedly increased risk of lung cancer. To date 21 states have made complete ascertainments of schools with this asbestos problem, and ten others have made partial ascertainments. An estimated 100 million square feet of school ceilings have been sprayed with asbestos in the 15,000 to 16,000 school districts of the United States (J. McSorley, EPA, personal communication).

EPA is preparing a "guidance package" on clearing schools of asbestos, which will be sent to each school district. The asbestos ceiling may be covered temporarily by a plastic spray.


Robert W. Miller, MD
National Cancer Institute-NIH, Bethesda, MD



From *Childhood Cancer Etiology Newsletter #55,* January 15, 1979.

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## COMMERCIOGENIC MALNUTRITION, A NEW PROBLEM AMONG INFANTS

One of the negative effects of commercial advertising is that, carried out within a profit-oriented policy, it has encouraged changes in infant feeding habits that are in keeping with local possibilities.

For it is not only working mothers who are turning to bottle feeding. Influenced by social pressure in favour of "modern" practices and by the impact of advertising, which suggests that processed milk is actually better for infants' health, there is a general feeling that bottle feeding is best, and the average length of breast feeding has fallen to only a few months. Frances Moore Lappe and Joseph Collins report that in Zambia, 54% of the seriously malnourished children admitted to the Ndola Children's Hospital have not even been fed milk, but instead imported soft drinks, their mothers believing that these were the best thing they could give their children.

Improper information as to their babies' real nutritional needs, and the inevitable dilution of the processed milk to little more than coloured water when money is low, are not the only dangers, however. The lack of abundant supplies of clean water and fuel for proper sterilization leads to repeated attacks of gastroenteritis, followed by marasmus and death. The term "commerciogenic malnutrition" has been used by Patrice Jelliffe to describe this new sequence of events.

Studies carried out in regions where infants are breast fed for as little as one month revealed deaths from diarrhoeal diseased to be three times higher than in regions where longer periods of breast feeding are practised. And over the last two decades, as the rate of breast feeding has decreased, the average age for the onset of severe malnutrition has dropped from 18 months to a more critical 8 months.

Submitted by Student

From Dossier: Peri-urban malnutrition, a neglected problem. Les carnets de l'enfance—Assignement children. Geneva, UNICEF, 43:32, 1978.

tection of the stable metabolic end products of prostaglandin synthesis may clarify some of these conflicting results.[14]

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## UNCLASSIFIED MENTAL RETARDATION

A disturbing number of cases of microcephaly with mental retardation seem unrelated either to obstetric history or to any recognized pediatric syndrome . . . the pathogenesis of such microcephaly may be related more to the timing of an insult in relation to the normal timing of neurogenesis in the brain, than to the specific nature of the insult; and that the vulnerable period for at least some microcephaly may therefore be during the multiplication of neuroblasts, which in human brain happens in the first half of the second trimester (about 12–20 weeks' gestation). Except for microneurons in certain recognised regions, neuroblast multiplication ceases at about mid-gestation when they differentiate into mature neurons.

The best evidence for this suggestion inevitably derives largely from experiments with animals, but there is also a body of circumstantial evidence from clinical observation in human beings . . .

A paper by Ounsted and her colleagues reports a reduced head circumference, at birth, of babies whose mothers received methyldopa during pregnancy as treatment for hypertension. Amongst several interesting findings, it was only when treatment began in the period from 16 to 20 weeks of gestation that the newborn head circumference was reduced. Treatment beginning before 16 and later than 20 weeks produced no detectable effect, nor was the amount of methyldopa prescribed related in any detectable way to the degree of reduction of head circumference.

Submitted by Student

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## MATERNAL EFFECT ON NEUROFIBROMATOSIS (NF)

The severity of childhood NF is greater when the mother is affected than when the father is or when the disease is due to a new mutation. Study of 62 cases in Seattle revealed severe (grade 3) complications, such as uncontrolled seizures, severe mental deficiency, and pseudoarthrosis, in 21 of 31 offspring of affected mothers as compared with four of 31 NF patients whose mothers were not affected (Miller M, Hall JG: *Lancet* 2:1071, 1978). The authors postulated "that some factor produced by affected women interacts only with fetuses who carry the neurofibromatosis gene." The factor, perhaps humoral, was thought to alter the intrauterine environment.

