JULY 1978

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NUMBER 1

Pediatrics

AMERICAN ACADEMY OF PEDIATRICS EVANSTON ILLINOIS 60204

PEDIAU 62(1) pp. 1-130 (1978)

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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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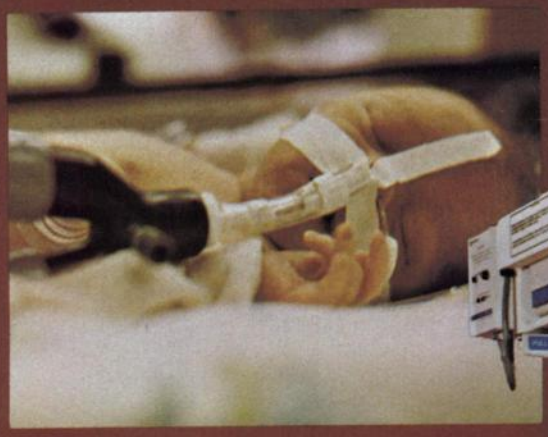

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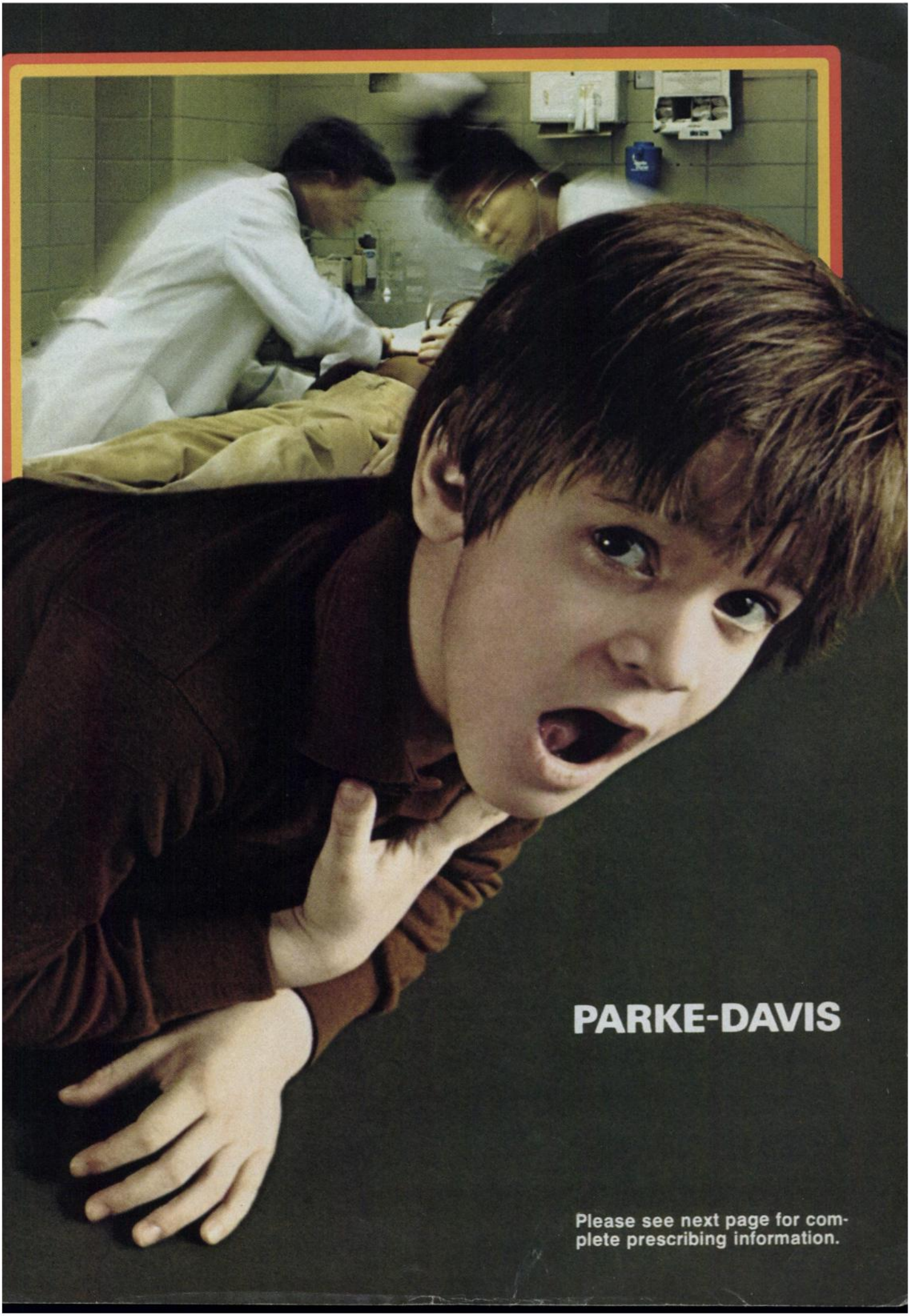
for epiglottitis caused by Hemophilus influenzae*

Chloromycetin®
Sodium Succinate (chloramphenicol sodium succinate for injection, USP)

*Chloromycetin (chloramphenicol) must be used only in those serious infections for which less potentially dangerous drugs are ineffective or contraindicated.

Epiglottitis is life-threatening in infants and children, almost always requiring humidification and frequently a tracheotomy in conjunction with immediate drug therapy.

When there is good clinical reason to believe that the infection is caused by *H influenzae*, Chloromycetin (chloramphenicol) therapy may be judiciously instituted without awaiting culture and sensitivity results. If the patient has a known or suspected allergy to penicillins, Chloromycetin should be considered one of the drugs of choice to initiate therapy.


PARKE-DAVIS
Please see next page for complete prescribing information.

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 & COMPANY, Detroit, Michigan 48232

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Send all manuscripts to Jerold F. Lucey, M.D., 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 in 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, and city and state, name of publisher, year of publication, and page numbers.

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

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.

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

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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BPA Membership Applied for, November 1976

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And just a touch of the right antibiotic can help clear it up.

Neosporin Ointment can help control minor cases of impetigo before other children catch it from your young patient, and it may be used as an adjunct to appropriate systemic therapy in more extensive disease. Neosporin Ointment provides broad, reliable antibiotic action against susceptible organisms—notably *Staphylococcus* and *Streptococcus*— with antibiotics that are seldom used systemically.

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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 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 1978 VOL. 62 NO. 1

Pediatrics

OFFICIAL PUBLICATION OF THE AMERICAN ACADEMY OF PEDIATRICS

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ARTICLES

REVIEW ARTICLE

ARTICLES (CONTINUED)


This asthmatic
isn't worried about his

next breath... he's active he's effectively maintained on

QUIBRON®

Each capsule or tablespoonful (15 ml) elixir contains theophylline (anhydrous) 150 mg and glyceryl guaiacolate (guaifenesin) 90 mg. Elixir: alcohol 15%

theophylline for effective around-the-clock therapy

Quibron may give the asthmatic up to eight hours of bronchodilation with each dose and provides dosages of theophylline which are now believed necessary to keep patients free of acute attacks and chronic wheezing.

100% free theophylline

Quibron helps achieve therapeutic serum theophylline levels with minimal dosage volume...delivers 100% free theophylline in comparison to many other compounds which contain from 47% to 91% effective theophylline.

individualized theophylline dosage schedule

Today's more efficient usage of theophylline calls for individualizing dosage. Treatment should be initiated at 150 mg theophylline every 6 hours for adults and 4 mg/kg every 6 hours for children. When necessary, to achieve greater efficacy the dosage may be cautiously adjusted upward while monitoring serum theophylline levels.

Mead Johnson PHARMACEUTICAL DIVISION

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) elixir 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 nitrosonaphtol 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 μg/ml.

How Supplied: Capsules in bottles of 100 and 1000 and unit-dose packs of 100; Elixir in bottles of 1 pint and 1 gallon.

See package insert for complete prescribing information.

AMERICAN ACADEMY OF PEDIATRICS

1801 Hinman Avenue
Evanston, IL 60204

SCHEDULE OF MEETINGS

ANNUAL MEETINGS

1978
Palmer House
Chicago
October 21 to 26

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

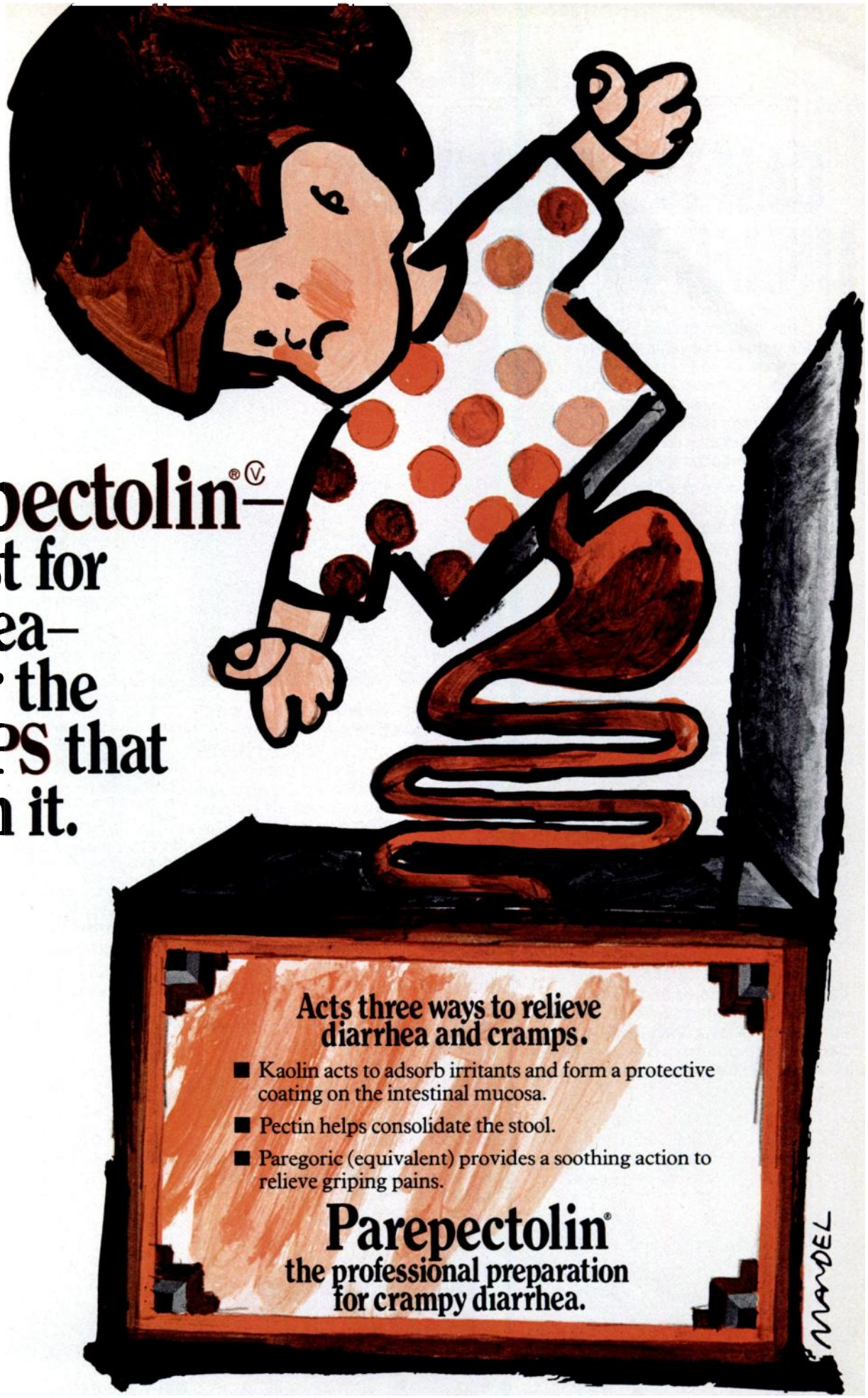
1980
Detroit Plaza Hotel
Detroit
October 25 to 30

1981
New Orleans
October 31 to Nov. 5

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

1983
San Francisco
October 22 to 27

Note: All Annual Meetings start on Saturday



WILLIAM H. RORER, INC., Fort Washington, Pa. 19034

THE R.A.U. PATIENT.

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

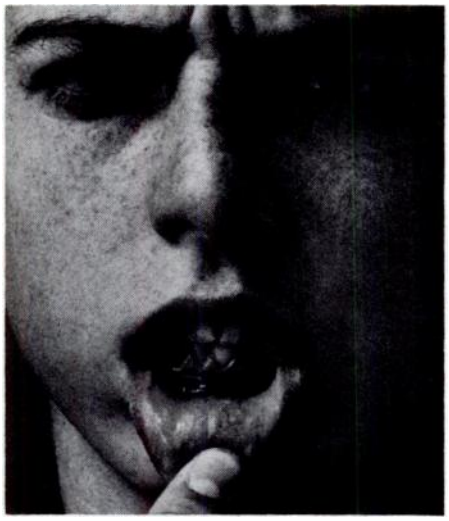
Twenty years of research are now shedding an entirely different light on the canker sore, or as physicians now call it–recurrent aphthous ulceration (R.A.U.). Because the apparently arbitrary exacerbations and remissions that characterize R.A.U. may actually be linked to the presence of emotional stress.[1-5]

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.

Proxigel Active Ingredient: Carbamide peroxide 11% in a water-free gel base.

Reed & Carnrick
Kenilworth, New Jersey 07033

PROXIGEL®

Oral Antiseptic & Cleanser

Adjunctive therapy for R.A.U.

