

OCTOBER 1989

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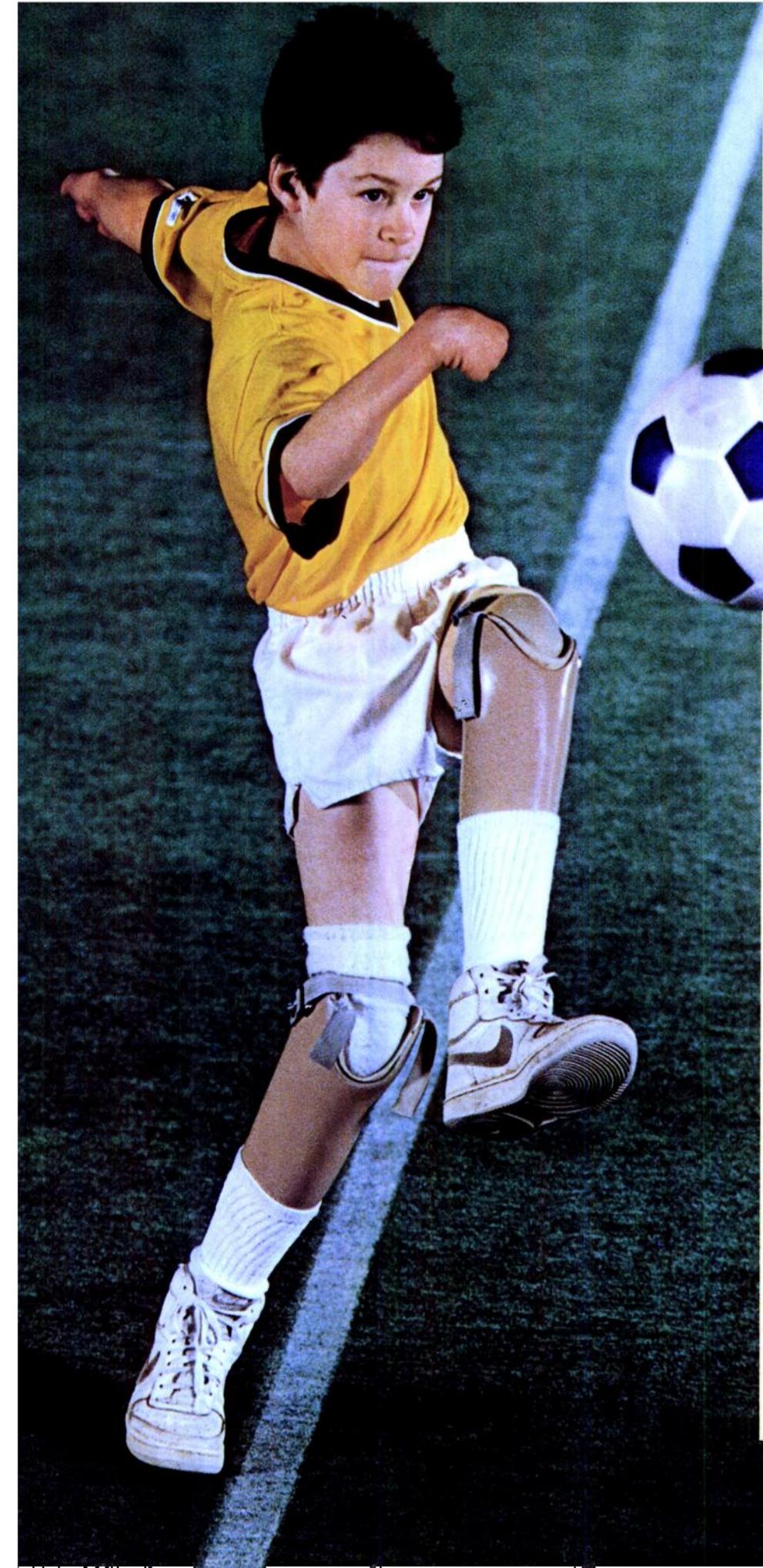
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Pediatrics





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References: 1. Newman WP III, et al: Relation of serum lipoprotein levels and systolic blood pressure to early atherosclerosis. *N Engl J Med* 314:138-144, 1986. 2. Mattson FH, Grundy SM: Comparison of effects of dietary saturated, monounsaturated and polyunsaturated fatty acids on plasma lipids and lipoproteins in man. *J Lipid Res* 26:194-202, 1985.

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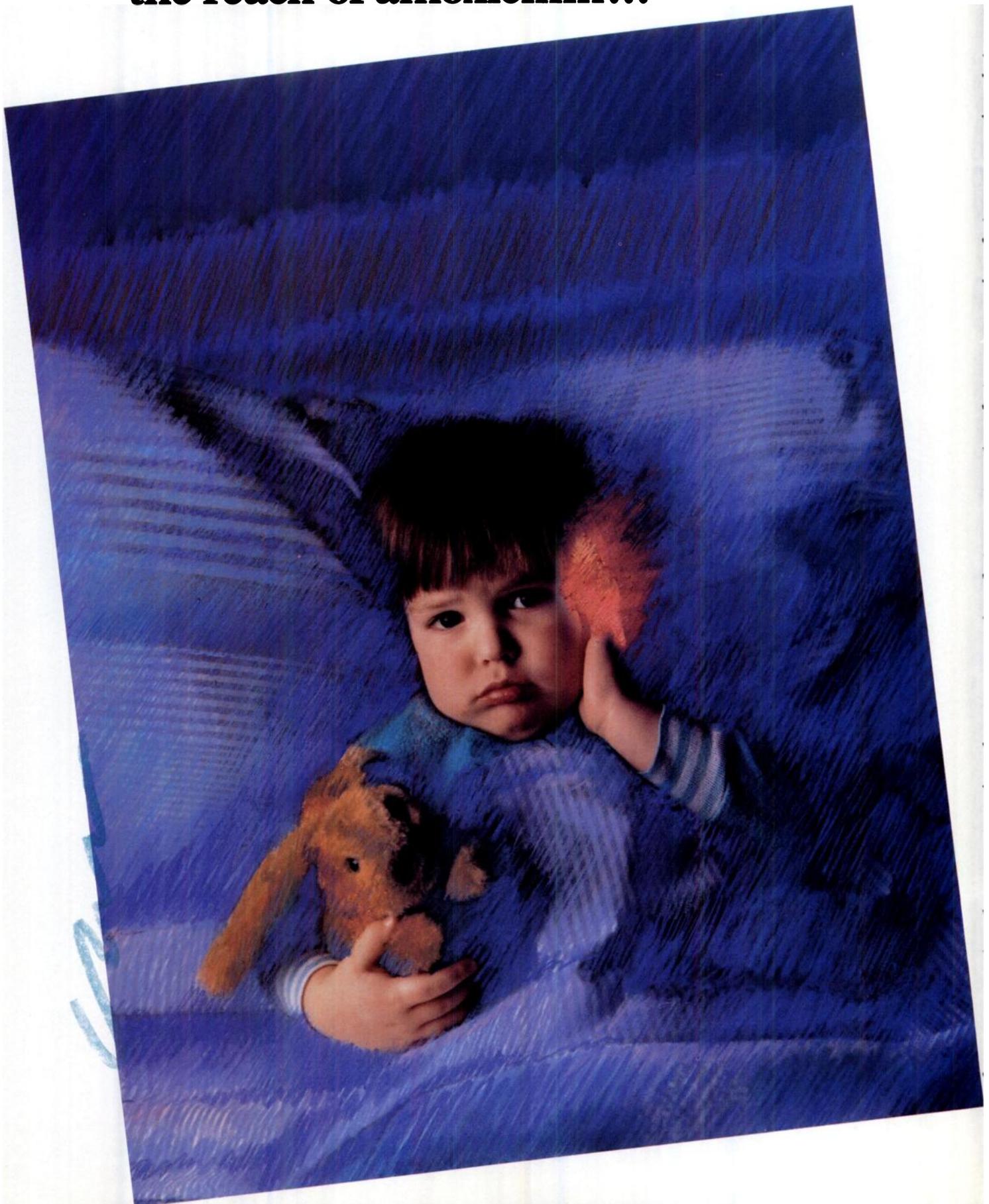
Good maternal nutrition is important for the preparation and maintenance of breast-feeding. Extensive or prolonged use of partial bottle-feeding, before breast-feeding has been well established, could make breast-feeding difficult to maintain. A decision not to breast-feed could be difficult to reverse. Professional advice should be followed on the need for and proper method of use of infant formula and on all matters of infant feeding. Infant formula should always be prepared and used as directed. Unnecessary or improper use of infant formula could present a health hazard. Social and financial implications should be considered when selecting the method of infant feeding.