As a further, but earlier published test of this concept, the mean age of onset of bilateral acoustic neuroma (central neurofibromatosis) was determined for 25 cases with affected mothers and 13 with affected fathers. The difference was statistically significant ($P < .01$) for maternal transmission, 18.3 ± 1.4 years, vs 24.1 ± 2.2 years for paternal transmission (Kanter WR, Eldridge R: *Lancet* 2: 903, 1978).

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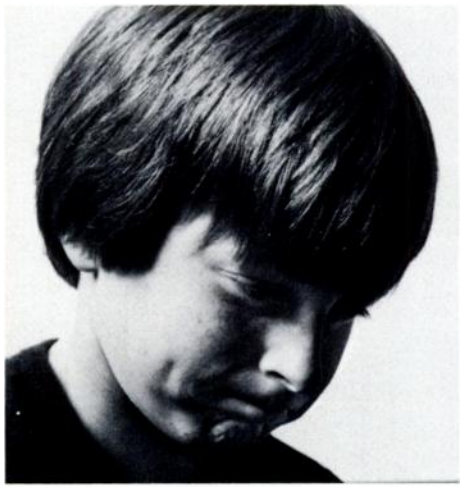
From *Childhood Cancer Etiology Newsletter #55*, January 15, 1979.



# Day-long behavior therapy without dosing problems at school

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## Just once a day. At home.

## Brief Summary of Prescribing Information

**INDICATIONS**—CYLERT is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms; moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonfocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

Attention Deficit Disorder and Hyperkinetic Syndrome are among the terms being used to describe the above signs and symptoms. In the past, a variety of terms has been associated with these signs and symptoms, including: Minimal Brain Dysfunction, Hyperkinetic Reaction of Childhood, Hyperkinetic Syndrome, Hyperactive Child Syndrome, Minimal Brain Damage, Minimal Cerebral Dysfunction, and Minor Cerebral Dysfunction.

**CONTRAINDICATIONS**—CYLERT (pemoline is contraindicated in patients with known hypersensitivity or idiosyncrasy to the drug. (See ADVERSE REACTIONS.)

**WARNINGS**—CYLERT is not recommended for children less than 6 years of age since its safety and efficacy in this age group have not been established.

Clinical experience suggests that in psychotic children, administration of CYLERT may exacerbate symptoms of behavior disturbance and thought disorder.

Data are inadequate to determine whether chronic administration of CYLERT may be associated with growth inhibition; therefore, growth should be monitored during treatment.

**PRECAUTIONS**—Drug treatment is not indicated in all cases of the behavioral syndrome characterized by moderate to severe distractibility, short attention span, hyperactivity, emotional lability and impulsivity. It should be considered only in light of the complete history and evaluation of the child. The decision to prescribe CYLERT should depend on the physician's assessment of the chronicity and severity of the child's symptoms and their appropriateness for his/her age. Prescription should not depend solely on the presence of one or more of the behavioral characteristics.

When these symptoms are associated with acute stress reactions, treatment with CYLERT is usually not indicated.

Long-term effects of CYLERT in children have not been well established.

Liver function tests should be performed prior to and periodically during therapy with CYLERT. The drug should be discontinued if abnormalities are revealed and confirmed by follow-up tests. (See ADVERSE REACTIONS regarding reports of abnormal liver function tests and jaundice.)

CYLERT should be administered with caution to patients with significantly impaired hepatic or renal function.

The interaction of CYLERT with other drugs has not been studied in humans. Patients who are receiving CYLERT concurrently with other drugs, especially drugs with CNS activity, should be monitored carefully.

CYLERT failed to demonstrate a potential for self-administration in primates. However, the pharmacologic similarity of pemoline to other psychostimulants with known dependence liability suggests that psychological and/or physical dependence might also occur with CYLERT. There have been isolated reports of transient psychotic symptoms occurring in adults following the long-term misuse of excessive oral doses of pemoline. CYLERT should be given with caution to emotionally unstable patients who may increase the dosage on their own initiative.

*Usage during Pregnancy and Lactation.* The safety of CYLERT (pemoline) for use during pregnancy and lactation has not been established.