AMERICAN ACADEMY OF PEDIATRICS

1801 Hinman Avenue
Evanston, IL 60204

SCHEDULE OF MEETINGS

SPRING SESSIONS

1979
Four Seasons Sheraton
Toronto
April 21 to 26

1980
Las Vegas Hilton
Las Vegas
April 19 to 24

1981
Washington, D.C.
April 4 to 9

1982
Honolulu
March 20 to 25

Note: All Spring Sessions start on Saturday

A new indication for Septra

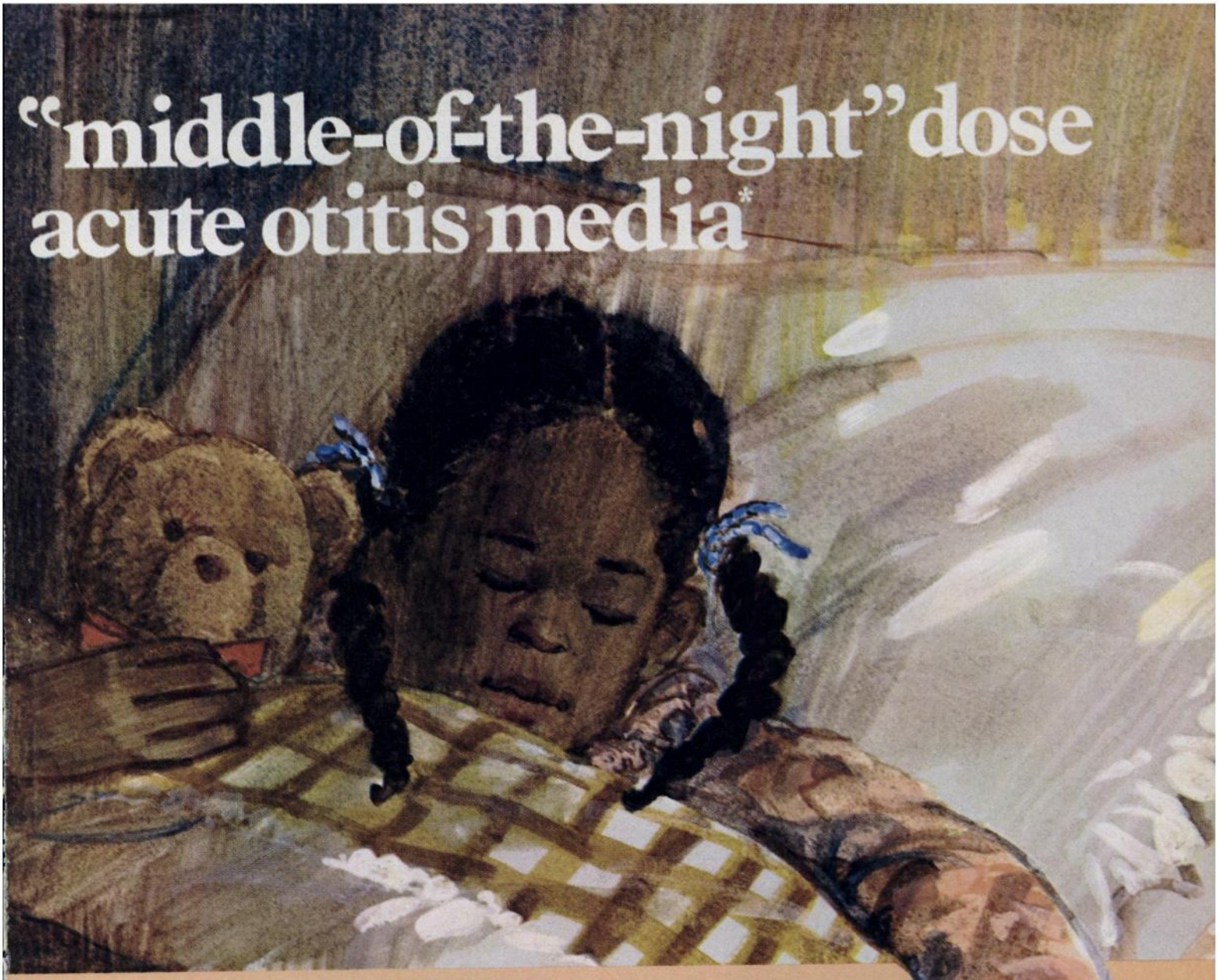
Getting a child with an earache off to sleep is hard enough, without getting her up again. With the q.i.d. and t.i.d. dosages of other antibacterials for acute otitis media, expecting compliance may be expecting a lot. Septra b.i.d. dosage convenience can change all that.

In a study of 94 children with bacterial otitis media confirmed by culture, Septra Suspension produced a success rate of 95.7%.†

Septra Suspension has proved highly effective in acute otitis media caused by the most common middle ear pathogens—*Haemophilus influenzae* and *Streptococcus pneumoniae.*

Though crystalluria has not been a problem with Septra, adequate fluid intake should be maintained and frequent urinalyses with careful microscopic examination performed during therapy. Septra is contraindicated in infants under two months. **Septra should not be used in the treatment of streptococcal pharyngitis.**

†Data on file, Medical Department, Burroughs Wellcome Co.
See last page of this advertisement for prescribing information.



"middle-of-the-night" dose acute otitis media*

Septra®

Suspension

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

b.i.d.

through-the-night efficacy against major middle ear pathogens

*Septra is now indicated for use in 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.

Septra® introduces b.i.d. dosage convenience to the treatment of acute otitis media in children

Septra® Suspension

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

- effective *in vitro* against major middle ear pathogens—*Haemophilus influenzae*, including ampicillin-resistant strains, and *Streptococcus pneumoniae**
- well tolerated by infants and children† (Contraindicated in infants under two months. See brief summary below for possible adverse reactions.)

Septra® Tablets

Each tablet contains:
80 mg trimethoprim and 400 mg sulfamethoxazole

- available in pleasant tasting cherry-flavored suspension or in tablet form for use in older children
- encourages compliance; unlike other antibacterials for otitis media, Septra requires no middle-of-the-night dose

---

Septra® Tablets and Suspension

Indications and Usage:

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.**

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 β-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 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.

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.

ACUTE OTITIS MEDIA IN CHILDREN: The recommended dose for children with 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. 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
20	9	1 (5 ml)	½
40	18	2 (10 ml)	1
60	27	3 (15 ml)	1½
80	36	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

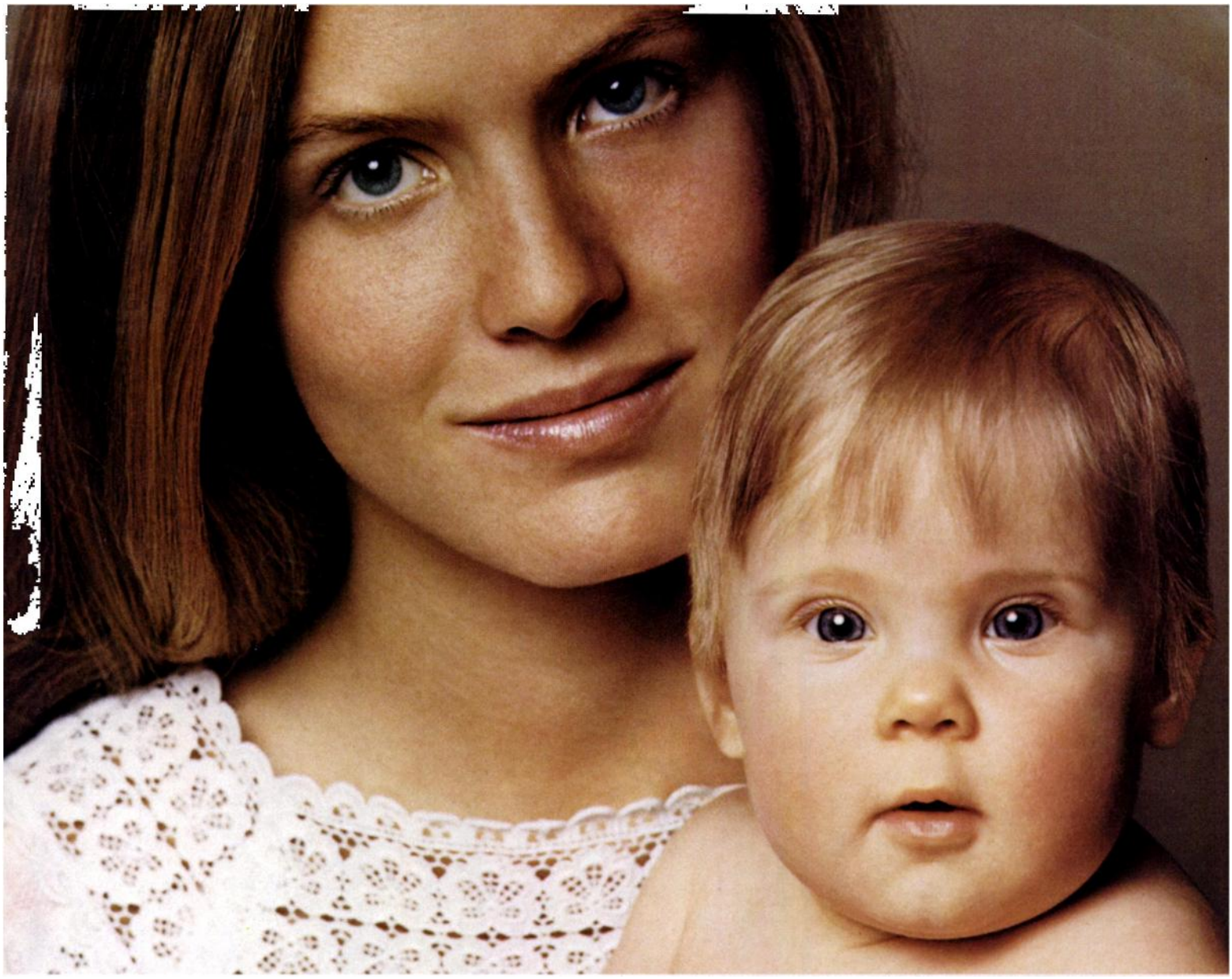
Supplied: SEPTRA TABLETS containing 80 mg trimethoprim and 400 mg sulfamethoxazole—bottles of 40, 100, 500 and 1000 tablets; unit dose pack of 100. ORAL SUSPENSION, containing the equivalent of 40 mg trimethoprim and 200 mg sulfamethoxazole in each teaspoonful (5 ml), cherry flavored—bottle of 450 ml.

Also available in double strength, oval-shaped, pink, scored tablets containing 160 mg trimethoprim and 800 mg sulfamethoxazole—bottles of 60 and unit dose packs of 100.

*Clinical results do not necessarily correspond with *in vitro* data.

†Data on file, Medical Department, Burroughs Wellcome Co.

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.

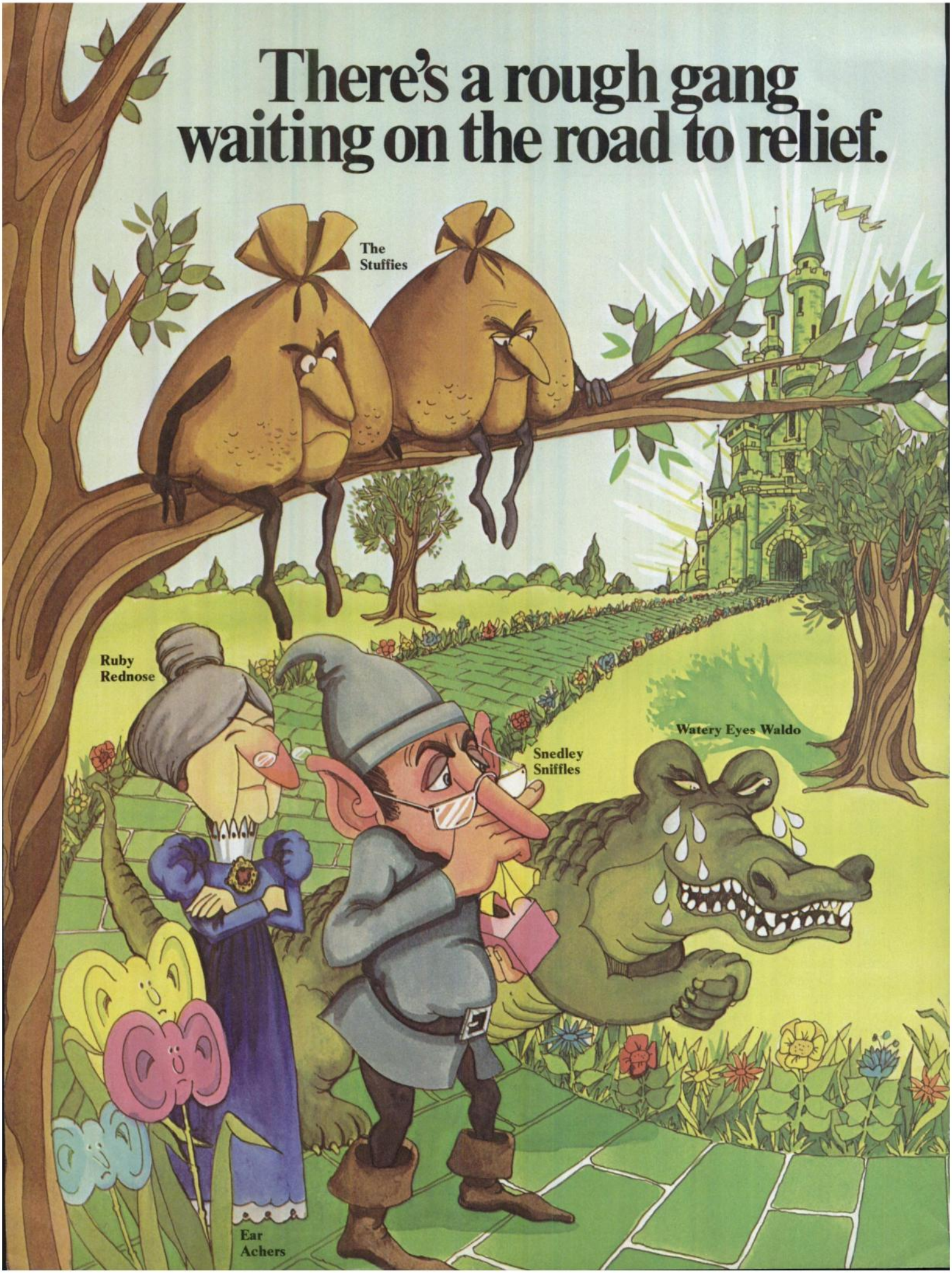
For a more in-depth discussion of this subject, as well as other aspects of infant nutrition, an educational newsletter series entitled "Dialogues in Infant Nutrition" is available. This is part of a continuing education program on infant nutrition. For copies of the newsletter, contact your Mead Johnson 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


There's a rough gang waiting on the road to relief.
The Stuffies
Ruby Rednose
Snedley Sniffles
Watery Eyes Waldo
Ear Achers

Get thru the ambush with

NOVAFED® Liquid
Decongestant and

NOVAFED® A Liquid
Decongestant Plus Antihistamine

They just love little kids. Snedley Sniffles, Watery Eyes Waldo or The Stuffies. The whole gang. Novafed Liquid and Novafed A Liquid keep Snedley and his road gang in check, for effective, fast-acting relief.

DOSAGE: Children over 12 years, 2 teaspoonfuls; 6 to 12 years, 1 teaspoonful; infants and children under 6 years, ½ teaspoonful. May be given every 4 hours. **Do not exceed 4 doses in a 24-hour period.**

Pleasant candy-stick flavor.
Children take it without fussing.

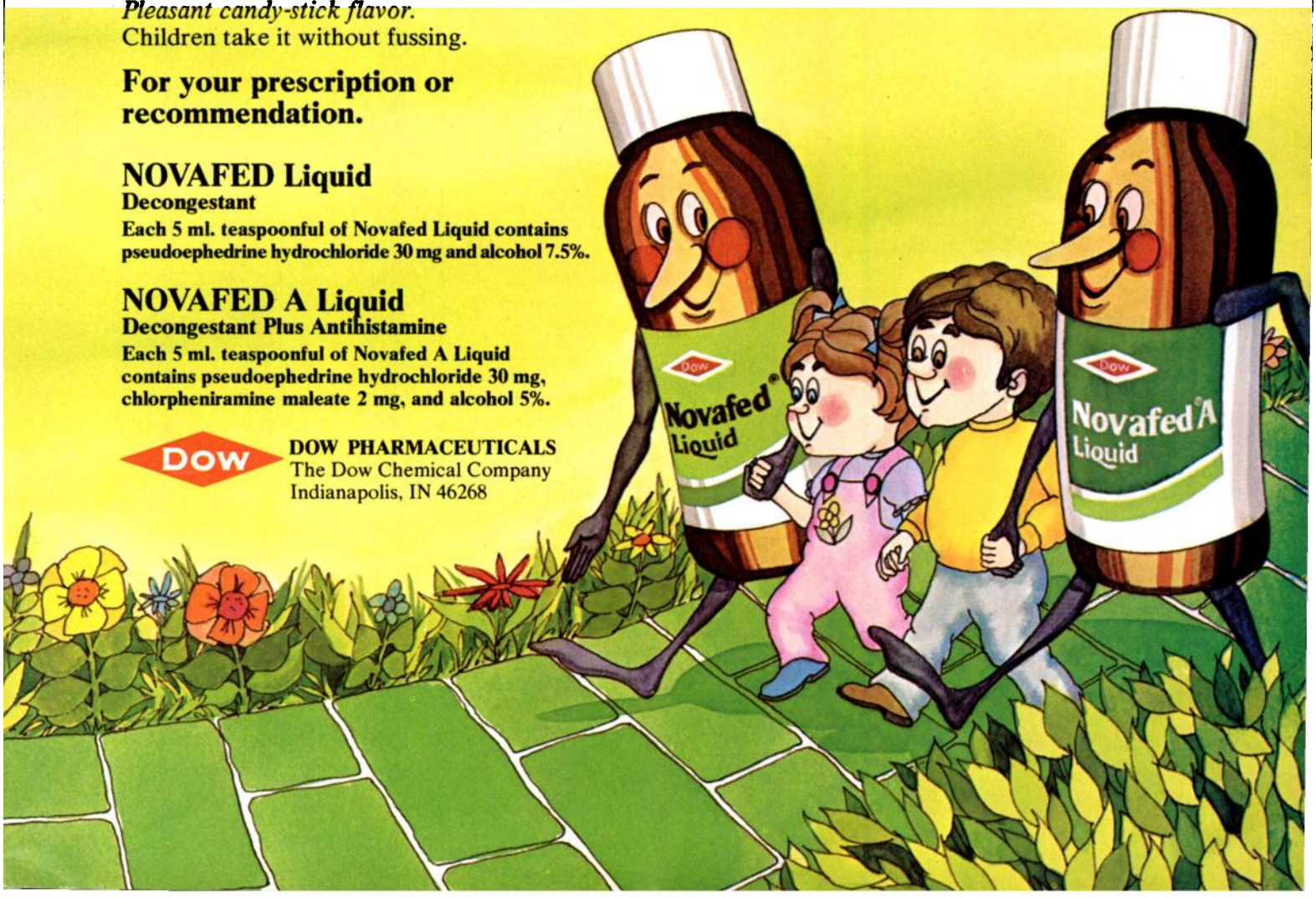
For your prescription or recommendation.