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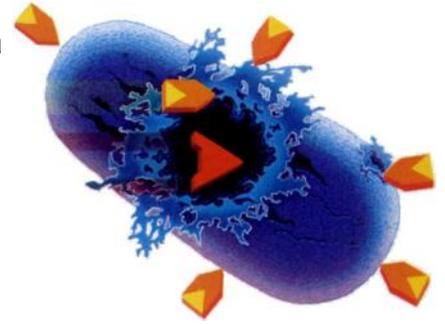
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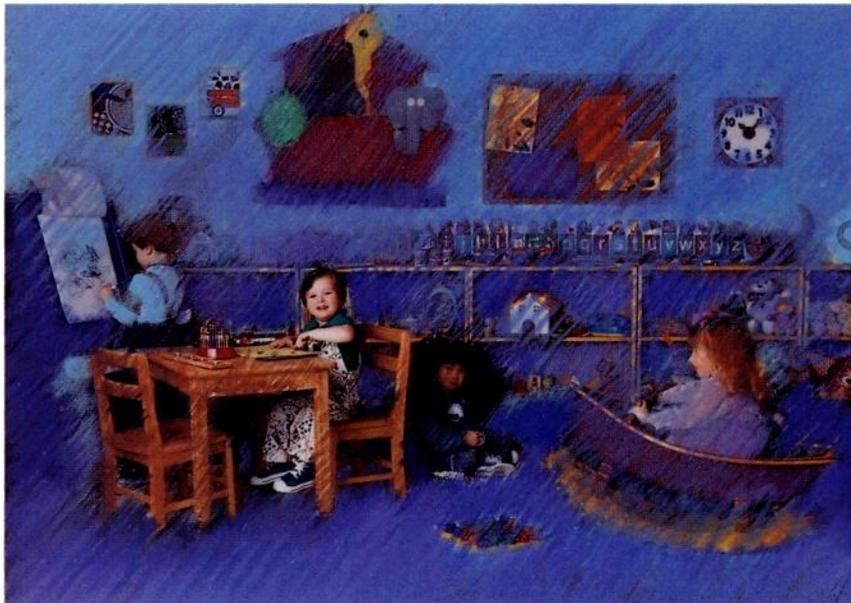


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Indications and Usage: AUGMENTIN[®] is indicated in the treatment of infections caused by susceptible strains of the designated organisms in the conditions listed below.

Lower Respiratory Infections caused by β -lactamase-producing strains of *Hemophilus influenzae* and *Branhamella catarrhalis*.

Otitis Media caused by β -lactamase-producing strains of *Hemophilus influenzae* and *Branhamella catarrhalis*.

Sinusitis caused by β -lactamase-producing strains of *Hemophilus influenzae* and *Branhamella catarrhalis*.

Skin and Skin Structure Infections caused by β -lactamase-producing strains of *Staphylococcus aureus*, *E. coli*, and *Klebsiella* spp.

Urinary Tract Infections caused by β -lactamase-producing strains of *E. coli*, *Klebsiella* spp. and *Enterobacter* spp.

While AUGMENTIN is indicated only for the conditions listed above, infections caused by ampicillin susceptible organisms are also amenable to AUGMENTIN treatment due to its amoxicillin content. Therefore, mixed infections caused by ampicillin susceptible organisms and β -lactamase-producing organisms susceptible to AUGMENTIN should not require the addition of another antibiotic.

Bacteriological studies to determine the causative organisms and their susceptibility to AUGMENTIN, should be performed together with any indicated surgical procedures.

Therapy may be instituted prior to obtaining the results from bacteriological and susceptibility studies to determine the causative organisms and their susceptibility to AUGMENTIN when there is reason to believe the infection may involve any of the β -lactamase-producing organisms listed above. Once the results are known, therapy should be adjusted, if appropriate.

Contraindications: A history of allergic reactions to any penicillin is a contraindication.

WARNINGS: SERIOUS AND OCCASIONALLY FATAL HYPERSENSITIVITY (ANAPHYLACTOID) REACTIONS HAVE BEEN REPORTED IN PATIENTS ON PENICILLIN THERAPY ALTHOUGH ANAPHYLAXIS IS MORE FREQUENT FOLLOWING PARENTERAL THERAPY. IT HAS OCCURRED IN PATIENTS ON ORAL PENICILLINS. THESE REACTIONS ARE MORE LIKELY TO OCCUR IN INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY AND/OR A HISTORY OF SENSITIVITY TO MULTIPLE ALLERGENS. THERE HAVE BEEN REPORTS OF INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY WHO HAVE EXPERIENCED SEVERE REACTIONS WHEN TREATED WITH CEPHALOSPORINS. BEFORE INITIATING THERAPY WITH ANY PENICILLIN, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO PENICILLINS, CEPHALOSPORINS, OR OTHER ALLERGENS. IF AN ALLERGIC REACTION OCCURS, AUGMENTIN SHOULD BE DISCONTINUED AND THE APPROPRIATE THERAPY INSTITUTED. SERIOUS ANAPHYLACTOID REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE, OXYGEN, INTRAVENOUS STEROIDS, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE ADMINISTERED AS INDICATED.