Studies in rats have shown an increased incidence of stillbirths and cannibalization when pemoline was administered at a dose of 37.5 mg./kg./day. Postnatal survival of offspring was reduced at doses of 18.75 and 37.5 mg./kg./day.

**ADVERSE REACTIONS**—Insomnia is the most frequently reported side effect of CYLERT; it usually occurs early in therapy, prior to an optimum therapeutic response. In the majority of cases it is transient in nature or responds to a reduction in dosage.

Anorexia with weight loss may occur during the first weeks of therapy. In the majority of cases it is transient in nature; weight gain usually resumes within three to six months.

Stomachache, skin rashes, increased irritability, mild depression, nausea, dizziness, headache, drowsiness, and hallucinations have been reported.

Elevations of SGOT, SGPT, and serum LDH have occurred in patients taking CYLERT, usually after several months of therapy. These effects appear to be reversible upon withdrawal of the drug, and are thought to be manifestations of a delayed hypersensitivity reaction. There have also been a few reports of jaundice occurring in patients taking CYLERT; a causal relationship between the drug and this clinical finding has not been established.

The following CNS effects have been reported with the use of CYLERT; dyskinetic movements of the tongue, lips, face and extremities, nystagmus and nystagmoid eye movements, and convulsive seizures. A definite causal relationship between CYLERT and these reactions has not been established.

Mild adverse reactions appearing early during the course of treatment with CYLERT often remit with continuing therapy. If adverse reactions are of a significant or protracted nature, dosage should be reduced or the drug discontinued.

**OVERDOSAGE**—Signs and symptoms of acute CYLERT overdosage may include agitation, restlessness, hallucinations, dyskinetic movements and tachycardia. The treatment for an acute overdosage of pemoline is essentially the same as that for an overdosage of any CNS stimulant. Management is primarily symptomatic and may include induction of emesis or gastric lavage, sedation, and other appropriate supportive measures.

Results of studies in dogs indicate that extracorporeal hemodialysis may be useful in the management of CYLERT overdosage, forced diuresis and peritoneal dialysis appear to be of little value.

**DOSAGE AND ADMINISTRATION**—CYLERT (pemoline) is administered as a single oral dose each morning. The recommended starting dose is 37.5 mg./day. This daily dose should be gradually increased by 18.75 mg. at one week intervals until the desired clinical response is obtained. The effective daily dose for most patients will range from 56.25 to 75 mg. The maximum recommended daily dose of pemoline is 112.5 mg.

Clinical improvement with CYLERT is gradual. Using the recommended schedule of dosage titration, significant benefit may not be evident until the third or fourth week of drug administration.

Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy.

**HOW SUPPLIED**—CYLERT (pemoline) is supplied as monogrammed, grooved tablets in three dosage strengths:

18.75 mg. tablets (white) in bottles of 100 (**NDC** 0074-6025-13)

37.5 mg. tablets (orange-colored) in bottles of 100 (**NDC** 0074-6057-13)

75 mg. tablets (tan-colored) in bottles of 100 (**NDC** 0074-6073-13)

CYLERT Chewable is supplied as monogrammed, grooved tablets in one dosage strength:

37.5 mg. tablets (orange-colored) in bottles of 100 (**NDC** 0074-6088-13)