NOVAFED Liquid
Decongestant
Each 5 ml. teaspoonful of Novafed Liquid contains pseudoephedrine hydrochloride 30 mg and alcohol 7.5%.

NOVAFED A Liquid
Decongestant Plus Antihistamine
Each 5 ml. teaspoonful of Novafed A Liquid contains pseudoephedrine hydrochloride 30 mg, chlorpheniramine maleate 2 mg, and alcohol 5%.

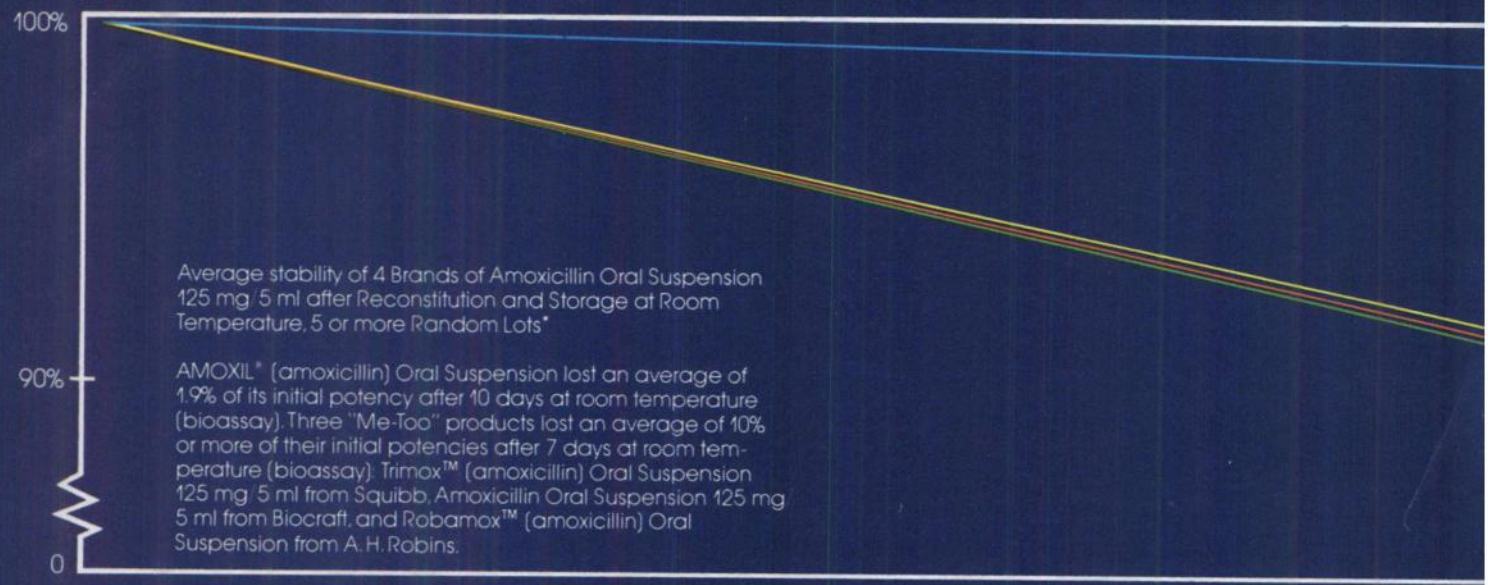
DOW

DOW PHARMACEUTICALS
The Dow Chemical Company
Indianapolis, IN 46268



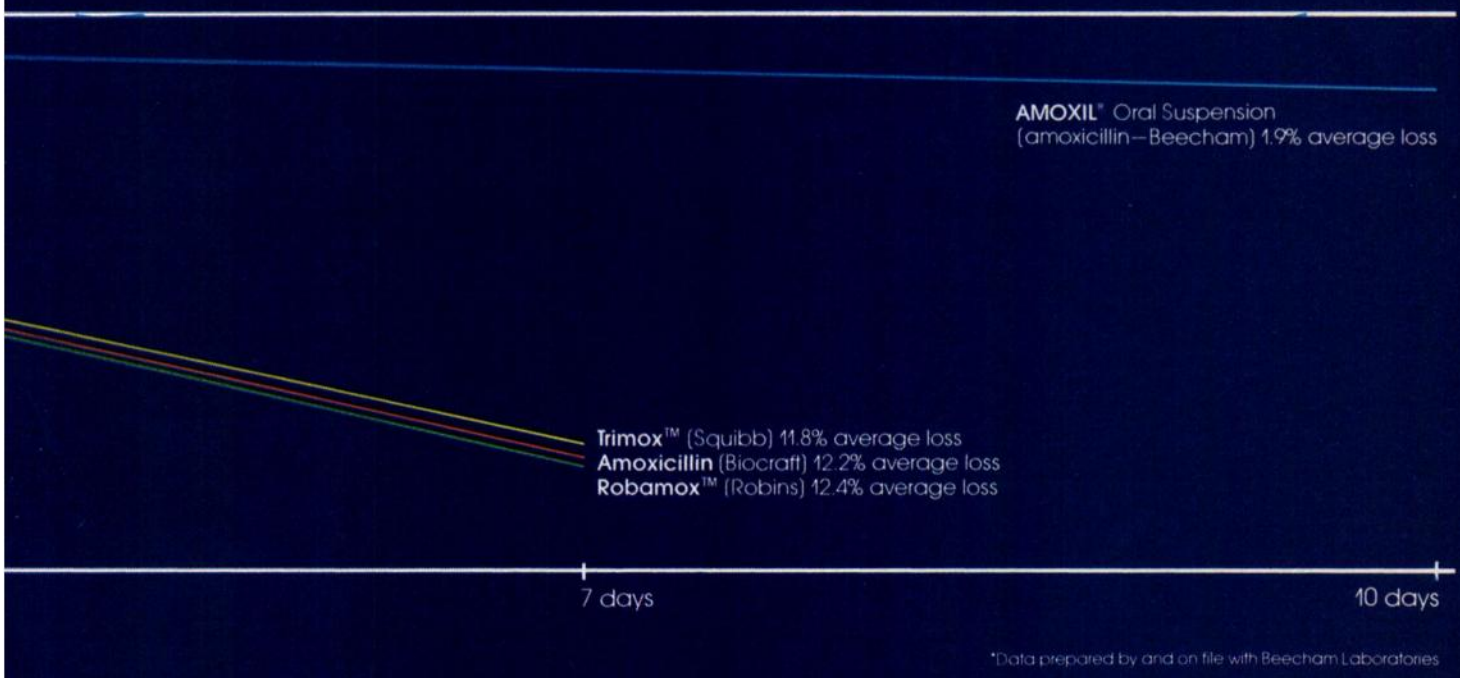
COMPARE ORAL SUSPENSION STABILITY AND SETTLING DIFFERENCES:

Amount of drug available after reconstitution



Compare the Label Differences:

AND SPECIFY "AMOXIL,"® (amoxicillin) NOT "AMOXICILLIN."



*Data prepared by and on file with Beecham Laboratories

Compare these stability curve differences:

The three "ME-TOO" amoxicillin for oral suspensions are labeled for 7 days reconstituted stability at room temperature, and bioassay results (above) show that these products lost an average of 10% or more of their initial potencies in 7 days after reconstitution when stored at room temperature. But AMOXIL® lost an average of only 1.9% of initial potency after 10 days at room temperature.

When 10-day therapy is prescribed, can you rely on a "keep in refrigerator" sticker? What if mother ignores the label? What if she forgets to refrigerate? What if the family takes a trip?

Compare the differences in suspendibility:

125 mg/5 ml amoxicillin oral suspensions...eight hours after reconstitution.

A high proportion of the amoxicillin is contained in the sediment seen on the bottom of the three "ME-TOO" products. Negligible sedimentation occurs with AMOXIL® oral suspension. What if the mother fails to "shake well" before administering a dose?

Amoxicillin was discovered and developed by Beecham. We trust that you will look upon our AMOXIL,® the innovator's brand, as deserving of your support.

Beecham laboratories

AMOXIL® (amoxicillin)

Please see next page for brief summary of prescribing information.

AMOXIL® (amoxicillin)

For complete prescribing information, consult Official Package Insert.

Indications: Amoxil® (amoxicillin) is similar to ampicillin in its bactericidal action against susceptible strains of Gram-negative organisms—H. influenzae, E. coli, P. mirabilis and N. gonorrhoeae; and Gram-positive organisms—Streptococci (including Streptococcus faecalis), D. pneumoniae and non-penicillinase-producing staphylococci. Culture and sensitivity studies should be obtained. Indicated surgical procedures should be performed.

Contraindications: A history of a previous hypersensitivity reaction to any of the penicillins is a contraindication.

Warning: Anaphylaxis may occur, particularly after parenteral administration and especially in patients with an allergic diathesis. Check for a history of allergy to penicillins, cephalosporins or other allergens. If an allergic reaction occurs, discontinue amoxicillin and institute appropriate treatment. Serious anaphylactic reactions require immediate emergency treatment with epinephrine, oxygen, intravenous steroids and airway management.

Usage in Pregnancy: Safety for use in pregnancy is not established.

Precautions: Mycotic or bacterial superinfections may occur. Cases of gonorrhea with a suspected primary lesion of syphilis should have darkfield examinations before receiving treatment. In all other cases where concomitant syphilis is suspected, monthly serological tests should be performed for a minimum of four months. Assess renal, hepatic and hematopoietic functions intermittently during long-term therapy.

Adverse reactions: Untoward reactions include: glossitis, nausea, vomiting and diarrhea, skin rashes, urticaria, exfoliative dermatitis, erythema multiforme and anaphylaxis (usually with parenteral administration). Although anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been noted, they are usually reversible and are believed to be hypersensitivity phenomena. Moderate elevations in SGOT have been noted.

Usual Dosage: Adults—250 to 500 mg orally q. 8h (depending on infection site and offending organisms). Children—20-40 mg/kg/day orally q. 8h (depending on infection site and offending organisms). Children over 20 kg should be given adult dose.

Gonorrhea, acute uncomplicated—3 Gms as a single oral dose (see PRECAUTIONS). Serious infections, such as meningitis or septicemia, should be treated with parenteral antibiotics.

Supplied:

Capsules—
250 mg in bottles of 100's and 500's, unit-dose cartons of 100.
500 mg in bottles of 50's and 500's, unit-dose cartons of 100.

for Oral Suspension—
125 mg/5 ml and 250 mg/5 ml in 80 ml, 100 ml and 150 ml bottles.

Pediatric Drops for Oral Suspension—
50 mg/ml in 15 ml bottles with calibrated dropper.

Beecham laboratories
Bristol, Tennessee 37620

Monitor for apnea without electrodes, wires, thermistors, straps, magnets or...

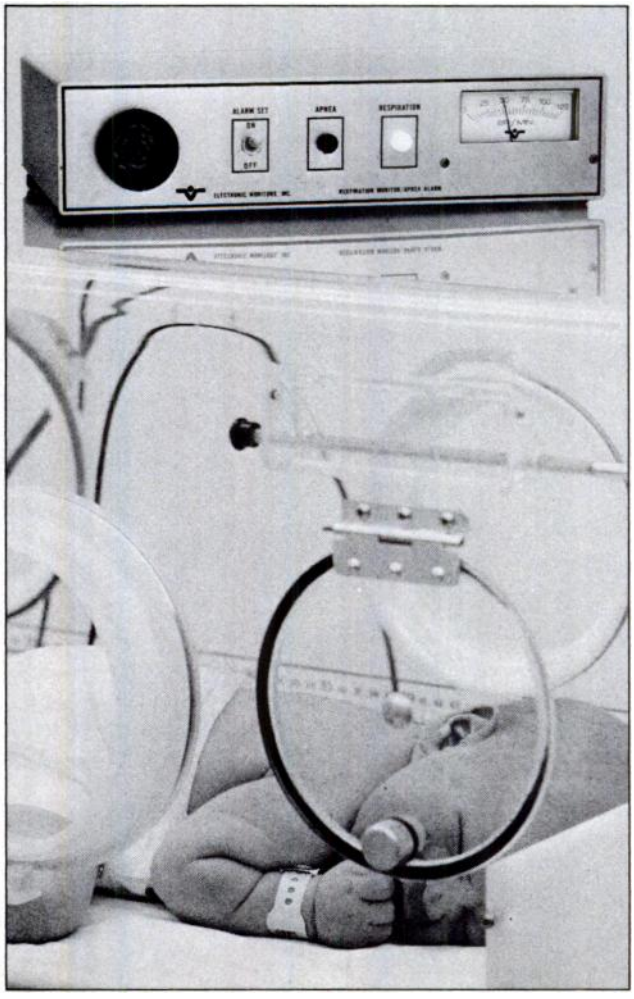
A highly sensitive transducer pad beneath the mattress detects the slightest respiratory movement. Should breathing stop, the RE-134 Apnea Monitor activates both audible and visual alarms. Alerts nurse to apnea within a pre-selectable 10, 15 or 20 seconds.

No electrodes. No wires. No weights. No irritating gels or tapes. Nothing to bother the baby . . . or hamper the nurse.

The small lightweight RE-134 console features automatic sensitivity control. Sensor pad slips easily under mattress, works reliably even when the baby's head is elevated.

For more details on the RE-134 Apnea Monitor, call your Electronic Monitors distributor. Or write Electronic Monitors, Inc., P. O. Box 8280, Fort Worth, Texas 76112; (817) 457-2747.

ELECTRONIC MONITORS, INC.



FACT 1. INTAL® (cromolyn sodium) WORKS LIKE THIS:

- It's the only truly and exclusively preventive drug in the treatment of bronchial asthma*
- It is not a bronchodilator[1]
- It is not an anti-inflammatory agent[1]
- Its mode of action is uniquely preventive! It acts *before* an asthma attack happens by preventing or decreasing the release of the chemical mediators that may trigger an attack. These include histamine and the slow reacting substance of anaphylaxis (SRS-A).