Precautions: General: While AUGMENTIN possesses the characteristic low toxicity of the penicillin group of antibiotics, periodic assessment of organ system functions, including renal, hepatic and hematopoietic function is advisable during prolonged therapy.

A high percentage of patients with mononucleosis who receive ampicillin develop a skin rash. Thus, ampicillin class antibiotics should not be administered to patients with mononucleosis.

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Drug Interactions: Probenecid decreases the renal tubular secretion of ampicillin. Concurrent use with AUGMENTIN may result in increased and prolonged blood levels of amoxicillin.

The concurrent administration of allopurinol and ampicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricemia present in these patients. There are no data with AUGMENTIN and allopurinol administered concurrently. AUGMENTIN should not be co-administered with Antabuse[®] (disulfiram).

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have not been performed to evaluate carcinogenic or mutagenic potential.

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

Labor and Delivery: Oral ampicillin class antibiotics are generally poorly absorbed during labor. Studies in guinea pigs have shown that intravenous administration of ampicillin decreased the uterine tone, frequency of contractions, height of contractions and duration of contractions. However, it is not known whether the use of AUGMENTIN in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

Nursing Mothers: Ampicillin class antibiotics are excreted in the milk; therefore, caution should be exercised when AUGMENTIN is administered to a nursing woman.

Adverse Reactions: AUGMENTIN is generally well tolerated. The majority of side effects observed in clinical trials were of a mild and transient nature and less than 3% of patients discontinued therapy because of drug related side effects. The most frequently reported adverse effects were diarrhea/loose stools (9%), nausea (3%), skin rashes and urticaria (3%), vomiting (1%), and vaginitis (1%).

The overall incidence of side effects, and in particular diarrhea, increased with the higher recommended dose. Other less frequently reported reactions include abdominal discomfort, flatulence and headache.

The following adverse reactions have been reported for ampicillin class antibiotics:

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

Hypersensitivity reactions: Skin rashes, urticaria, angioedema, serum sickness-like reactions, urticaria or skin rash accompanied by arthritis/arthralgia, myalgia, and frequently fever, erythema multiforme (rarely Stevens-Johnson Syndrome), and an occasional case of exfoliative dermatitis have been reported. These reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur the drug should be discontinued, unless the opinion of the physician dictates otherwise. Serious and occasional fatal hypersensitivity (anaphylactic) reactions can occur with oral penicillin (See Warnings).

Liver: A moderate rise in SGOT and/or SGPT has been noted in patients treated with ampicillin class antibiotics as well as with AUGMENTIN, but the significance of these findings is unknown. As with some other penicillins, and some cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

Hemic and Lymphatic Systems: Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia and agranulocytosis have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. A slight thrombocytosis was noted in less than 1% of the patients treated with AUGMENTIN.

Central Nervous System: Reversible hyperactivity, agitation, anxiety, insomnia, confusion, behavioral changes, and/or dizziness have been reported rarely.

Dosage: Adults: The usual adult dose is one AUGMENTIN 250 tablet every eight hours. For more severe infections and infections of the respiratory tract, the dose should be one AUGMENTIN 500 tablet every eight hours.

Since both the AUGMENTIN 250 and 500 tablets contain the same amount of clavulanic acid (125 mg, as the potassium salt), two AUGMENTIN 250 tablets are not equivalent to one AUGMENTIN 500 tablet. Therefore, two AUGMENTIN 250 tablets should not be substituted for one AUGMENTIN 500 tablet for treatment of more severe infections.

Children: The usual dose is 20 mg/kg/day, based on amoxicillin component, in divided doses every eight hours. For otitis media, sinusitis and other more severe infections, the dose should be 40 mg/kg/day, based on the amoxicillin component, in divided doses every eight hours. Also available as AUGMENTIN 125 and 250 chewable tablets.

Children weighing 40 kg and more should be dosed according to the adult recommendations.

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- 1:15 pm Problem Statement: Diagnosis Treatment Regimens, Postoperative Evaluation
- 1:30 pm Pathologic Anatomy of Craniosynostosis
- 2:00 pm Clinical Definition of Craniosynostosis Syndromes
- 2:30 pm Diagnosis and Initial Management of Craniosynostosis
- 3:00 pm Craniosynostosis and Intracranial Pressure
- 3:30 pm Results and Complications of the Surgical Treatment of Craniosynostosis
- 4:00 pm Evaluation of Surgical Therapy
- 4:25 pm Summary
- 4:30 pm Section Business Meeting

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Book

1. Kavet J. Trends in the utilization of influenza vaccine: an examination of the implementation of public policy in the United States. In: Selby P, ed. *Influenza: Virus, Vaccines, and Strategy*, Orlando, FL: Academic Press Inc; 1976:297-308