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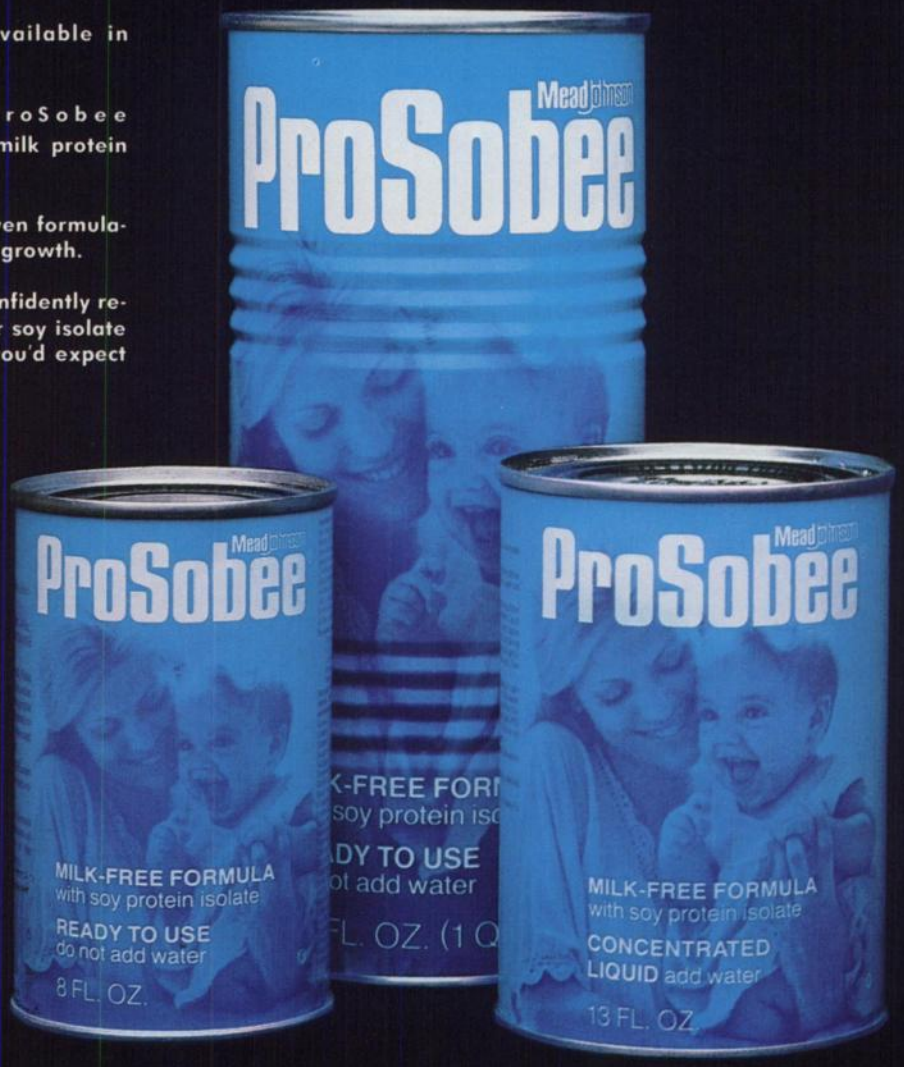


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# ProSobee®



ProSobee® milk-free formula with soy isolate.

L-K11-78

CORTISPORIN® OTIC SUSPENSION Sterile
(Polymyxin B-Neomycin-Hydrocortisone)
DESCRIPTION: Each cc contains:
Aerosporin®
**(Polymyxin B Sulfate)** ..... **10,000 units**
Neomycin sulfate ..... 5 mg
(equivalent to 3.5 mg neomycin base)
Hydrocortisone ..... 10 mg (1%)
The vehicle contains the inactive ingredients cetyl alcohol, propylene glycol, polysorbate 80, purified water 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 longstanding cases of chronic otitis media because of the possibility of ototoxicity caused by neomycin.

CORTISPORIN® OTIC SOLUTION Sterile
(Polymyxin B-Neomycin-Hydrocortisone)
DESCRIPTION: Each cc contains:
Aerosporin®
**(Polymyxin B Sulfate)** ..... **10,000 units**
Neomycin sulfate ..... 5 mg
(equivalent to 3.5 mg neomycin base)
Hydrocortisone ..... 10 mg (1%)
The vehicle contains the inactive ingredients glycerin, hydrochloric acid, propylene glycol, purified water 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.