FACT 2. INTAL® (cromolyn sodium) WORKS WITH THESE PATIENTS:

- Patients with bronchial asthma which is severe enough to warrant continuous symptomatic therapy.
- Patients who have experienced a breakthrough on their first line bronchodilator medication.
- Patients who cannot tolerate the side effects produced by the xanthine or adrenergic agents they may be taking.
- Patients on steroid therapy or for whom the physician is considering steroid therapy.

FACT 3. INTAL® (cromolyn sodium) REALLY WORKS:

Years of Studies Show Reduced Symptoms[2,4,6,10,12]

- Less wheezing
- Less interruption of sleep
- Less coughing
- Less breathlessness

Better Quality of Life[3,12]

- Better attendance at school
- Fewer absentee days from work
- More freedom for an active life
- Feeling of greater well being

Measured Respiratory Improvement[5,7,13] in FEV_1, MMV, PEFR

Reduction in Concomitant Medication

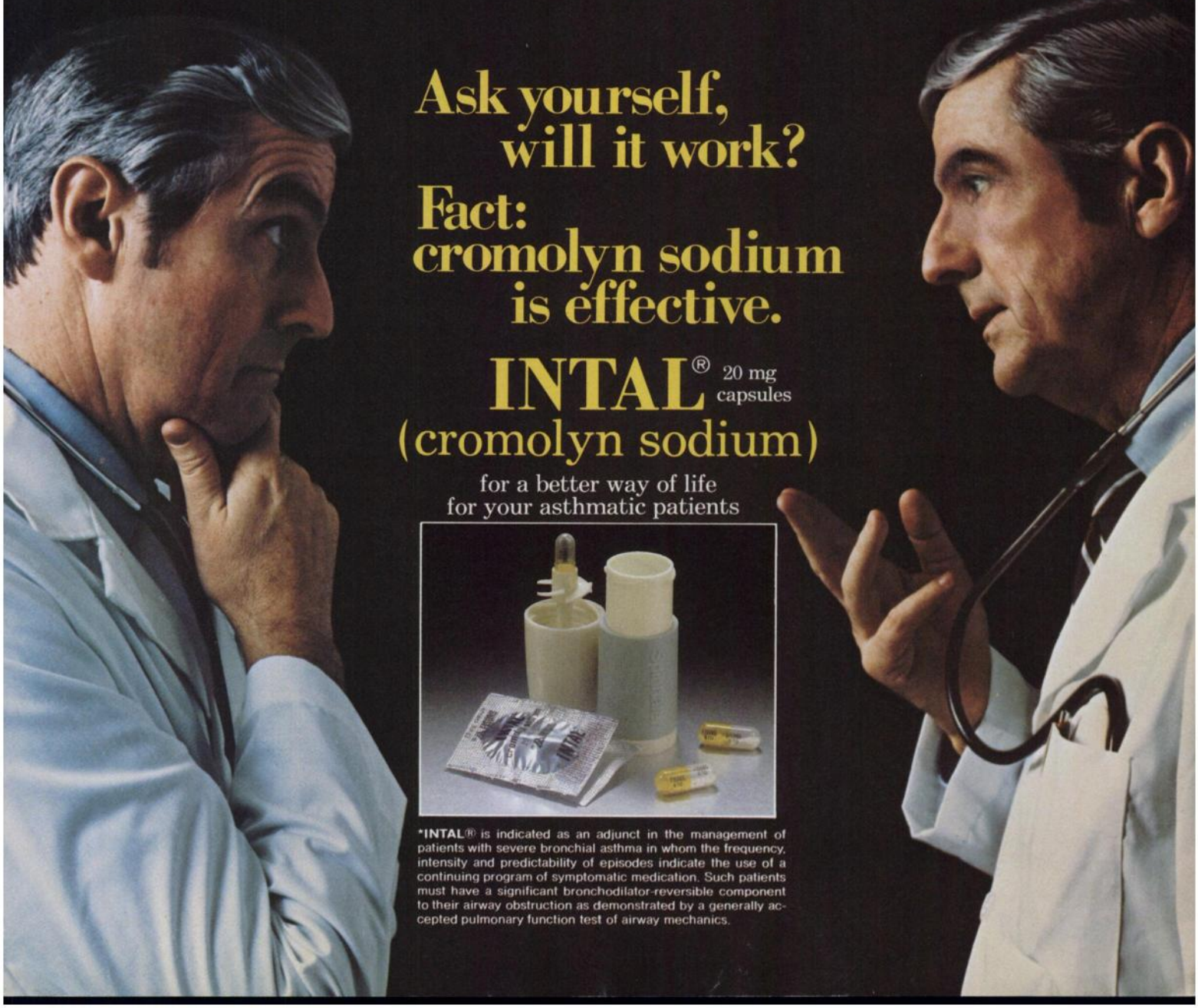
- Bronchodilators (tablets or capsules)[2,4,13,16]
- Oral Nebulizers[2,4,11]
- Steroids,[4,8,13]

INTAL® (cromolyn sodium) is further supported by the fact that it does all this with a high degree of safety, and as reported in the literature, a low incidence of side effects.[4-7,10-16]

FISONS

Fisons Corporation, Bedford, Mass. 01730

Please see following page for brief summary of prescribing information.



Ask yourself, will it work?

Fact: cromolyn sodium is effective.

INTAL® 20 mg capsules (cromolyn sodium)

for a better way of life
for your asthmatic patients

*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.

INTAL®

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

(cromolyn sodium) 20 mg capsules

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 300 capsules. SPINHALER® turbo-inhalers are supplied separately in individual containers.

CAUTION: Federal law prohibits dispensing without prescription.

October 1977

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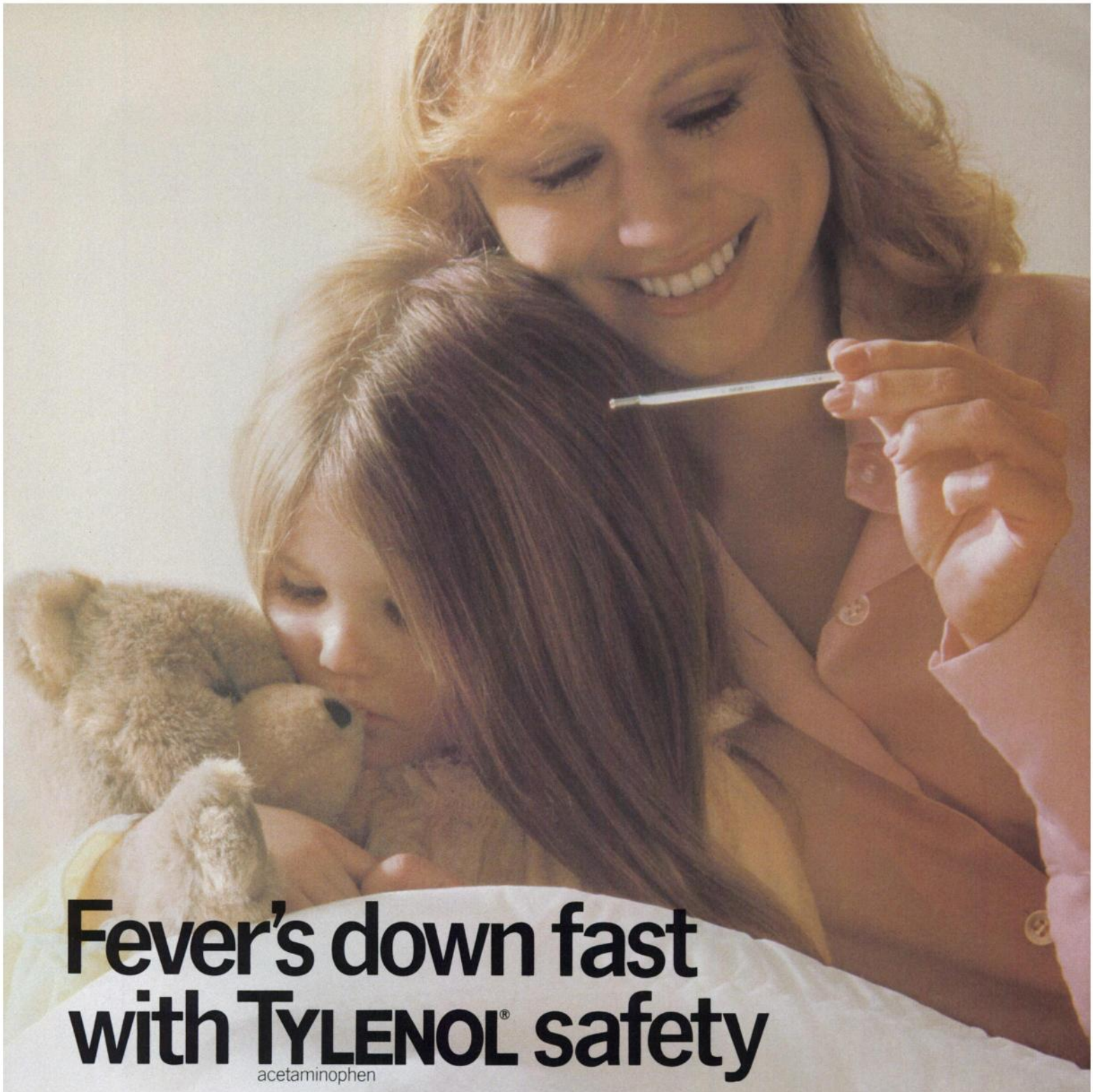

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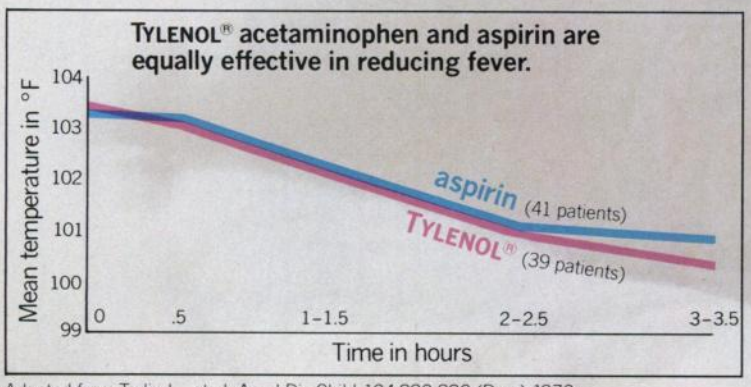

Adapted from Tarlin,L., et al: Am J Dis Child *124*:880-882 (Dec.) 1972.

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Ritalin (methylphenidate): an important element in the remedial program

Only accurate medical diagnosis can differentiate the child with MBD from the child who is simply overactive, as many normal children are, and from the child who has personality and behavioral disorders not associated with MBD.

When the diagnosis is MBD, Ritalin can prove to be an important element in a remedial program that can provide immediate and long-term benefit.

For Ritalin has demonstrated its effectiveness in reducing such manifestations as hyperactivity,[1,2] distractibility,[1] and disorganized behavior.[1]

Ritalin can help improve classroom performance, interpersonal relations

The alleviation of these symptoms often makes the child more responsive to the nonpharmacological modalities,[3] thus helping him to improve his classroom performance[2,4] and his interpersonal relations.[5,6]

Therapy with Ritalin should be considered only after a medical diagnosis of MBD has been made. Dosage should be periodically interrupted. Often these interruptions reveal some "stabilization" in the child's behavior even

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Only when medication is indicated

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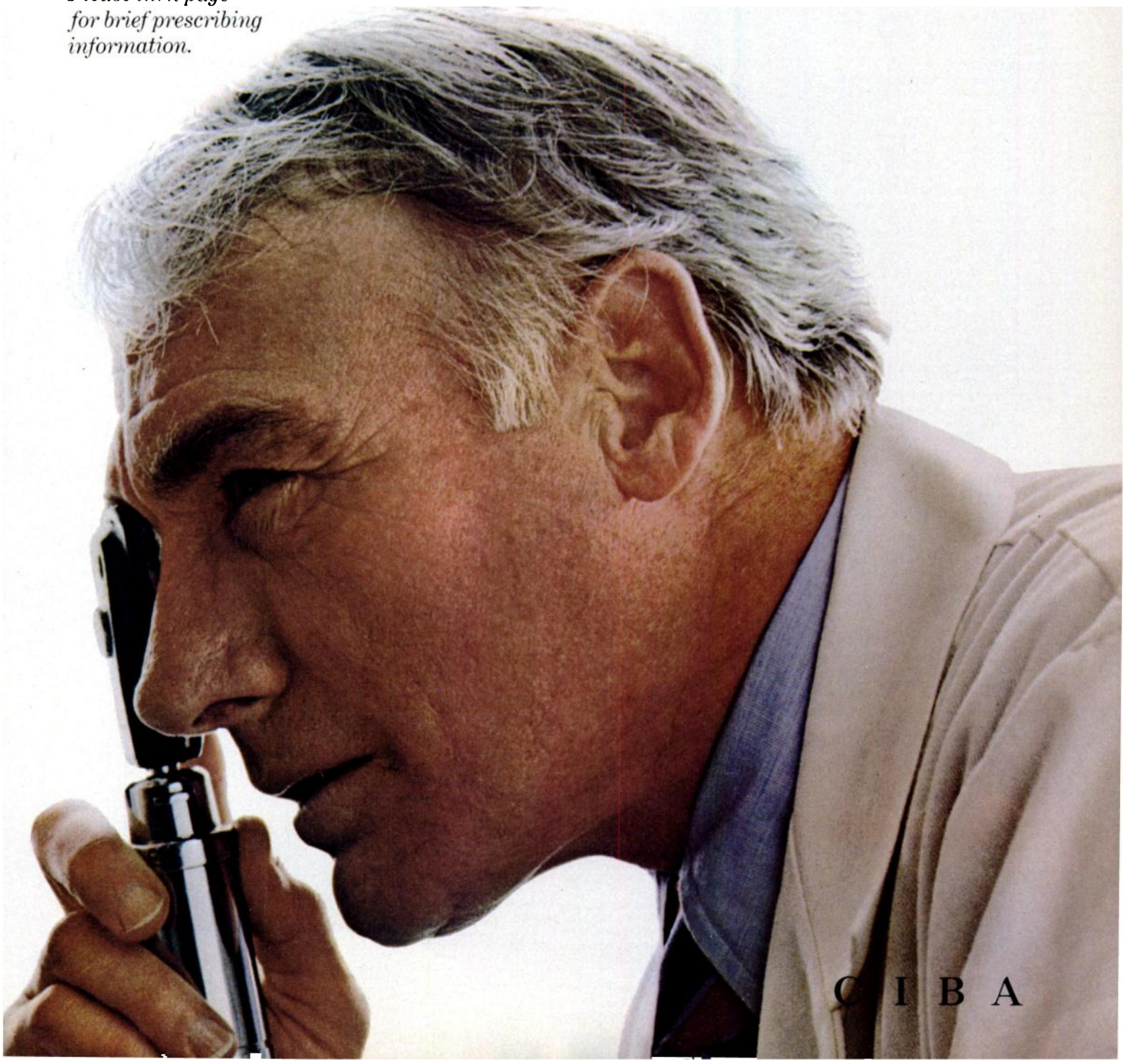

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INDICATIONS
Minimal Brain Dysfunction in Children—as adjunctive therapy to other remedial measures (psychological, educational, social)

Special Diagnostic Considerations

Specific etiology of Minimal Brain Dysfunction (MBD) is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources.