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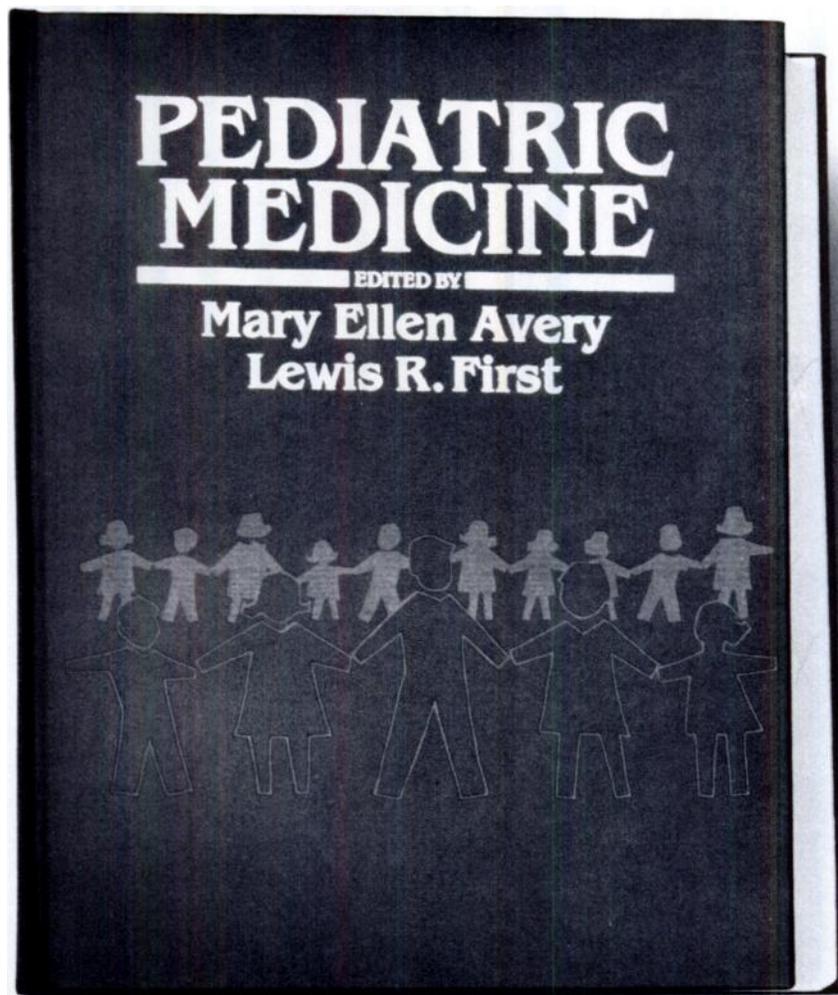
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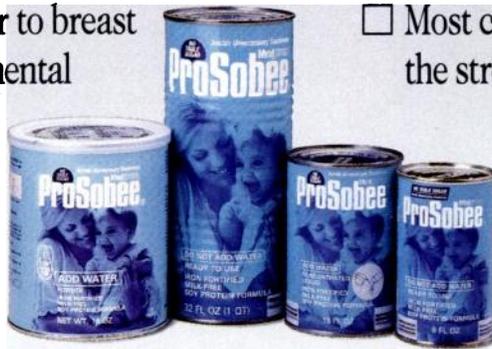
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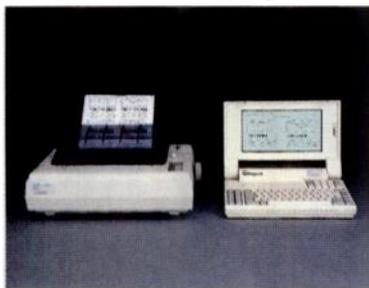
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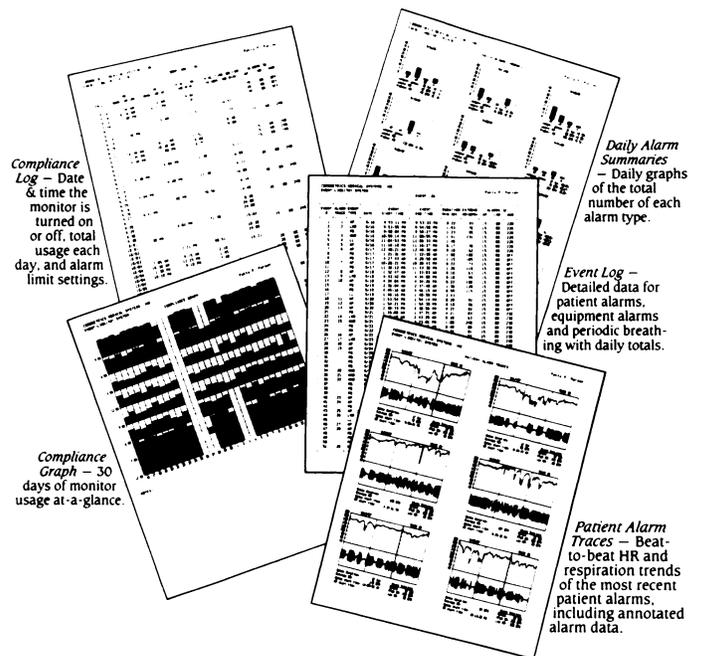
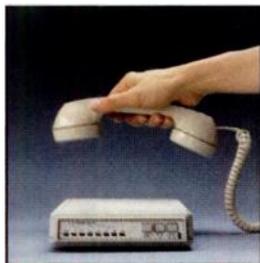
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Help make the common cold less common.

Recent research indicates: Colds are "caught" ... by hand.

Today we know that we are far more likely to catch a cold from our fingers than from a sneeze or a cough.¹ Rhinovirus on a cold sufferer's hands can be easily passed on to other hands. And when contaminated fingers probe a nose or rub an eye, the result is often a common cold infection.



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References:

1. Turner R, Hendley JO: How colds spread: Surprising new data. *J Resp Dis* 1982; 3:98

2. Klump TG: The common cold: New concepts of transmission and prevention. *Med Times* 1980; 108:35

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RICHARD W. GAST
PRESIDENT

... on the consumer promotion of infant formula.

There is a development that undermines your control over the infant's diet and health, and that undermines breastfeeding—the advertisement of formulas directly to the mother through TV, magazines and mail.

On June 1, the President of the American Academy of Pediatrics sent a letter to all Fellows of the Academy reaffirming its stance against consumer advertising, and expressing concern that other formula companies might follow Nestlé/Carnation.

This concern was justified. On June 15, it was announced at a press conference that Mead Johnson/Bristol-Myers will be producing an infant formula to be sold and marketed under the Gerber label. Part of the program is a multimillion-dollar budget for advertising the formula directly to mothers via TV and print.

Speaking at the press conference, Gerber Products Division President Robert L. Johnston, Jr., said that Gerber was entering the market because it had, "identified significant changes in usage that convinced us the timing was right...."

"First," he said, "there is a rapid decline in breast-feeding after mothers leave the hospital." And, "... parent decision regarding baby formula brand selection has grown...."

The irony is inescapable and appalling. In other words, because breastfeeding is declining, more infant formulas should be promoted to the mother. In other words, because some mothers are making feeding decisions on their own, even more mothers should follow suit.

When Nestlé/Carnation entered the marketplace and, again, when Mead Johnson/Bristol-Myers joined with Gerber, we reexamined the Ross philosophy of promoting SIMILAC® Infant Formulas. The result of our deliberations was an even deeper resolve to support the doctor/patient relationship.

Our philosophy remains unchanged. Ross Laboratories has no plans to resort to direct consumer advertising for SIMILAC and our other infant formula products.

We will continue as an ally of health care professionals by supporting your prerogative to prescribe and recommend products as training and experience dictate.

We stand behind you.

Richard W. Gast

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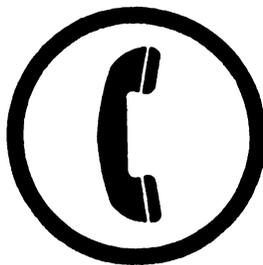
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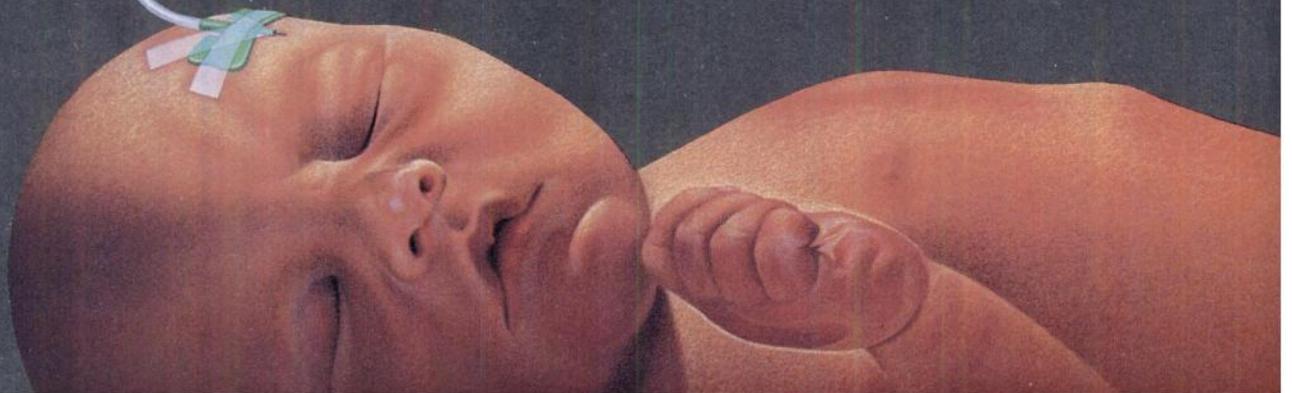
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-

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The bottom line.