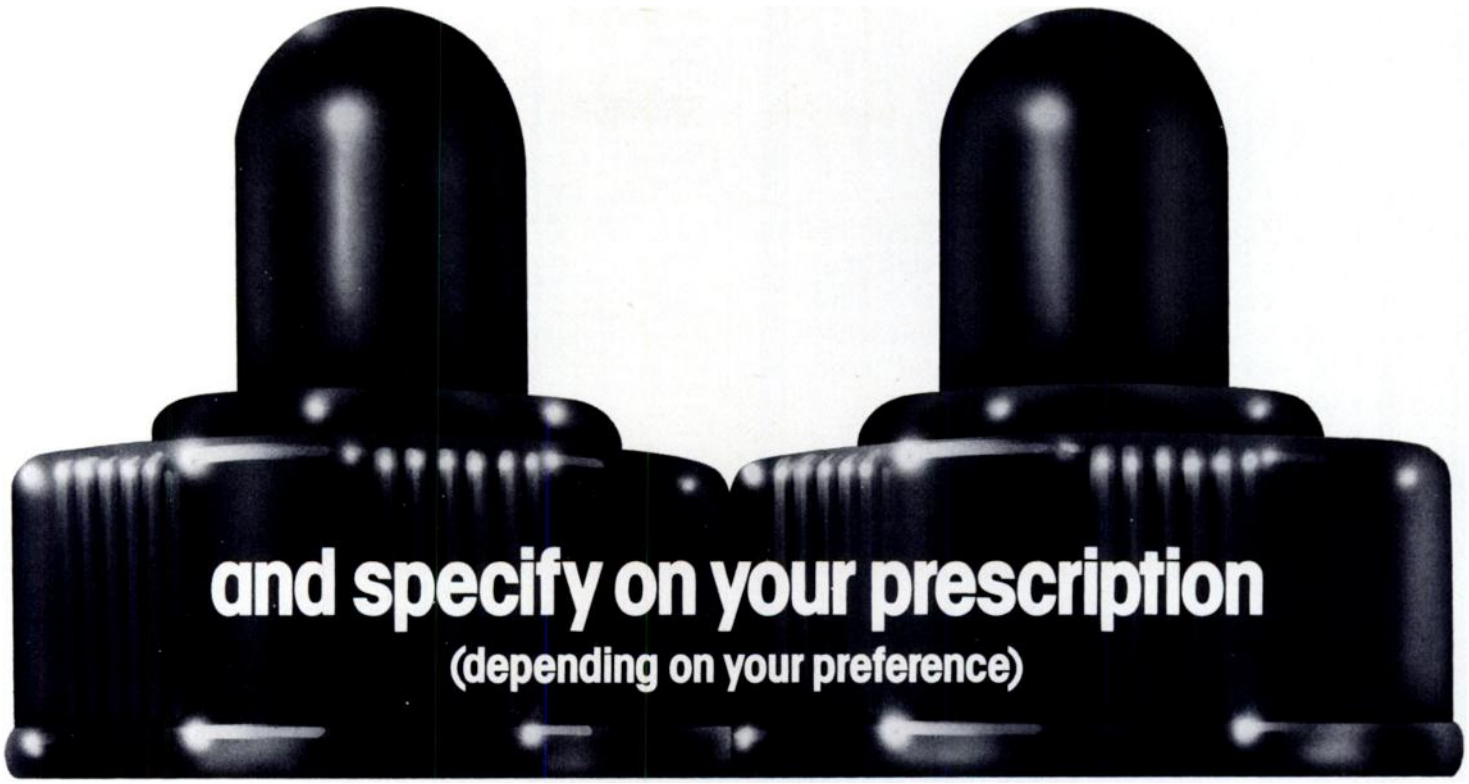
CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS COMMON TO BOTH PRODUCTS
CONTRAINDICATIONS: These products are contraindicated in those individuals who have shown hypersensitivity to any of the components, and in herpes simplex, vaccinia and varicella.
WARNINGS: As with other antibiotic 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.

# Take your choice... of effective therapy for susceptible external ear infections

## Solution or Suspension

*Two otic products, giving you the assurance of:*

- ☐ years of therapeutic success, clinical acceptance
- ☐ wide range of antibacterial activity, including many strains of *Pseudomonas aeruginosa,* the most common otic pathogen, as well as *Proteus* and staph
- ☐ direct anti-inflammatory action, relieving associated itching, swelling and pain
- ☐ acid pH to help restore normal acidity of the ear canal
- ☐ economy for your patients—usually less cost than with other comparable otics




## Cortisporin® Otic
# SOLUTION Sterile
**(polymyxin B-neomycin-hydrocortisone)**

A clear solution (does not have to be shaken) providing clear visualization of field. Indicated for treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics. Stinging and burning have been reported when this drug has gained access to the middle ear.