Characteristics commonly reported include: chronic history of short attention span, distractibility, emotional lability, impulsivity, and moderate to severe hyperactivity; minor neurological signs and abnormal EEG. Learning may or may not be impaired. The diagnosis of MBD must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.

Drug treatment is not indicated for all children with MBD. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.

CONTRAINDICATIONS
Marked anxiety, tension, and agitation, since Ritalin may aggravate these symptoms. Also contraindicated in patients known to be hypersensitive to the drug and in patients with glaucoma.

WARNINGS
Ritalin should not be used in children under six years, since safety and efficacy in this age group have not been established.

Sufficient data on safety and efficacy of long-term use of Ritalin in children with minimal brain dysfunction are not yet available. Although a causal relationship has not been established, suppression of growth (*ie*, weight gain and or height) has been reported with long-term use of stimulants in children. Therefore, children requiring long-term therapy should be carefully monitored.

Ritalin should not be used for severe depression of either exogenous or endogenous origin or for the prevention of normal fatigue states.

Ritalin may lower the convulsive threshold in patients with or without prior seizures, with or without prior EEG abnormalities, even in absence of seizures. Safe concomitant use of anticonvulsants and Ritalin has not been established. If seizures occur, Ritalin should be discontinued.

Use cautiously in patients with hypertension. Blood pressure should be monitored at appropriate intervals in all patients taking Ritalin, especially those with hypertension.

Symptoms of visual disturbances have been encountered in rare cases. Difficulties with accommodation and blurring of vision have been reported.

Drug Interactions

Ritalin may decrease the hypotensive effect of guanethidine. Use cautiously with pressor agents and MAO inhibitors. Ritalin may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (phenobarbital, diphenylhydantoin, primidone), phenylbutazone, and tricyclic antidepressants (imipramine, desipramine). Downward dosage adjustments of these drugs may be required when given concomitantly with Ritalin.

Usage in Pregnancy

Adequate animal reproduction studies to establish safe use of Ritalin during pregnancy have not been conducted. Therefore, until more information is available, Ritalin should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.

Drug Dependence

Ritalin should be given cautiously to emotionally unstable patients, such as those with a history of drug dependence or alcoholism, because such patients may increase dosage on their own initiative.

Chronically abusive use can lead to marked tolerance and psychic dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during drug withdrawal, since severe depression as well as the effects of chronic overactivity can be unmasked. Long-term follow-up may be required because of the patient's basic personality disturbances.

PRECAUTIONS
Patients with an element of agitation may react adversely; discontinue therapy if necessary.

Periodic CBC, differential, and platelet counts are advised during prolonged therapy.

ADVERSE REACTIONS
Nervousness and insomnia are the most common adverse reactions but are usually controlled by reducing dosage and omitting the drug in the afternoon or evening. Other reactions include: hypersensitivity (including skin rash, urticaria, fever, arthralgia, exfoliative dermatitis, erythema multiforme with histopathological findings of necrotizing vasculitis, and thrombocytopenic purpura); anorexia; nausea; dizziness; palpitations; headache; dyskinesia; drowsiness; blood pressure and pulse changes, both up and down; tachycardia; angina; cardiac arrhythmia; abdominal pain; weight loss during prolonged therapy. Toxic psychosis has been reported. Although a definite causal relationship has not been established, the following have been reported in patients taking this drug: leukopenia and/or anemia; a few instances of scalp hair loss.

In children, loss of appetite, abdominal pain, weight loss during prolonged therapy, insomnia, and tachycardia may occur more frequently; however, any of the other adverse reactions listed above may also occur.

DOSAGE AND ADMINISTRATION
Children with Minimal Brain Dysfunction (6 years and over)

Start with small doses (*eg*, 5 mg before breakfast and lunch) with gradual increments of 5 to 10 mg weekly. Daily dosage above 60 mg is not recommended. If improvement is not observed after appropriate dosage adjustment over a one-month period, the drug should be discontinued.

If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage, or, if necessary, discontinue the drug.

Ritalin should be periodically discontinued to assess the child's condition. Improvement may be sustained when the drug is either temporarily or permanently discontinued.

Drug treatment should not and need not be indefinite and usually may be discontinued after puberty.

HOW SUPPLIED
Tablets, 20 mg (peach, scored); bottles of 100 and 1000.

Tablets, 10 mg (pale green, scored); bottles of 100, 500, 1000 and Accu-Pak® blister units of 100.

Tablets, 5 mg (pale yellow); bottles of 100, 500, and 1000.

Consult complete product literature before prescribing.

C76-16 Rev. 7/76

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Tedral Suspension: each 5 ml teaspoonful of suspension contains 65 mg theophylline, 12 mg ephedrine hydrochloride, and 4 mg phenobarbital.

Tedral Elixir: each 5 ml teaspoonful contains 32.5 mg theophylline, 6 mg ephedrine hydrochloride, and 2 mg phenobarbital; alcohol content is 15%.

Indications. Tedral, Tedral Suspension and Tedral Elixir are indicated for the symptomatic relief of bronchial asthma, asthmatic bronchitis, and other bronchospastic disorders. They may also be used prophylactically to abort or minimize asthmatic attacks and are of value in managing occasional, seasonal and perennial asthma.

Tedral Suspension and Tedral Elixir are convenient for persons who may have difficulty in swallowing tablets.

These Tedral formulations are adjuncts in the total management of the asthmatic patient. Acute or severe asthmatic attacks may necessitate supplemental therapy with other drugs by inhalation or other parenteral routes.

Contraindications. Sensitivity to any of the ingredients; porphyria.

Warnings. Drowsiness may occur. PHENOBARBITAL MAY BE HABIT-FORMING.

Precautions. Use with caution in the presence of cardiovascular disease, severe hypertension, hyperthyroidism, prostatic hypertrophy, or glaucoma.

Adverse Reactions. Mild epigastric distress, palpitation, tremulousness, insomnia, difficulty of micturition, and CNS stimulation have been reported.

Average Dosage. Prophylactic or Therapeutic.

Tedral. Adults—One or two tablets every 4 hours. Children—(Over 60 lb) one-half the adult dose.

Tedral Suspension. Note: One teaspoonful is equivalent to *one-half* Tedral tablet. Adults—Two to four teaspoonfuls every 4 hours. Children—One teaspoonful per 60 lb body weight, every 4-6 hours unless prescribed otherwise by physician. Should be given to children under 2 years of age only with extreme caution.
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Tedral Elixir. Note: One teaspoonful is equivalent to *one-quarter* Tedral tablet. Children—One teaspoonful per 30 lb body weight, every 4-6 hours unless prescribed otherwise by physician. Should be given to children under 2 years of age only with extreme caution. Adults—One to two tablespoonfuls every four hours.

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VOLUME 62 • JULY 1978 • NUMBER 1

Pediatrics

ARTICLES

Tap Water Scald Burns in Children

Kenneth W. Feldman, M.D., Robert T. Schaller, M.D., Jane A. Feldman, M.Ed., *and* Mollie McMillon

From the Odessa Brown Children's Clinic and Burn Unit of the Children's Orthopedic Hospital and Medical Center and the Ambulatory Division, Department of Pediatrics, University of Washington School of Medicine, Seattle

ABSTRACT. Tap water scald burns account for 7% to 17% of all childhood scald burns that require hospitalization. Often the burns are severe and disabling. Toddlers and preschool children are the most frequent victims. In 45% of the injuries, the unsupervised victim or a peer turned on the tap water; in 28% the cause was abuse. Eighty percent of the homes tested had unsafe bathtub water temperatures of 54 C (130 F) or greater, exposing the occupants to the risk of full-thickness scalds with 30-second exposure to hot water. Such burns may be prevented passively by limiting household water temperatures to less than 52 C (125 F). New water heaters could be preset at this temperature and families could be taught to turn down the temperature on existing units. *Pediatrics* 62:1-7, 1978, *burns, accidents, child abuse.*

The most effective approaches to prevention of childhood accidents do not depend on the cooperation of the child or the person who is taking care of him. Recent examples of passive preventive techniques include flame-resistant clothing and poison-prevention packaging. Methods that require active effort (e.g., automobile safety restraints) have also reduced injury, but their effectiveness is hampered by poor compliance.

Scald burns are the most common type of thermal injury in children[1,2] and their prevention has been frustrated because of the need for active methods. Scald burns caused by hot tap water are a subgroup that has received little attention but that may be amenable to both active and passive modes of prevention. This study was undertaken to assess the magnitude of the problem and to determine the feasibility of preventive measures.

Charts of hospitalized scald burn victims and emergency surveillance data were analyzed to determine whether the characteristics of the victims and circumstances of their injuries suggested modes of prevention. Home water temperatures were surveyed to determine the frequency of exposure to dangerous water temperatures. Households were questioned about their knowledge of the risk of hot tap water, satisfaction with the quantity and temperature of their hot water, and past preventive efforts such as turning down the water heater thermostat. Pediatric health care professionals also were questioned about their knowledge of appropriate home water temperatures.

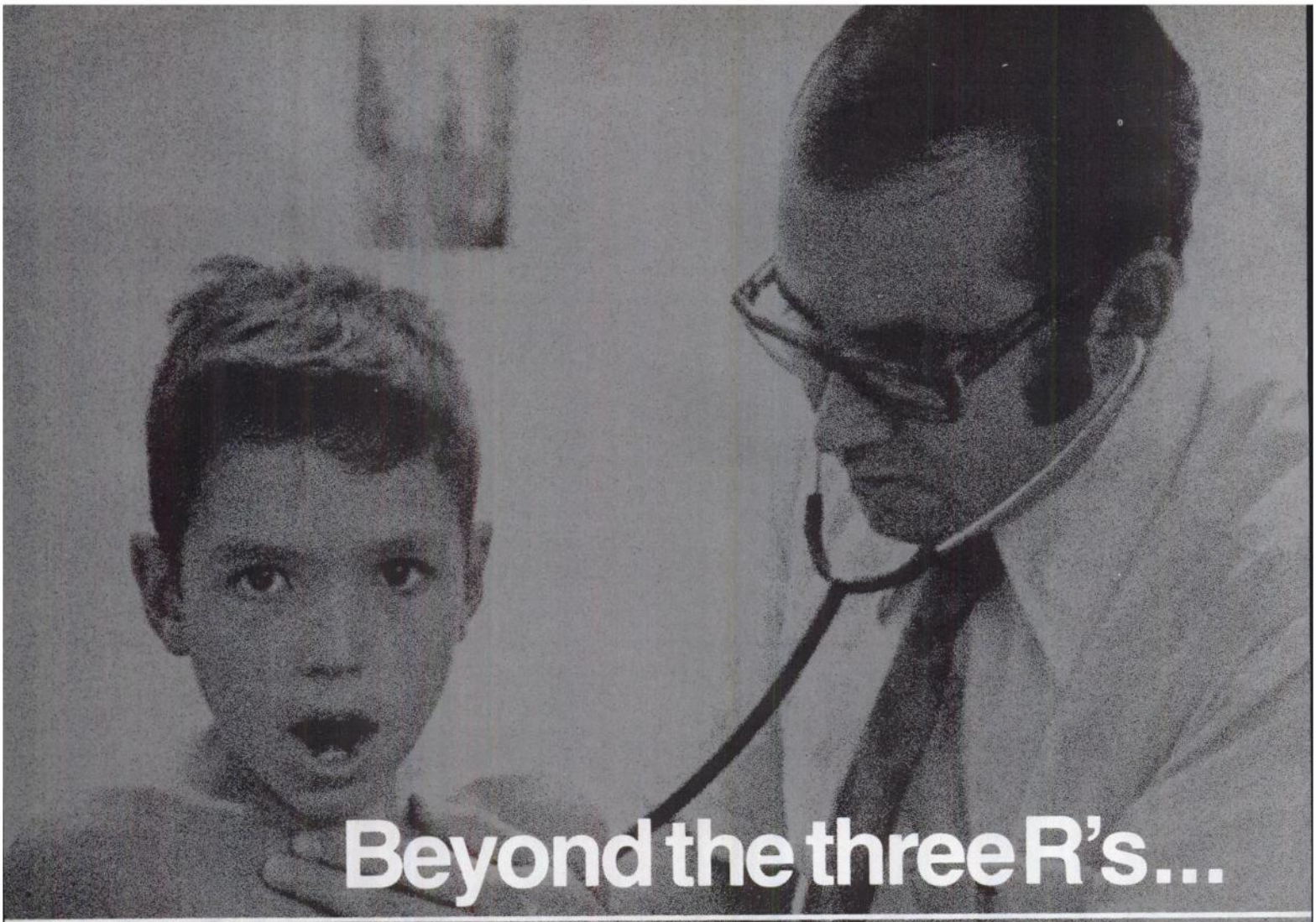
MATERIALS AND METHODS

Emergency Room Surveillance

The computer data bank of the National Electronic Injury Surveillance System (NEISS) of the

Received October 1; revision accepted for publication December 25, 1977.

ADDRESS FOR REPRINTS: (K.W.F.) Odessa Brown Children's Clinic, 2017 East Spruce Street, Seattle, WA 98122.



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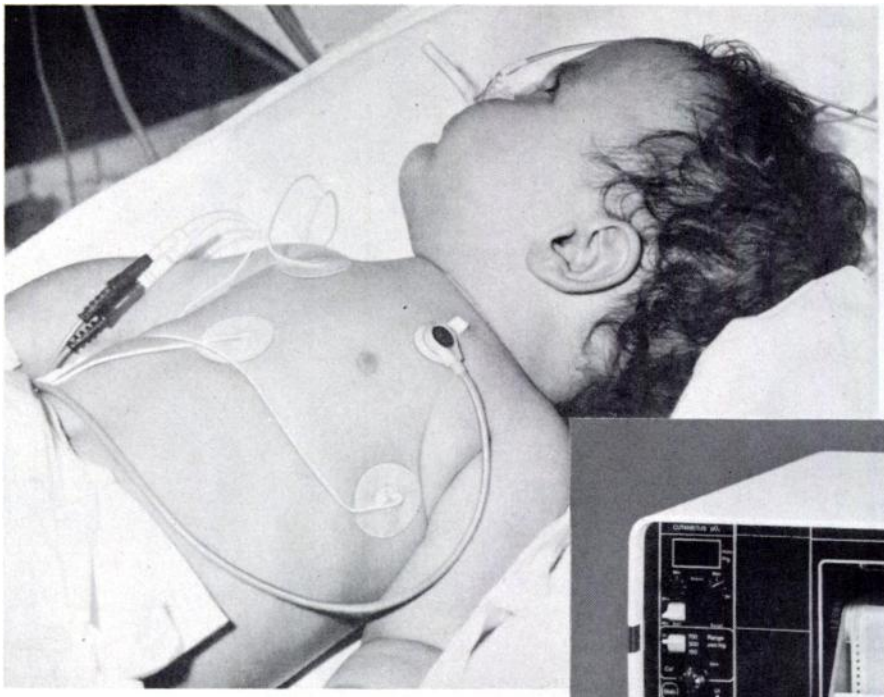