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Claforan[®]

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STERILE & INJECTION

Brief Summary INDICATIONS AND USAGE

Treatment

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

- Lower respiratory tract infections**, including pneumonia, caused by *Streptococcus pneumoniae* (formerly *Diplococcus pneumoniae*), *Streptococcus pyogenes*[†] (Group A streptococci) and other streptococci (excluding enterococci, e.g., *Streptococcus faecalis*), *Staphylococcus aureus* (penicillinase and non-penicillinase producing), *Escherichia coli*, *Klebsiella* species, *Haemophilus influenzae* (including ampicillin-resistant strains), *Haemophilus parainfluenzae*, *Proteus mirabilis*, *Serratia marcescens*,[†] *Enterobacter* species, indole-positive *Proteus* and *Pseudomonas* species (including *P. aeruginosa*).
- Genitourinary infections**. Urinary tract infections caused by *Enterococcus* species, *Staphylococcus epidermidis*, *Staphylococcus aureus*[†] (penicillinase and non-penicillinase producing), *Citrobacter* species, *Enterobacter* species, *Escherichia coli*, *Klebsiella* species, *Proteus mirabilis*, *Proteus vulgaris*,[†] *Proteus inconstans* Group B, *Morganella morganii*[†], *Providencia rettgeri*[†], *Serratia marcescens*, and *Pseudomonas* species (including *P. aeruginosa*). Also, uncomplicated gonorrhea of single or multiple sites caused by *Neisseria gonorrhoeae*, including penicillinase producing strains.
- Gynecologic infections**, including pelvic inflammatory disease, endometritis and pelvic cellulitis caused by *Staphylococcus epidermidis*, *Streptococcus* species, *Enterococcus* species, *Enterobacter* species[†], *Klebsiella* species[†], *Escherichia coli*, *Proteus mirabilis*, *Bacteroides* species (including *Bacteroides fragilis*),[†] *Clostridium* species, anaerobic cocci (including *Peptostreptococcus* species and *Peptococcus* species) and *Fusobacterium* species (including *F. nucleatum*[†]).
- Bacteremia/Septicemia** caused by *Escherichia coli*, *Klebsiella* species, *Serratia marcescens*, *Staphylococcus aureus*, and *Streptococcus* species (including *S. pneumoniae*).
- Skin and skin structure infections** caused by *Staphylococcus aureus* (penicillinase and non-penicillinase producing), *Staphylococcus epidermidis*, *Streptococcus pyogenes* (Group A streptococci) and other streptococci, *Enterococcus* species, *Acinetobacter* species[†], *Escherichia coli*, *Citrobacter* species (including *C. freundii*[†]), *Enterobacter* species, *Klebsiella* species, *Proteus mirabilis*, *Proteus vulgaris*[†], *Morganella morganii*, *Providencia rettgeri*[†], *Pseudomonas* species, *Serratia marcescens*, *Bacteroides* species, and anaerobic cocci (including *Peptostreptococcus*[†] species and *Peptococcus* species).
- Intra-abdominal infections** including peritonitis caused by *Streptococcus* species[†], *Escherichia coli*, *Klebsiella* species, *Bacteroides* species, anaerobic cocci (including *Peptostreptococcus*[†] species and *Peptococcus*[†] species), *Proteus mirabilis*[†], and *Clostridium* species[†].
- Bone and/or joint infections** caused by *Staphylococcus aureus* (penicillinase and non-penicillinase producing strains), *Streptococcus* species (including *S. pyogenes*[†]), *Pseudomonas* species (including *P. aeruginosa*[†]), and *Proteus mirabilis*[†].
- Central nervous system infections**, e.g., meningitis and ventriculitis, caused by *Neisseria meningitidis*, *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Klebsiella pneumoniae*[†], and *Escherichia coli*[†].

[†] Efficacy for this organism, in this organ system, has been studied in fewer than 10 infections.

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

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

Prevention

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

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

Effective use for elective surgery depends on the time of administration. To achieve effective tissue levels, Claforan should be given 1/2 to 1 1/2 hours before surgery. (See **DOSAGE AND ADMINISTRATION** section.)

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

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

CONTRAINDICATIONS

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

WARNINGS

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

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

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

Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should be managed with fluid, electrolyte, and protein supplementation as indicated.

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

PRECAUTIONS

Claforan* (cefotaxime sodium) should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

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

ment, severity of infection, and susceptibility of the causative organism.

Although there is no clinical evidence supporting the necessity of changing the dosage of cefotaxime sodium in patients with even profound renal dysfunction, it is suggested that, until further data are obtained, the dose of cefotaxime sodium be halved in patients with estimated creatinine clearances of less than 20 mL/min/1.73 m².

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

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

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

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

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

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

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

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

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

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

ADVERSE REACTIONS

Claforan is generally well tolerated. The most common adverse reactions have been local reactions following IM or IV injection. Other adverse reactions have been encountered infrequently. The most frequent adverse reactions (greater than 1%) are:

Local (4.3%)—Injection site inflammation with IV administration. Pain, induration, and tenderness after IM injection.

Hypersensitivity (2.4%)—Rash, pruritus, fever, and eosinophilia.

Gastrointestinal (1.4%)—Colitis, diarrhea, nausea, and vomiting.

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

Nausea and vomiting have been reported rarely.

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

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

Genitourinary System—Moniliasis, vaginitis.

Central Nervous System—Headache.

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

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

DOSAGE AND ADMINISTRATION

Adults

Dosage and route of administration should be determined by susceptibility of the causative organisms, severity of the infection, and the condition of the patient (see table for dosage guidelines). Claforan may be administered IM or IV after reconstitution. Premixed Claforan Injection is intended for IV administration after thawing. The maximum daily dosage should not exceed 12 grams.

GUIDELINES FOR DOSAGE OF CLAFORAN

Type of Infection	Daily Dose (grams)	Frequency and Route
Gonorrhea	1	1 gram IM (single dose)
Uncomplicated infections	2	1 gram every 12 hours IM or IV
Moderate to severe infections	3-6	1-2 grams every 8 hours IM or IV
Infections commonly needing antibiotics in higher dosage (e.g., septicemia)	6-8	2 grams every 6-8 hours IV
Life-threatening infections	up to 12	2 grams every 4 hours IV
To prevent postoperative infection in contaminated or potentially contaminated surgery, the recommended dose is a single 1 gram IM or IV administered 30 to 90 minutes prior to start of surgery.		