## Cortisporin® Otic
# SUSPENSION Sterile
**(polymyxin B-neomycin-hydrocortisone)**

A white suspension for treating infections of mastoidectomy and fenestration cavities caused by organisms susceptible to the antibiotic as well as superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics.

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- ***Well tolerated and children like the pleasant raspberry flavor***

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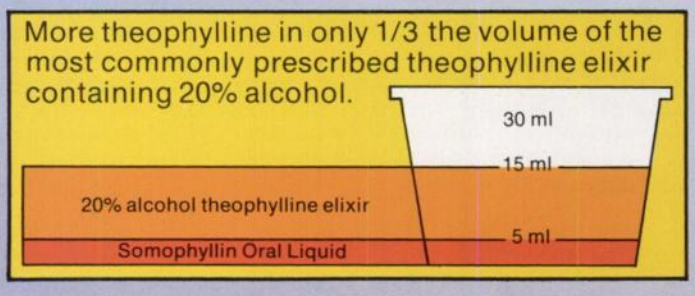
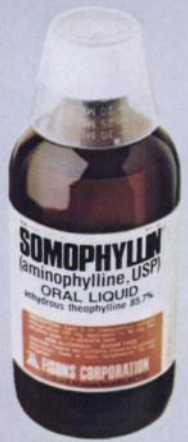
*Aside from the problem of incompatibility with concomitant medications, such as antihistamines, anticonvulsants, hypoglycemics, sedatives and tranquilizers,[2,3] alcohol is: Habituating, Dehydrating,[4,5] Soporific and Emetic—all effects that are in opposition to the therapeutic effect you want.*




**Somophyllin is indicated for the symptomatic relief of bronchial asthma, pulmonary emphysema, chronic bronchitis, and other pulmonary disease associated with bronchospasm.*

*† Calculation based on 12 fl. oz. containers and a 4.5% alcohol content*

*Please see facing page for brief summary of prescribing information*

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### The Maltreatment Syndrome in Children — A Medical, Legal and Social Guide

**Fourth Edition**

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# THE R.A.U. PATIENT.

# CAN THE PROBLEMS IN HIS MOUTH BE LINKED TO THE PROBLEMS ON HIS MIND?

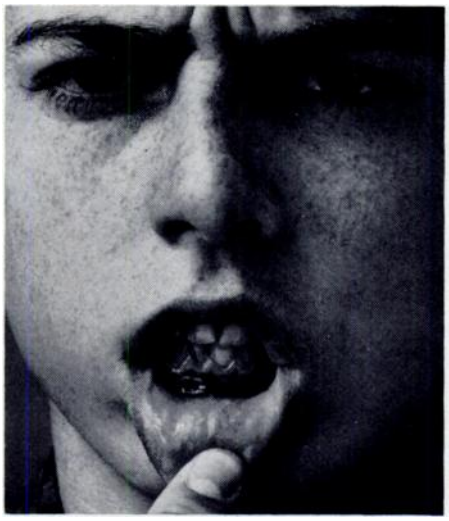
Twenty years of research are now shedding an entirely different light on the canker sore, or as physicians now call it–recurrent aphthous ulceration (R.A.U.). Because the apparently arbitrary exacerbations and remissions that characterize R.A.U. may actually be linked to the presence of emotional stress.[1-5]

## R.A.U.—how to recognize it

The aphthous ulcer appears out of nowhere and usually disappears without incident. So most patients dismiss it as little more than a bothersome fact of life. But R.A.U. is actually a complex medical syndrome. It is characterized by single or multiple lesions of 2-20 mm in diameter that appear repeatedly on any of the moist mucous membranes of the mouth. A positive history of recurrences, the healthy appearance of surrounding tissue and the absence of associated systemic disorders will distinguish it from any other oral disease, including a herpetic infection.[4]

## Extremely high incidence seen in students under stress

Ship et al[5] uncovered the most extensive evidence of the relationship between R.A.U. and stress in a major study of medical, dental, nursing and veterinary students in the University of Pennsylvania area. Of over 1700 students, 55% suffered from R.A.U. Furthermore, the medical histories of 64% of the students revealed that the group with R.A.U. reported significantly more emotional problems than those without the disease—problems that were in fact related to the frequency of each attack.