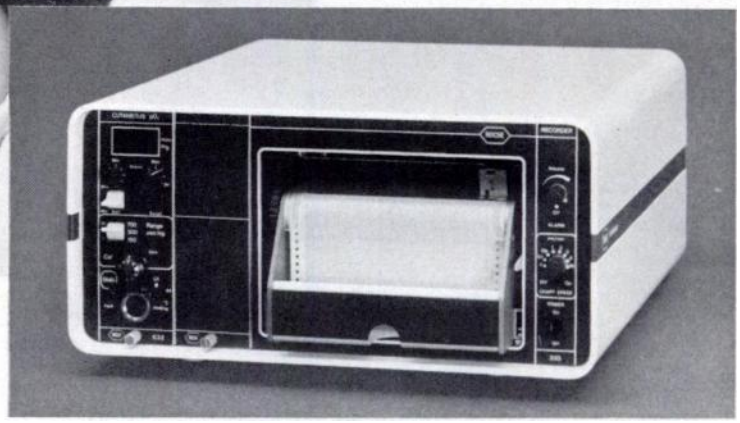

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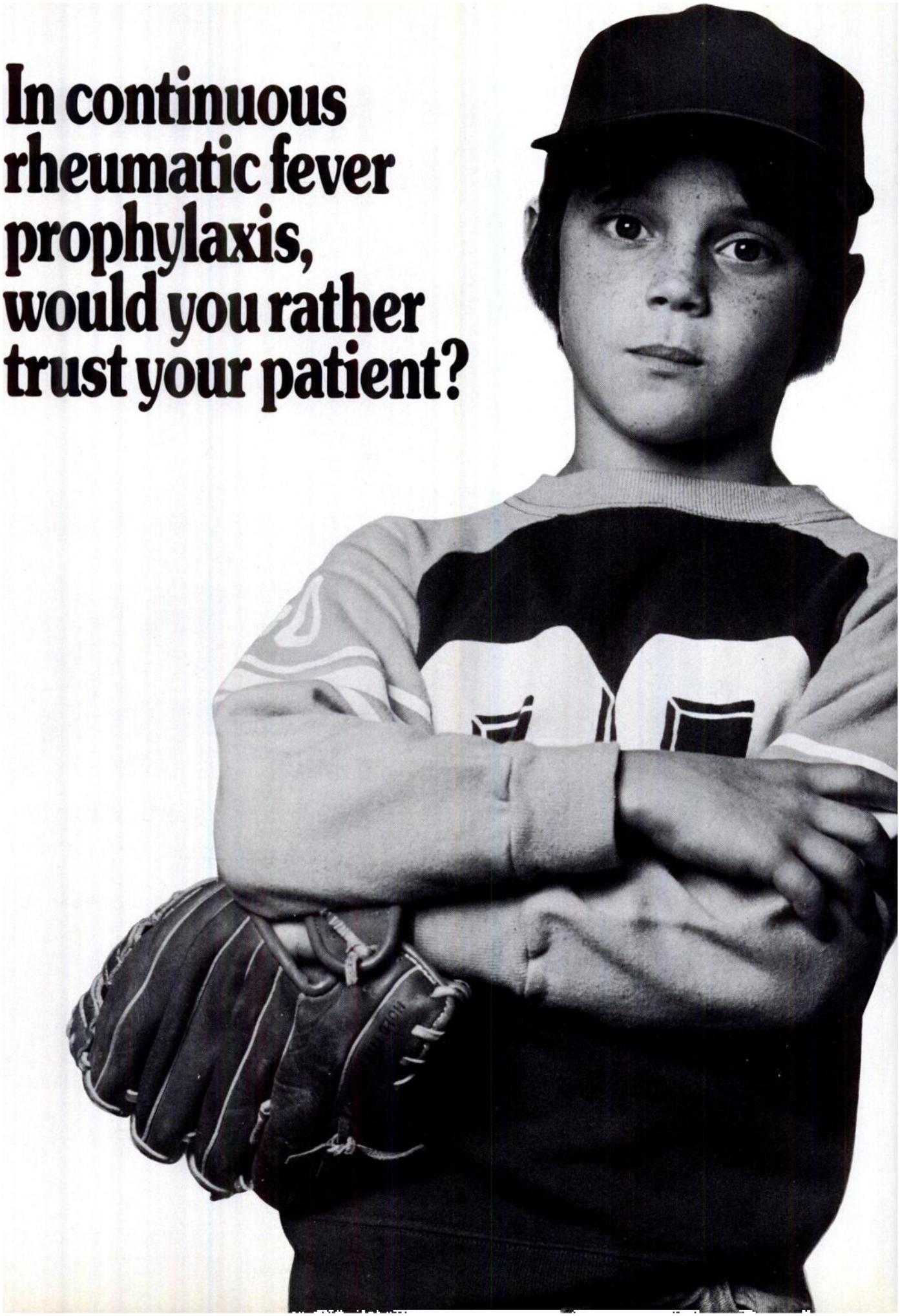

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*Rheumatic Fever Committee of the Council on Rheumatic Fever and Congenital Heart Disease of the American Heart Association.

FOR DEEP INTRAMUSCULAR INJECTION ONLY.
Indications: In treatment of infections due to penicillin G-sensitive microorganisms susceptible to the low and very prolonged serum levels common to this dosage form. Therapy should be guided by bacteriological studies (including sensitivity tests) and clinical response.

The following infections usually respond to adequate dosage of IM penicillin G benzathine.

Streptococcal infections (Group A—without bacteremia). Mild to moderate upper respiratory infections (e.g., pharyngitis).

Venereal infections —Syphilis, yaws, bejel, and pinta.

Medical conditions in which penicillin G benzathine therapy is indicated as prophylaxis:

Rheumatic fever and/or chorea —Prophylaxis with penicillin G benzathine has proven effective in preventing recurrence of these conditions. It has also been used as followup prophylactic therapy for rheumatic heart disease and acute glomerulonephritis.

Contraindications: Previous hypersensitivity reaction to any penicillin.

Warnings: Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported. Anaphylaxis is more frequent following parenteral therapy but has occurred with oral penicillins. These reactions are more apt to occur in individuals with history of sensitivity to multiple allergens. Severe hypersensitivity reactions with cephalosporins have been well documented in patients with history of penicillin hypersensitivity. Before penicillin therapy, carefully inquire into previous hypersensitivity to penicillins, cephalosporins and other allergens. If allergic reaction occurs, discontinue drug and treat with usual agents, e.g., pressor amines, antihistamines and corticosteroids.

Precautions: Use cautiously in individuals with histories of significant allergies and/or asthma.

Carefully avoid intravenous or intraarterial use, or injection into or near major peripheral nerves or blood vessels, since such injection may produce neurovascular damage.

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

Prolonged use of antibiotics may promote overgrowth of non-susceptible organisms including fungi. Take appropriate measures if superinfection occurs.

Adverse Reactions: Hypersensitivity reactions reported are skin eruptions (maculopapular to exfoliative dermatitis), urticaria and other serum sickness-like reactions, laryngeal edema and anaphylaxis. Fever and eosinophilia may frequently be only reaction observed. Hemolytic anemia, leucopenia, thrombocytopenia, neuropathy and nephropathy are infrequent and usually associated with high parenteral doses.

As with other antisyphilitics, Jarisch-Herxheimer reaction has been reported.

Composition: (units penicillin G benzathine as active ingredient in aqueous suspension): 300,000 units per ml.—10-ml. multi-dose vial. Each ml. also contains sodium citrate buffer, approximately 6 mg. lecithin, 3 mg. povidone, 1 mg. carboxymethylcellulose, 0.5 mg. sorbitan monopalmitate, 0.5 mg. polyoxyethylene sorbitan monopalmitate, 1.2 mg. methylparaben and 0.14 mg. propylparaben.

600,000 units in 1-ml. TUBEX® (sterile cartridge-needle unit) Wyeth, packages of 10.

900,000 units, 1.5-ml. fill in 2-ml. TUBEX, packages of 10.

1,200,000 units in 2-ml. TUBEX, packages of 10, and in 2-ml. single-dose disposable syringe, package of 10.

2,400,000 units in 4-ml. single-dose disposable syringe, packages of 10.

Each TUBEX or disposable syringe also contains sodium citrate buffer and, as w/v, approximately 0.5% lecithin, 0.6% carboxymethylcellulose, 0.6% povidone, 0.1% methylparaben and 0.01% propylparaben.

INJECTION
Bicillin® L-A
(sterile penicillin G benzathine suspension)

Once-a-month rheumatic fever prophylaxis.

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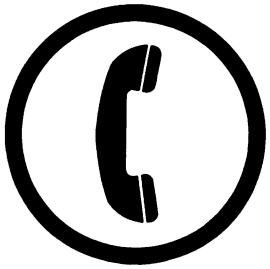

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Most Physicians Have Patients Who Need a Bowel Retraining Program

Introducing the Fleet Bowel Retraining Program

For the Patient Who Needs Bowel Retraining: Immediate Results Without Systemic Involvement.

For the chronically constipated patient, a bowel retraining program may offer a solution to the problem of oral laxative dependence. The Fleet Bowel Retraining Program is excellent in its systematic and physiologic approach which includes the use of diet and exercise combined with the concurrent use of Fleet Enema for a short initial period.

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- Take one Fleet® Enema daily, at intervals of two or three days, until normal defecation reflexes have been re-established. Fleet® Enema combats the oral laxative habit with its physiologic mode of action and lack of oral administration. The enema is known " . . . to cleanse only the distal colon and thus . . . it most nearly approximates, in its results, a normal bowel movement."[1]
- Establish dietary habits that will facilitate regularity. This includes increasing fluid intake and eating such foods as bran, whole grains, leafy vegetables and fruits.
- Increase exercise and activity level. Daily exercise is an important part of the program because it helps maintain good muscle tone throughout the body, including the intestinal tract.

As with any habit that has taken time to develop, chronic constipation can't be changed overnight. During the retraining period, Fleet Enema may be taken at intervals to combat any tendency to lapse back to oral laxatives until good bowel habits are re-established.

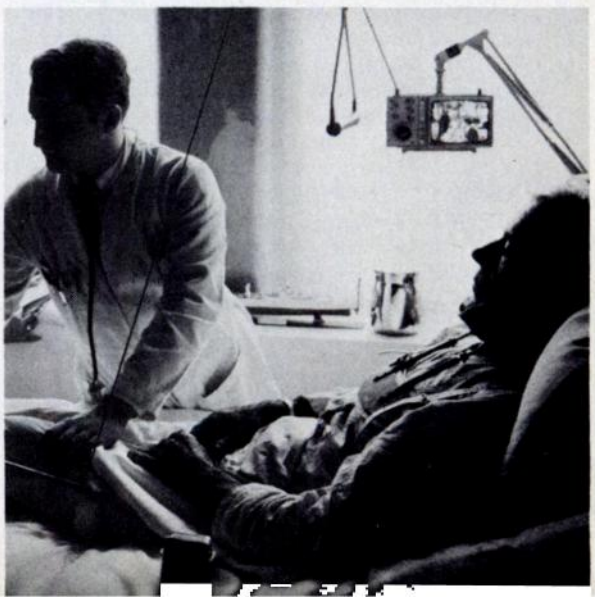
And for the Acute Patient with Immediate Needs: Avoid Oral Laxative Introduction.

When an acutely ill patient needs immediate relief from constipation, you can prescribe an oral laxative for him and his symptoms will be relieved promptly. But you may be needlessly setting him on the road to chronic laxative dependence by unnecessarily involving his whole system. Don't let him get started down that road in the first place.

Think, instead, of recommending a short-term solution. Prescribe Fleet Enema promptly for a short (3-day) period and provide immediate relief without the risk of oral laxative dependence. Fleet Enema now so he won't need retraining later.

- Physiologic Mode of Action
- Not Orally Administered
- No Systemic Involvement

[1]Steinberg H, Almy TP: *Drugs of Choice* 1964–1965, Modell (ed), Saint Louis, C V Mosby Co, 1964, p 351.



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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 capsules, USP)

Brief Summary of Prescribing Information.
Benadryl (diphenhydramine hydrochloride capsules, USP)
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; dermographism; as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled
Antiemetic: 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

Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the other indications as follows.
"Probably" effective: **Antihistaminic:** Mild, local allergic reactions to insect bites; physical allergy; minor drug and serum reactions characterized by pruritus
Sedation: For intractable insomnia and insomnia predominant in certain medical disorders
Final classification of the less-than-effective indications requires further investigation.

CONTRAINDICATIONS—This drug should not be used in premature or newborn infants. Do not use in patients with:

Hypersensitivity to diphenhydramine hydrochloride	Prostatic hypertrophy
Asthmatic attack	Stenosing peptic ulcer
Narrow-angle glaucoma	Pyloroduodenal obstruction
	Bladder-neck obstruction

Preparations containing diphenhydramine hydrochloride should not be given to patients receiving monoamine oxidase inhibitors.
WARNINGS—Overdosage or accidental ingestion of large quantities of antihistamines may produce convulsions or death, especially in infants and children. As in the case of other preparations containing central nervous system depressant drugs, patients receiving diphenhydramine hydrochloride should be cautioned about probable additive effects with alcohol and other central nervous system depressants (hypnotics, sedatives, and tranquilizers).
Patients who become drowsy on diphenhydramine hydrochloride should be cautioned against engaging in activities requiring mental alertness, such as driving a car or operating heavy machinery or appliances.
Pregnancy Warning: Although there is no evidence that the use of diphenhydramine hydrochloride is detrimental to the mother or fetus, the use of any drug in pregnancy or lactation should be carefully assessed.
As with all anticholinergic drugs, an inhibitory effect on lactation may occur.
PRECAUTIONS—Diphenhydramine has an atropine-like action which should be considered when prescribing diphenhydramine hydrochloride. Use with caution in patients with a history of asthma.
ADVERSE REACTIONS—The following side effects may occur in patients taking diphenhydramine hydrochloride: drowsiness; confusion; nervousness; restlessness; nausea; vomiting; diarrhea; blurring of vision; diplopia; difficulty in urination; constipation; tightness of the chest and wheezing; thickening of bronchial secretions; dryness of mouth, nose, and throat; tingling, heaviness, weakness of hands; nasal stuffiness; vertigo; palpitation; headache; insomnia; urticaria; drug rash; photosensitivity; hemolytic anemia; hypotension; epigastric distress; anaphylactic shock.
DOSAGE AND ADMINISTRATION—A single oral dose of diphenhydramine hydrochloride is quickly absorbed, with maximum activity occurring in approximately one hour. The duration of activity following an average dose of Benadryl (diphenhydramine hydrochloride, USP) is from four to six hours.
The usual adult dosage is 50 mg three or four times daily.
Children (over 20 lb): 12.5 to 25 mg three or four times daily.
Maximum daily dosage not to exceed 300 mg. For physicians who wish to calculate the dose on the basis of body weight or surface area, the recommended dosage is 5 mg/kg/24 hours or 150 mg/m^2/24 hours.
The basis for determining the most effective dosage regimen will be the response of the patient to medication and the condition under treatment.
In motion sickness, full dosage is recommended for prophylactic use, the first dose to be given 30 minutes before exposure to motion and similar doses before meals and upon retiring for the duration of exposure. **RG**

PD-JA-2303-1-P(3-78)

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New from Westwood Pharmaceuticals

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For prompt clinical improvement in corticosteroid-responsive dermatoses

89% of patients with atopic dermatitis on WestCort™ therapy showed clinical improvement.* 44% of all patients cleared.

Eight double blind, bilateral controlled clinical trials* were conducted involving 126 patients with atopic dermatitis. Duration of treatment varied from 7 to 28 days and dosage was 2 to 3 times daily. Studies compared WestCort to various agents, including placebo.