Cesarean Section Patients

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

Neonates, Infants, and Children

The following dosage schedule is recommended.

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

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

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

Impaired Renal Function—see PRECAUTIONS section

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

*US Patent 4,152,432 CLAFORAN[®] REG TM ROUSSEL-UCLAF

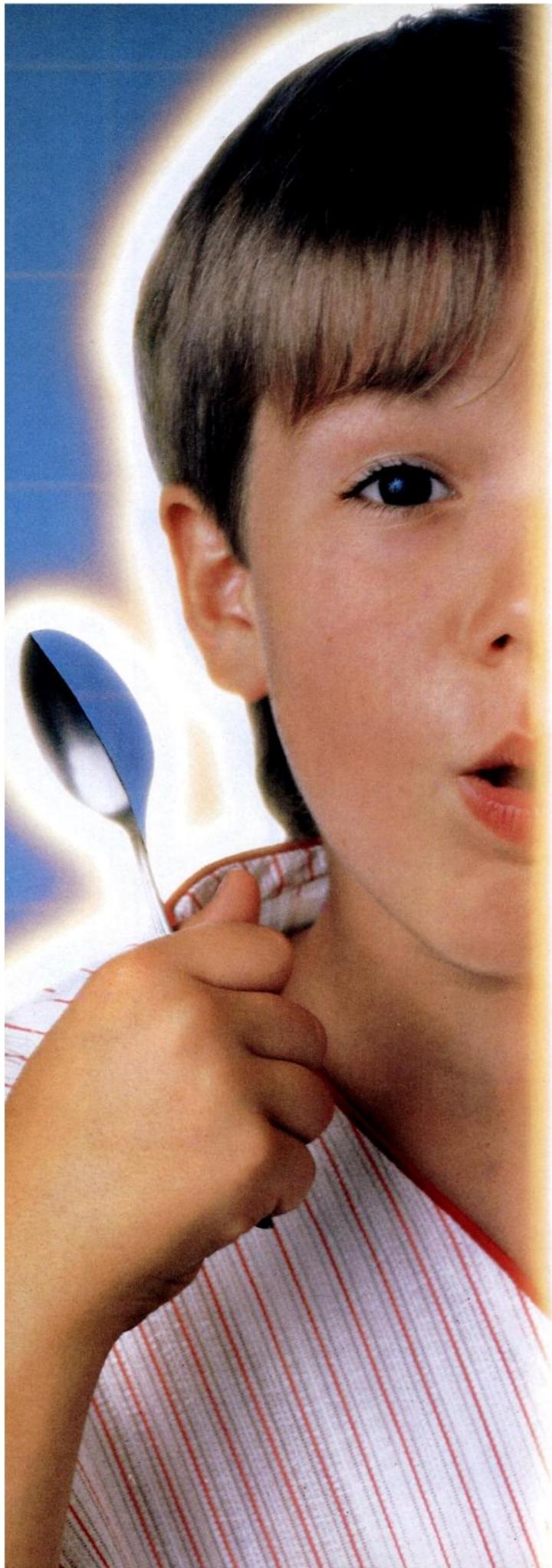
7179RT
Revised 10/87

Hoechst-Roussel Pharmaceuticals Inc.
Somerville, New Jersey 08876

Hoechst 

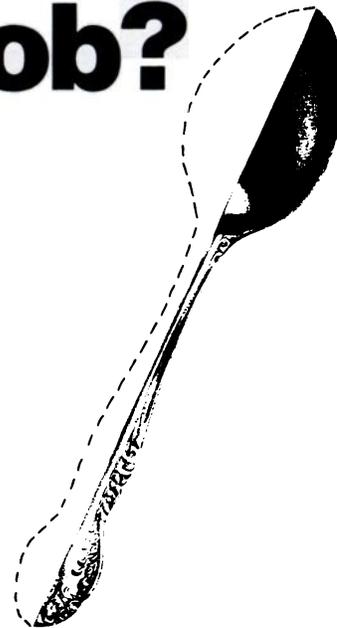
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Cough medicines that work at only one site may do only half the job

- But TUSSI-ORGANIDIN[®] and TUSSI-ORGANIDIN[®] DM act at the two sources of cough

Treats neurologic cough impulses

- With codeine or dextromethorphan

Treats the respiratory source of cough

- Relieves dry hacking cough
- Soothes irritated tracheal mucosa

Rx ONLY

TUSSI-ORGANIDIN[®] contains Codeine

LIQUID Each teaspoonful (5 mL) contains: ORGANIDIN[®] (iodinated glycerol containing 15 mg organically bound iodine), 30 mg; codeine phosphate (WARNING: May be habit-forming), 10 mg.

Rx ONLY

TUSSI-ORGANIDIN[®] DM

LIQUID Each teaspoonful (5 mL) contains: ORGANIDIN[®] (iodinated glycerol containing 15 mg organically bound iodine), 30 mg; dextromethorphan hydrobromide, 10 mg.

Please see following page for prescribing information.



WALLACE LABORATORIES

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Cranbury, New Jersey 08512

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See us at Booth 941 & 945

TUSSI-ORGANIDIN® contains

LIQUID Each teaspoonful (5 mL) contains ORGANIDIN® (codonated glycerol containing 15 mg organically bound iodine), 30 mg codeine phosphate (WARNING: May be habit-forming), 10 mg

TUSSI-ORGANIDIN® DM

LIQUID Each teaspoonful (5 mL) contains ORGANIDIN® (codonated glycerol containing 15 mg organically bound iodine), 30 mg dextromethorphan hydrobromide, 10 mg

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

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

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

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

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

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

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

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

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

Nursing Mothers—Do not administer to a nursing woman.

ADVERSE REACTIONS: Side effects have been rare, including those which may occur with the individual ingredients and which may be modified as a result of their combination.

Organidin—Gastrointestinal irritation, rash, hypersensitivity, thyroid gland enlargement, and acute parotitis. **Codeine**—Nausea, vomiting, constipation, drowsiness, and miosis.

DRUG ABUSE AND DEPENDENCE: Controlled Substance—Schedule V.

Dependence—Codeine may be habit-forming.

OVERDOSAGE: No reports of any serious problems.

DOSAGE AND ADMINISTRATION: Adults: 1 to 2 teaspoonfuls every 4 hours. **Children:** ½ to 1 teaspoonful every 4 hours.

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

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

Rev. 6/83

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

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

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

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

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

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

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

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

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

Nursing Mothers—Do not administer to a nursing woman.

ADVERSE REACTIONS: Side effects have been rare, including those which may occur with the individual ingredients and which may be modified as a result of their combination.