## Correlation between R.A.U. and other ulcerative syndromes

Naturally a highly-selected population survey should be interpreted with caution. But additional findings by Ship in a subsequent investigation[4] suggest that the connection between R.A.U. and the mind under stress is more than coincidental: for the typical R.A.U. patient, the problem of ulcers doesn't stop in the oral cavity. Gastrointestinal and/or vulvovaginal ulcers plus a variety of other disorders, especially allergies, are often present as well.

## Treatment remains palliative

No one knows the precise etiology of R.A.U. Its high incidence in environments notorious for intense pressure and mental strain, and its correlation with disorders long known to be at least partly psychogenic, strongly implicate stress as a leading factor. But until we can positively discern and treat the primary cause of R.A.U., treatment is still centered on debriding the lesion and relieving the pain.

## Proxigel: to cleanse and help soothe minor oral inflammations

Proxigel is the ideal antiseptic to recommend for the R.A.U. patient in your practice and is also useful as adjunctive therapy in gingivitis, periodontitis, stomatitis, Vincent's infection and denture irritation.

Its unique viscous base adheres to affected areas—for longer debriding action on necrotic or pathological tissue.

Proxigel also helps to inhibit odor-causing bacteria. It is bactericidal against pathogens and other microorganisms which may be found in the oral cavity.

And Proxigel helps soothe painful tissue and thus aids in healing.

**References:** **1.** Francis, T.: Recurrent aphthous stomatitis and Behcet's disease, *Oral Surg. 30*:476, October 1970. **2.** Greenfield, D.S. and Fasciano, R.W.: Oral ulcerative disease in young adults: diagnosis and management, *J. Am. Coll. Health Assoc. 23*:167, December 1974. **3.** McCarthy, P. and Shklar, G.: *Diseases of the Oral Mucosa,* McGraw-Hill Book Company, New York, 1964, p. 192-200. **4.** Ship, I.I.: Epidemiologic aspects of recurrent aphthous ulcerations, *Oral Surg. 33*:400, March 1972. **5.** Ship, I.I., Morris, A.L., Durocher, R.T. *et al:* Recurrent aphthous ulcerations and recurrent herpes labialis in a professional school student population, *Oral Surg. 13*:1191, 1317,1438, Oct. 1960, Nov. 1960, Dec. 1960.

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**OTITIS MEDIA (ACUTE):** AURALGAN is indicated for relief of pain and reduction of inflammation in the congestive and serous stages of acute otitis media. It is effective adjuvant therapy when antibiotics or sulfonamides are administered systemically.

**Administration: Otitis media (acute):** Instill AURALGAN, permitting the solution to run along the wall of the canal until it is filled. Avoid touching ear with dropper. Then, moisten cotton pledget with AURALGAN and insert into the meatus. Repeat every one to two hours (or three or four times a day).

**REMOVAL OF CERUMEN:** AURALGAN facilitates the removal of excessive or impacted cerumen.

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**Note:** Keep well closed. Do not rinse dropper after use.

**SUPPLIED:** No. 1000 -- AURALGAN Otic Solution, in package containing 15 ml (1/2 fl oz.) bottle with separate dropper-screw cap attachment.

# ...in acute otitis media

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Each ml contains:

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| Antipyrine | 54.0 mg |
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different sites. Only one colony was selected from each positive site. If several colonies had been serotyped, colonization with multiple types may have a more common finding. Indeed multiple serotypes were recovered in approximately 5% of positive vaginal cultures in women attending a venereal disease clinic.[14] Whether geographic factors, seasonal variations, or sites involved may influence the frequencies of serotype distributions is still to be defined.

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## RHABDOMYOSARCOMA AND NEUROFIBROMATOSIS (NF)

Five new cases of rhabdomyosarcoma in NF plus nine from the literature bring to 14 the total known to date (McKeen EA, et al: *J Pediatr,* 93:992, 1978). Among all U.S. children, 1964 to 1977, 1.3 cases were expected by chance as compared with seven observed in a data collection that fell far short of complete ascertainment.

In consequence of this study we now know of three cancers associated with NF that are presumably not derived from the neural crest, the source of the developmental anomalies in the syndrome. The other two are nonlymphocytic leukemia (Bader JL, Miller RW: *J Pediatr* 92:925, 1978) and Wilms' tumor (Stay EJ, Vawter G: *Cancer* 39:2550, 1977). McKeen et al concluded that either NF is more than a neurocristopathy, or the three tumors are unexpectedly derived from tissues related to the neural crest. (Thus by piecing together three recent clinical discoveries, a new perception of NF may emerge.)