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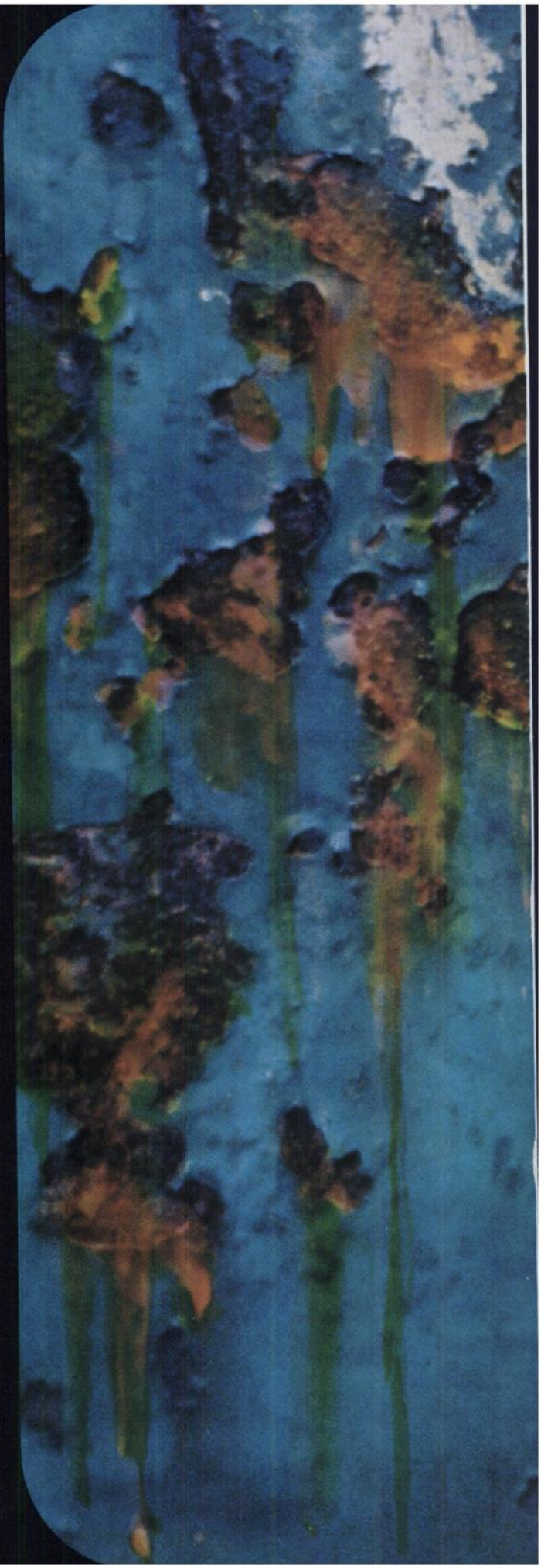
The most important symptoms to the patient are usually pruritus and erythema. In separate studies involving 31 patients with atopic dermatitis, 94% experienced a reduction in these symptoms after approximately two weeks of therapy.



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• Effective
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Unique all-purpose cream vehicle enhances steroid release and optimizes epidermal penetration

- Effective for corticosteroid-responsive dermatoses.
- Emollient cream is light-textured, water miscible, and non-greasy.
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- Less expensive than many of the most frequently prescribed fluorinated and non-fluorinated corticosteroids available.
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*Information on file at Westwood Pharmaceuticals Inc.

Please see following page for complete prescribing information.

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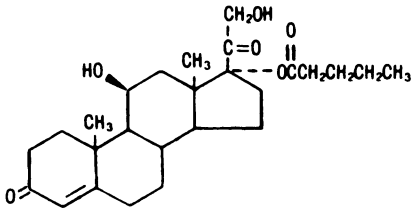
CAUTION: Federal law prohibits dispensing without prescription.

WestCort™

(HYDROCORTISONE VALERATE) CREAM, 0.2%

DESCRIPTION: Westcort Cream contains hydrocortisone valerate, an active, non-fluorinated ester of the corticosteroid hydrocortisone. It has the following chemical name: 11 β,21-dihydroxy-17α-valeryloxy-4-pregnene-3, 20-dione.

The structural formula is:



Each gram of Westcort Cream contains 2.0 mg. hydrocortisone valerate in a hydrophilic base composed of white petrolatum, stearyl alcohol, propylene glycol, amphoteric-6, carbomer 940, sodium phosphate, sodium lauryl sulfate, sorbic acid (as preservative) and water.

ACTIONS: Westcort (hydrocortisone valerate) Cream is effective primarily because of its anti-inflammatory, anti-pruritic, and vasoconstrictive actions.

INDICATIONS: Westcort Cream is intended for the relief of the inflammatory manifestations of corticosteroid responsive dermatoses.

CONTRAINDICATIONS: Topical steroids are contraindicated in viral diseases of the skin, such as vaccinia and varicella. Topical steroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation. Westcort Cream is not for ophthalmic use.

PRECAUTIONS: If irritation develops, use of the product should be discontinued and appropriate therapy instituted.

In the presence of infection, an appropriate antifungal or antibacterial agent should be administered concomitantly. If a favorable response does not occur promptly, the steroid should be discontinued until the infection has been adequately controlled.

If extensive areas are treated, or if occlusive dressings are used, the possibility exists of increased systemic absorption of the steroid, and suitable precautions should be taken.

Although topical steroids have not been reported to have an adverse effect on the fetus, the safety of their use during pregnancy has not been definitely established. Therefore, they should not be used extensively, in large amounts, or for prolonged periods of time on pregnant patients.

ADVERSE REACTIONS: The following local adverse reactions have been reported with the use of topical corticosteroids: burning sensations, itching, irritation, dryness, folliculitis, secondary infection, skin atrophy, striae, hypertrichosis, acneiform eruptions, and hypopigmentation.

If occlusion is used, it should be noted that the following side effects have been reported with topical steroids used in this manner: maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

DOSAGE AND ADMINISTRATION: A small amount should be massaged gently into the affected areas 2 to 3 times daily, as needed.

HOW SUPPLIED: Westcort (hydrocortisone valerate) Cream, 0.2% is supplied in 15 g., NDC 0072-8100-15; 45 g., NDC 0072-8100-45; and 60 g., NDC 0072-8100-60 tubes.

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The Committee on Fetus and Newborn recommends regionalization of perinatal care so all patients, especially those at risk, can be cared for in a facility best suited to handle them. Included in this edition of *Standards and Recommendations for Hospital Care of Newborn Infants* are guidelines for setting up networks of perinatal services to provide care for all mothers and infants within a region.

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This book was written for anyone involved with or interested in improving maternal, fetal, and neonatal health care.

Indexed; 178 pages.

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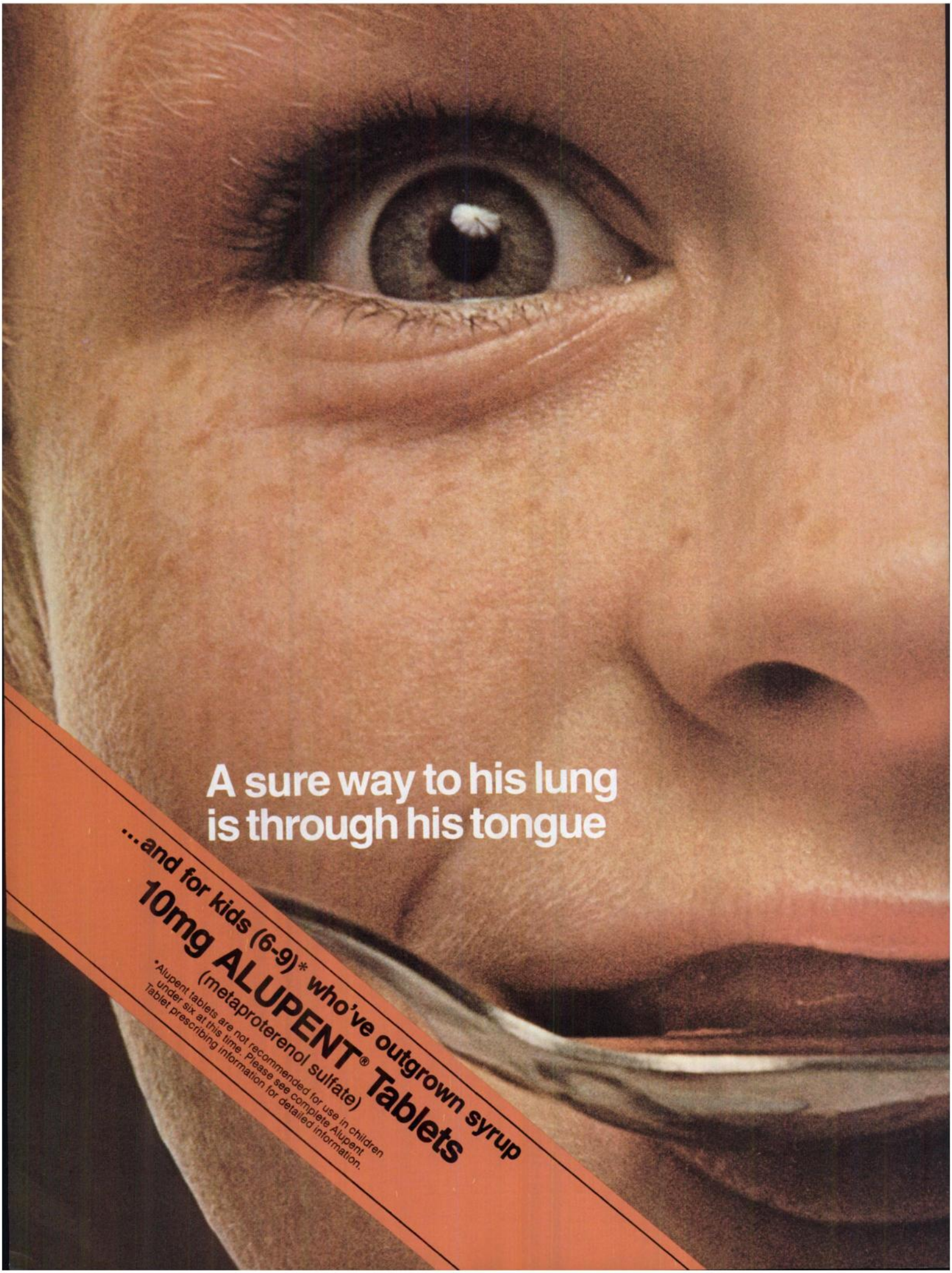
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Alupent® Syrup
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10 mg/5 ml

Indications: Bronchial asthma and reversible bronchospasm which may occur in association with bronchitis and emphysema.

Contraindications: Cardiac arrhythmias associated with tachycardia.

Precautions: Use extreme care when administering additional sympathomimetic drugs. Sufficient time should elapse before administering another sympathomimetic agent. Use great caution with metaproterenol sulfate and other sympathomimetics in patients with hypertension, coronary artery disease, congestive heart failure, hyperthyroidism and diabetes, or when there is sensitivity to sympathomimetic amines.

Usage in Pregnancy: Safety in pregnancy has not been established. Do not use except with caution, weighing patient benefit against potential risk to fetus.

Studies in mice, rabbits and rats have shown no significant teratogenic effects at oral doses up to 50 mg/kg (310 times the recommended daily human inhalational dose and 31 times the recommended daily human oral dose). In rabbits, fetal loss and teratogenic effects have been observed at and above oral doses of 50 and 100 mg/kg, respectively.

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Symptoms of Overdosage: The symptoms of overdosage are those of excessive beta-adrenergic stimulation listed under Adverse Reactions.

How Supplied: Cherry-flavored syrup, 10 mg per teaspoonful (5 ml), in 16 oz bottles.

Also available as 20 mg tablets in bottles of 100 and as a micronized powder in a 15 ml metered dose inhaler.

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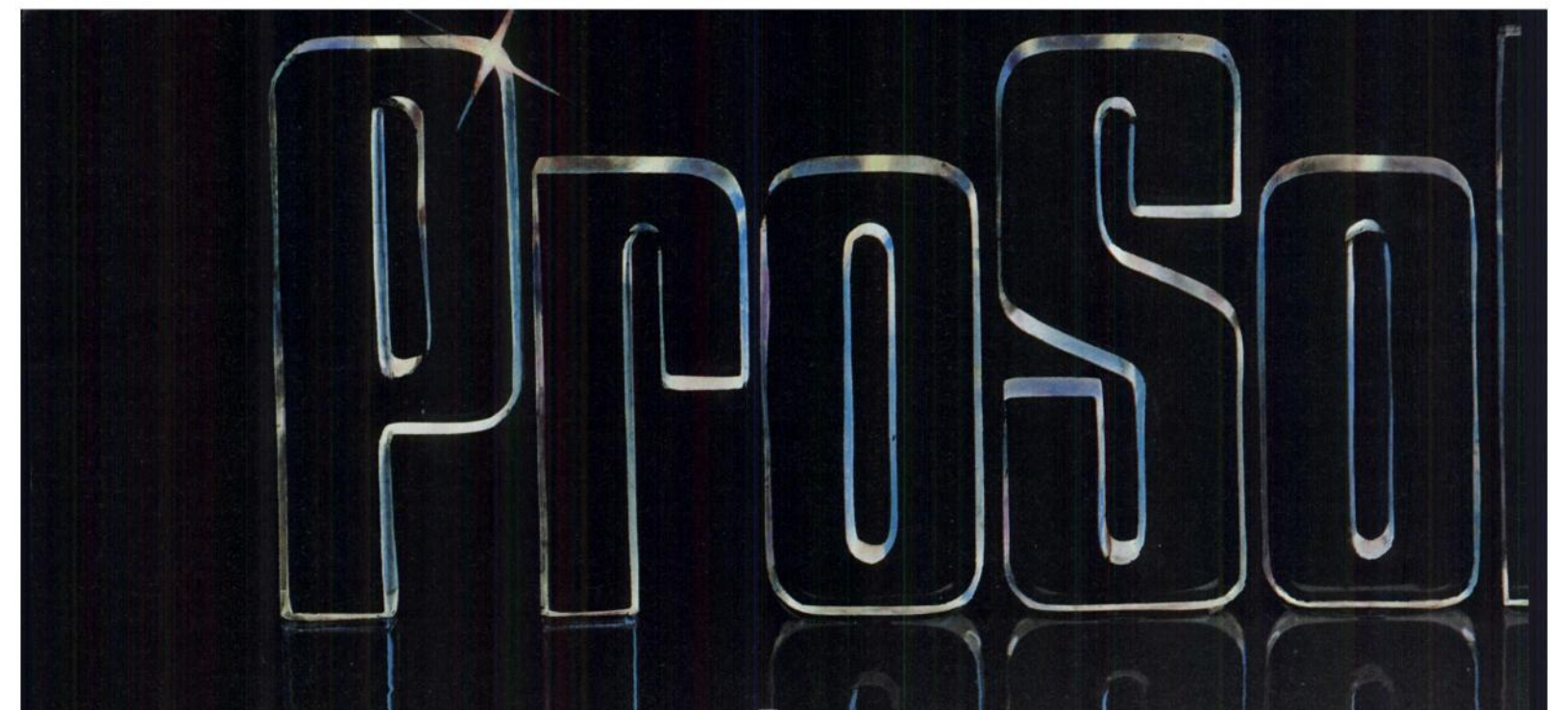