Organidin—Gastrointestinal irritation, rash, hypersensitivity, thyroid gland enlargement, and acute parotitis. **Dextromethorphan**—Drowsiness or gastrointestinal disturbances.

OVERDOSAGE: No reports of any serious problems.

DOSAGE AND ADMINISTRATION: Adults: 1 to 2 teaspoonfuls every 4 hours. **Children:** ½ to 1 teaspoonful every 4 hours.

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

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

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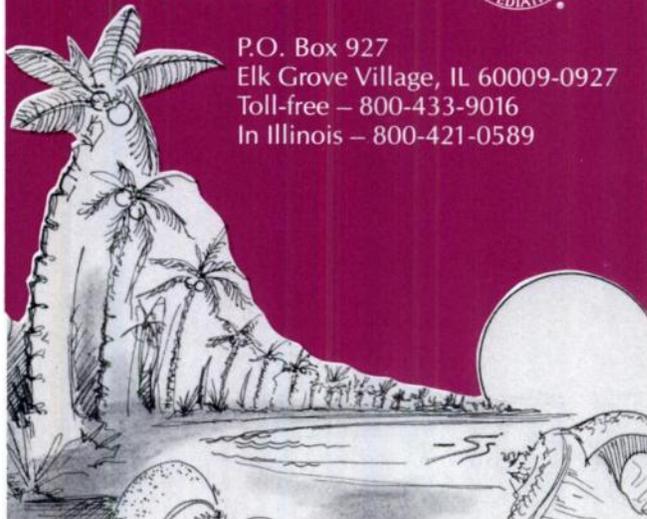
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Department of Education, CME Registration

American Academy of Pediatrics



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about

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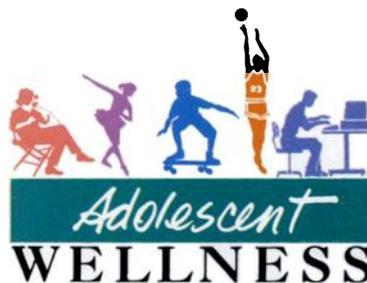
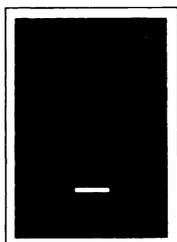
The award-winning **Adolescent Wellness** program is a comprehensive learning system developed by pediatricians and leading experts in adolescent psychiatry. It is made available to pediatricians, at no cost, by Lederle Biologicals.

This multimedia educational program is endorsed by the American Academy of Pediatrics and is intended to serve as a resource for you, your adolescent patients, and their parents.



Two modules presently in circulation explore alcohol/substance abuse and depression/suicide. Components for pediatricians include course monographs, videotapes, and a newsletter series. Elements designed for patients and parents are consultation guides, a video lending library, and a pediatrician services brochure.

Modules now in development address teenage sexuality and eating disorders.



Designed and produced for



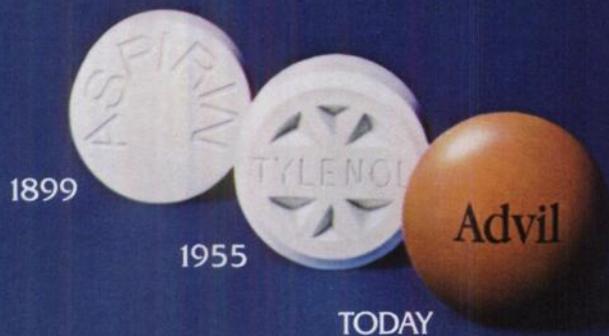
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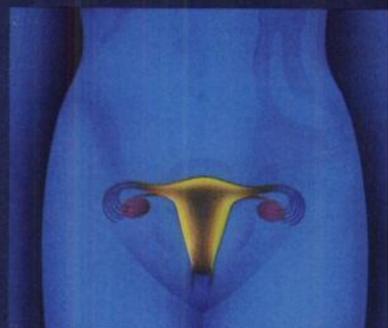
Please advise patients and parents to read and follow product labeling. Patients should not take this product if they have had a severe allergic reaction to aspirin.

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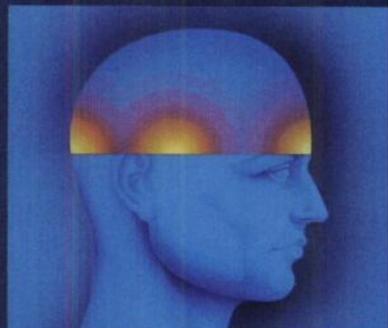
Appearance of the brown ADVIL tablet is a trademark of
Whitehall Laboratories N.Y., N.Y. © 1986



FEVER



DYSMENORRHEA



HEADACHE



MUSCLE ACHES

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ANNOUNCEMENT OF GENERAL PEDIATRIC RECERTIFICATION EXAMINATION AND SUBSPECIALTY RECERTIFICATION EXAMINATIONS

The American Board of Pediatrics announces that the next recertification examination will be offered on **Friday, May 18, 1990**, in approximately 70 cities. Half of this examination will cover Recent Advances in Comprehensive General Pediatrics. Half will include aspects of the following Topics for Annual Review: endocrinology, metabolic disease, nutrition, genitourinary system disease, fluid and electrolyte metabolism, and gastrointestinal disease—metabolic.

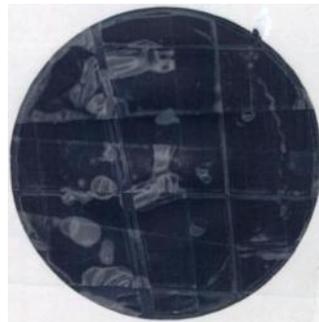
This examination is open to all certified Diplomates of the Board who have subscribed to the recertification program prior to December 15, 1989.

Further information and a subscription form may be obtained by contacting:

American Board of Pediatrics
111 Silver Cedar Court
Chapel Hill, N.C. 27514-1651
(919) 929-0461

The subspecialty recertification examination will be administrated also on **Friday, May 18, 1990**, in the same cities as the general recertification examination. The first half of this examination will consist of a common set of questions on general pediatrics selected by subspecialists. The second half will be a separate examination for each subspecialty.

Registration materials will automatically be mailed on January 17, 1990, to anyone who is certified in pediatric cardiology, pediatric endocrinology, pediatric hematology-oncology, neonatal-perinatal medicine, or pediatric nephrology.



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At Gerber[®], we believe that mother’s milk is the ideal first food for babies, and we support a mother’s decision to breast-feed as long as possible during a baby’s first year.