Robert W. Miller, MD
National Cancer Institute-NIH, Bethesda, MD



From *Childhood Cancer Etiology Newsletter #55,* January 15, 1979.

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## SPINA BIFIDA SUCCESSFULLY TREATED BY POTASSIUM IODIDE INJECTIONS IN 1861

The following case report of a "cure" of spina bifida by injection of potassium iodide is similar to other comparable reports in American medical journals a century or more ago. The lack of detailed descriptions of the size and characteristics of the spina bifida in these reports casts serious doubts about the so-called "cures."

In "Spina Bifida Treated by Iodine" (Am Med Times 3:187, 1861), Professor Brainard reports a case of spina bifida which he treated by iodine injection. The patient was a girl aged 3 years. A small-sized hydrocele trocar was carried into the base of the tumor, and six ounces of fluid drawn off, pressure with the thumb at the same time being made, so as to close, as perfectly as possible, the opening in the spinal column. Half an ounce of solution made of iodine gr. v., iodid. potass. gr. XV., aq. distil. ℥ j., at the temperature of the body, was injected, and after a few seconds allowed to flow out; distilled water, of the temperature of the body, was then thrown in to wash out the iodine, and two ounces of fluid first drawn from the sac, kept at the temperature of the body, was reinjected, the canula withdrawn, and pressure applied.

One injection sufficed to effect a cure. This is the seventh case which he has treated in this manner, and in no case has he seen it produce dangerous symptoms.

Three of the cases were accompanied by hydrocephalus, and were all permanently cured—one with 13 injections, one with two, and the last with one.

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

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## OSTEOSARCOMA AND HEPATIC ANGIOSARCOMA AFTER CHILDHOOD EXPOSURE TO THOROTRAST

From 1930 until 1950, Thorotrast, which contains radioactive thorium dioxide, was used as an angiographic contrast agent in diagnostic radiology. A substantial number of patients subjected to this procedure have developed hepatic hemangiosarcomas or myelogenous leukemia. Osteosarcoma (OS) has been a rare sequel, perhaps because most of the Thorotrast-exposed patients were adults.

OS has just been reported in two patients seen at National Cancer Institute, in both of whom Thorotrast was used for cerebral angiography as a diagnostic procedure for epilepsy during childhood. One, a male, exposed at 2 years of age, developed OS at 24, and the other, a female, exposed at 16 years, developed the tumor at 48, with a possible multicentric focus about two years later. The sites were atypical for OS: the disphysis of the humerus in the man, and the acetabulum and midhumeral shaft in the woman. An autoradiograph of the man's lymph node showed alpha particle tracks from the deposited radioactive thorium. The authors suggested that OS may be a late, late effect only now becoming apparent among children treated several decades ago (Sindelar WF, Costa J, Ketcham A: *Cancer* 42:2604, 1978).

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From *Childhood Cancer Etiology Newsletter #55*, January 15, 1979.

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## THE LIGHT OF DARKNESS

It would seem to me that man cannot live without mysteries. One could say, the great biologists worked in the very light of darkness. We have been deprived of this fertile night. The moon, to which as a child I used to look up on a clear night, really is no more; never again will it fill grove and glen with its soft and misty gleam. What will have to go next? I am afraid I shall be misunderstood when I say that through each of these great scientific-technological exploits the points of contact between humanity and reality are diminished irreversibly.

Somebody who had read (my) words said to me: "You seem to appreciate the natural sciences only as long as they are not successful. Darkness illuminated becomes light." I could only answer: "What is success in science? Illuminated darkness is not light. We find ourselves in the cavern of limitless possibilities. Take a flashlight with you, and you may find you are only in a lumber room. If I know what I shall find, I do not want to find it. Uncertainty is the salt of life." And he said: "When you say darkness, you mean obscurity." This I denied; but I do not think we achieved conciliation.

Submitted by Student

From Chargaff E: *Heraclitean Fire.* New York, Rockefeller University Press, 1978