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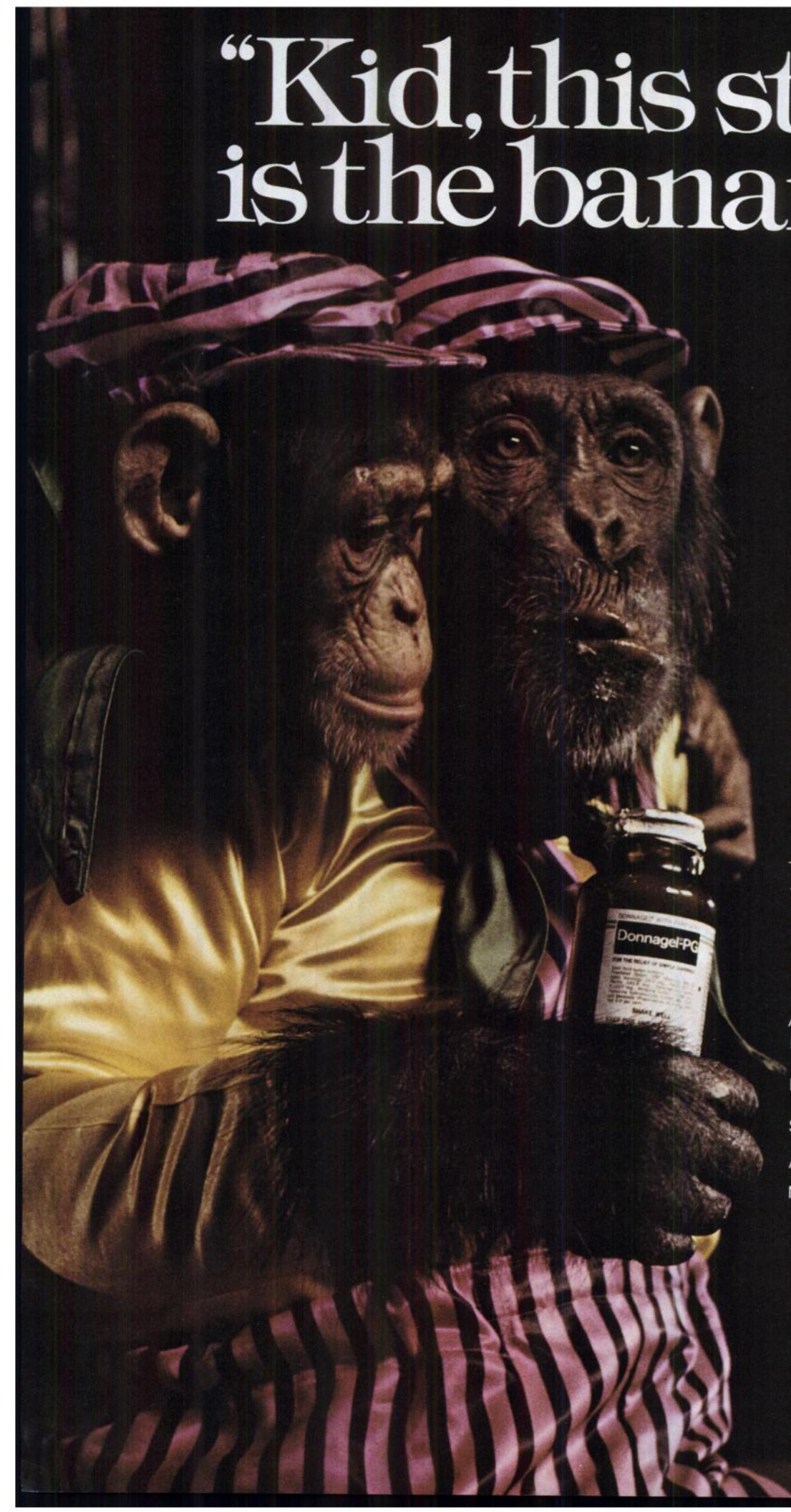

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Hyoscine hydrobromide	0.0065 mg.
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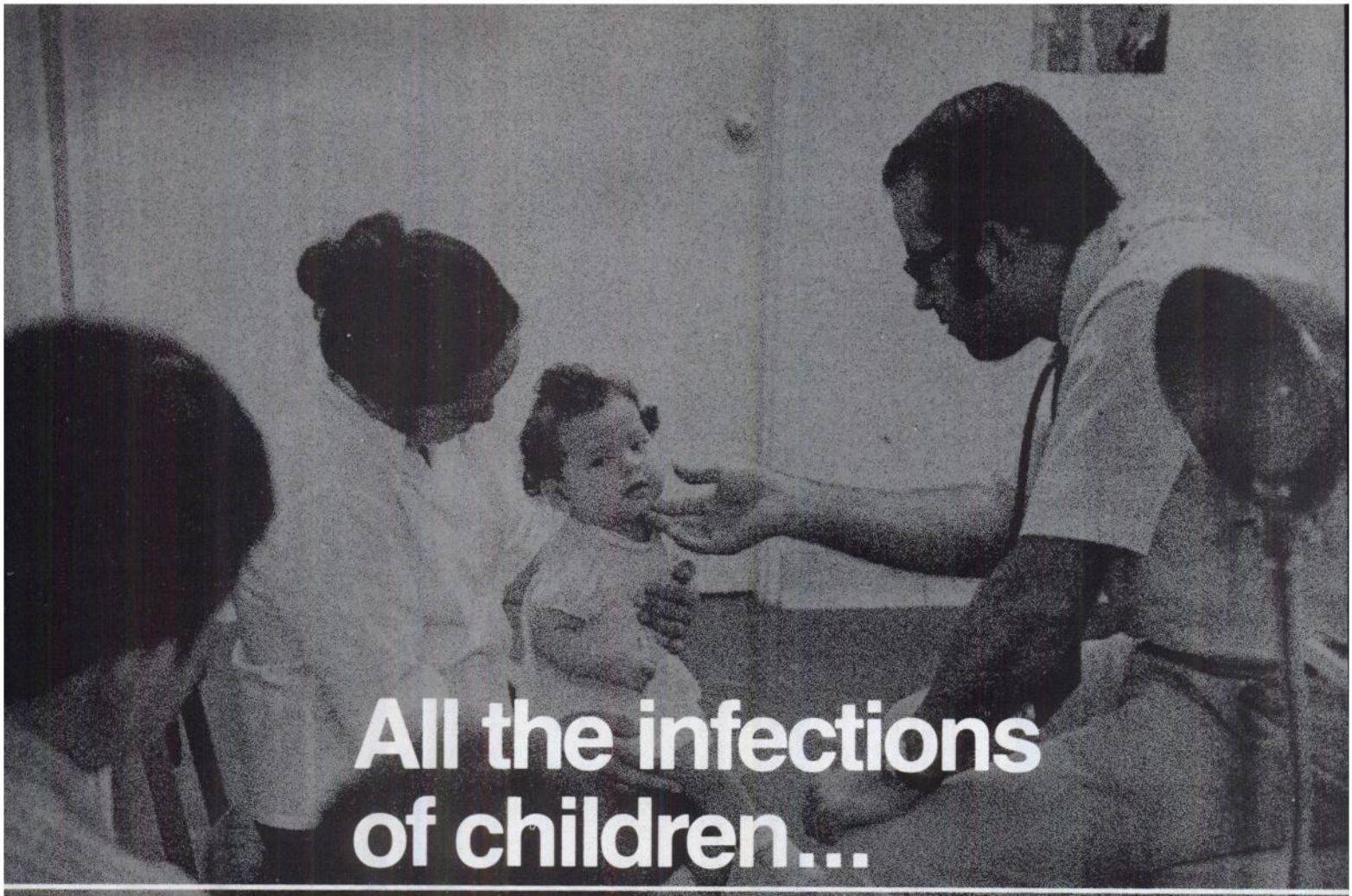

All the infections of children...

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1. Salk, J.E.: Poliomyelitis Vaccination in the Fall of 1956. Am. J. Public Health, **47**:1, 1957.

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1. **Morbidity and Mortality Weekly Report.** Published by the Center for Disease Control, Atlanta, Ga, Vol 26, No 40, pp 329-336.

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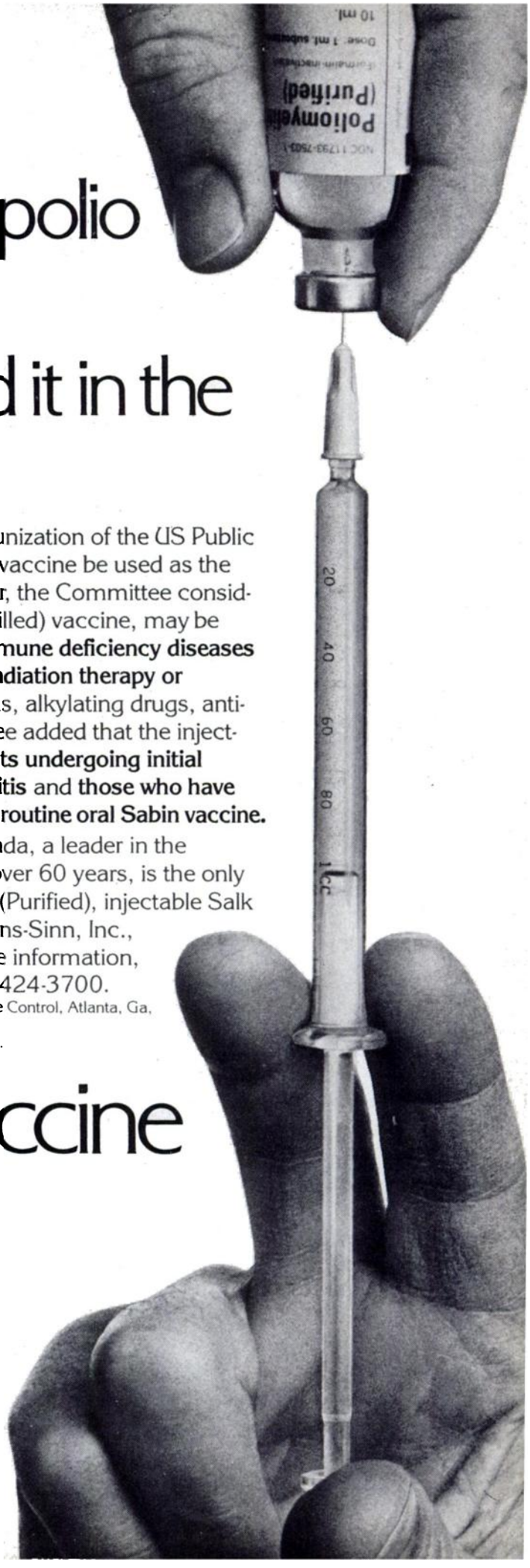

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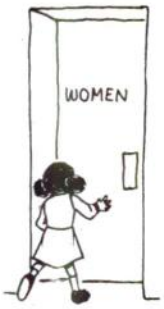

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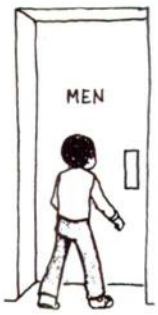

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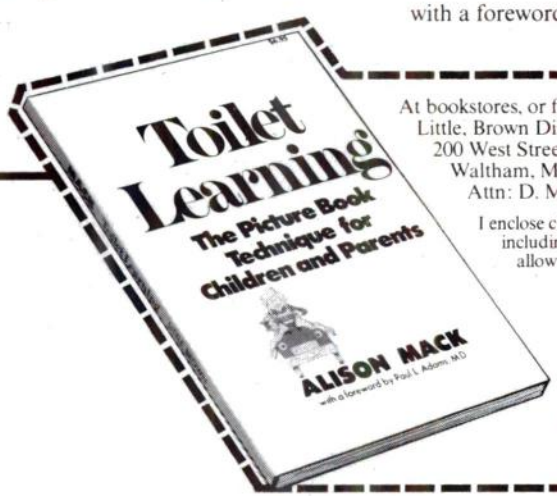

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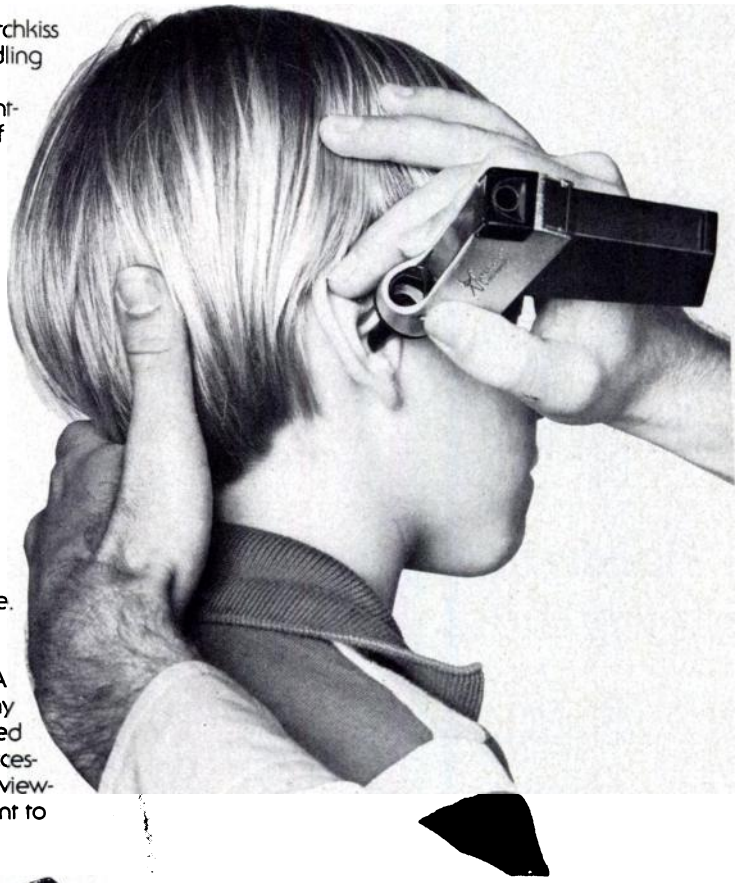

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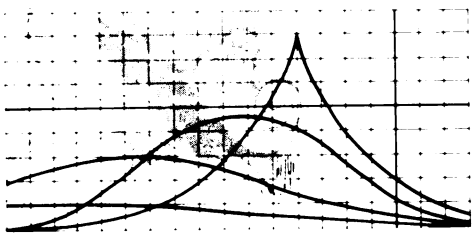

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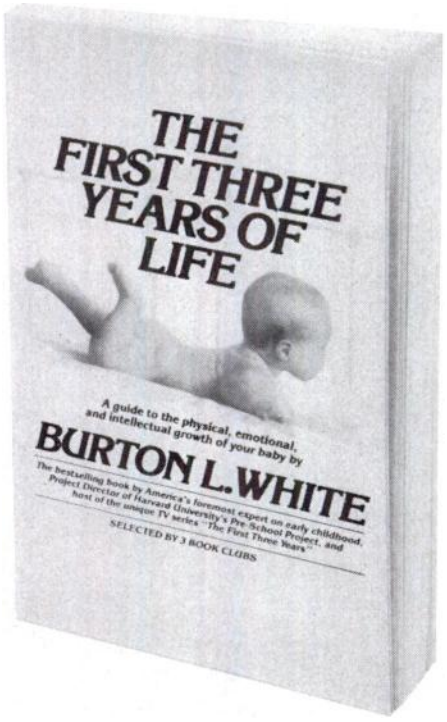

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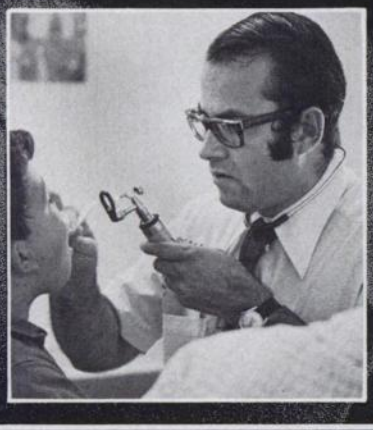

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