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The 82:18 casein/whey protein composition is one that is exceptionally well tolerated by babies. In a recent clinical study, babies fed the Gerber™ Baby Formula formulation not only tolerated it well — consistent with historical controls — but had similar measurements of growth and development to those fed breast milk and milk-based formulas in other studies.¹

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Reference

1. An evaluation of casein-based infant formula in newborns from birth until four months of age. Data on file.



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Caloric Distribution	Gerber™ Baby Formula	Breast Milk
Protein % kcal	9	6
Fat % kcal	48	56
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Gerber™ Baby Formula Nutrient Sources

Protein – Nonfat milk 82:18 casein/whey
 Fat – Soy oil predominant (corn oil in powder form)
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Protein g/qt	14.2	14.2-14.4
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CHO g/qt	69	66-68
Key Minerals	Gerber™ Baby Formula	Others (Similac® and Enfamil®)*
Calcium mg/qt	480	440-480
Phosphorus mg/qt	370	300-370
Potassium mg/qt	690	690-770
Chloride mg/qt	450	400-480
Low-iron mg/qt	1	1
Iron-fortified mg/qt	11.5	11.5-12

*Similac is a registered trademark of Ross Laboratories.
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Safety first

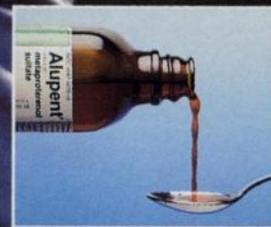


...and tasty too!

Effective beta₂-selective relief
of bronchospasm
associated with asthma

Fast Action, Fast Relief in Asthma

Alupent[®] Syrup
(metaproterenol sulfate) 10 mg/5 ml



Adverse reactions similar to those of other sympathomimetic agents.
Please see following page for brief summary of prescribing information.



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Fast Action, Fast Relief in Asthma

Alupent[®] Syrup

(metaproterenol sulfate)

Bronchodilator

Tablets 10 and 20 mg	Inhalation Aerosol 10 mL	Syrup 10 mg/5 mL	Inhalation Solution 5%	Inhalation Solution Unit-dose Vials 0.4% and 0.6%
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Brief Summary of Prescribing Information

CONTRAINDICATIONS Use in patients with cardiac arrhythmias associated with tachycardia is contraindicated.

Although rare, immediate hypersensitivity reactions can occur. Therefore, Alupent[®] (metaproterenol sulfate USP) is contraindicated in patients with a history of hypersensitivity to any of its components.

WARNINGS Excessive use of adrenergic aerosols is potentially dangerous. Fatalities have been reported following excessive use of Alupent[®] (metaproterenol sulfate USP) as with other sympathomimetic inhalation preparations, and the exact cause is unknown. Cardiac arrest was noted in several cases.

Alupent, like other beta adrenergic agonists, can produce a significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure, symptoms, and/or ECG changes. As with other beta adrenergic aerosols, Alupent can produce paradoxical bronchospasm (which can be life threatening). If it occurs, the preparation should be discontinued immediately and alternative therapy instituted.

Alupent[®] (metaproterenol sulfate USP) should not be used more often than prescribed. Patients should be advised to contact their physician in the event that they do not respond to their usual dose of a sympathomimetic amine aerosol.

PRECAUTIONS General: Extreme care must be exercised with respect to the administration of additional sympathomimetic agents.

Since metaproterenol is a sympathomimetic amine, it should be used with caution in patients with cardiovascular disorders, including ischemic heart disease, hypertension or cardiac arrhythmias, in patients with hyperthyroidism or diabetes mellitus, and in patients who are unusually responsive to sympathomimetic amines or who have convulsive disorders. Significant changes in systolic and diastolic blood pressure could be expected to occur in some patients after use of any beta adrenergic bronchodilator.

Information for Patients: Extreme care must be exercised with respect to the administration of additional sympathomimetic agents. A sufficient interval of time should elapse prior to administration of another sympathomimetic agent.

Drug Interactions: Other beta adrenergic aerosol bronchodilators should not be used concomitantly with Alupent because they may have additive effects. Beta adrenergic agonists should be administered with caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, since the action of beta adrenergic agonists on the vascular system may be potentiated.

Carcinogenesis/Mutagenesis/Impairment of Fertility: In an 18-month study in mice, Alupent produced an increase in benign ovarian tumors in females at doses corresponding to 320 and 640 times the maximum recommended dose (based on a 50 kg individual). In a two-year study in rats, a non-significant incidence of benign leiomyomata of the mesovarium was noted at 640 times the maximum recommended dose. The relevance of these findings to man is not known. Mutagenic studies with Alupent have not been conducted. Reproduction studies in rats revealed no evidence of impaired fertility.

Pregnancy Teratogenic Effects. Pregnancy Category C: Alupent[®] (metaproterenol sulfate USP) has been shown to be teratogenic and embryotoxic in rabbits when given orally in doses 620 times the human inhalation dose and 62 times the human oral dose. There are no adequate and well-controlled studies in pregnant women. Alupent should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Oral reproduction studies in mice, rats and rabbits showed no teratogenic or embryocidal effects at 50 mg/kg, corresponding to 310 times the human inhalation dose and 31 times the human oral dose. Teratogenic effects in the rabbit included skeletal abnormalities and hydrocephalus with bone separation.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Alupent[®] (metaproterenol sulfate USP) is administered to a nursing woman.

Pediatric Use: Consult package insert for age limit.

ADVERSE REACTIONS Adverse reactions are similar to those noted with other sympathomimetic agents. Adverse reactions such as tachycardia, hypertension, palpitations, nervousness, tremor, nausea and vomiting have been reported.

The most frequent adverse reaction to Alupent[®] (metaproterenol sulfate USP) administered by metered-dose inhaler among 251 patients in 90-day controlled clinical trials was nervousness. This was reported in 6.8% of patients. Less frequent adverse experiences, occurring in 1-4% of patients were headache, dizziness, palpitations, gastrointestinal distress, tremor, throat irritation, nausea, vomiting, cough and asthma exacerbation. Tachycardia occurred in less than 1% of patients.

HOW SUPPLIED Inhalation Aerosol: Each Alupent[®] Inhalation Aerosol contains 150 mg of metaproterenol sulfate as a micronized powder in inert propellants. Each metered dose delivers through the mouthpiece 0.65 mg metaproterenol sulfate (each mL contains 15 mg). Alupent Inhalation Aerosol with Mouthpiece (NDC 0597-0070-17), net contents 14g (10mL), equipped with blue protective cap. Alupent Inhalation Aerosol Refill (NDC 0597-0070-18), net contents 14g (10 mL).

Store between 59°F (15°C) and 77°F (25°C). Avoid excessive humidity.

Inhalation Solution: Alupent Inhalation Solution is supplied as a 5% solution in bottles of 10 mL or 30 mL with accompanying calibrated dropper. Store below 77°F (25°C). Protect from light. Do not use the solution if it is brown or has a precipitate.

Alupent Inhalation Solution Unit-dose Vial is supplied as a 0.4% or 0.6% clear colorless or nearly colorless solution containing 2.5 mL, with 25 vials per box. Store below 77°F (25°C). Protect from light. Do not use the solution if it is brown or has a precipitate.

Syrup: Alupent is available as a cherry-flavored syrup, 10 mg per teaspoonful (5 mL), in 16 fl oz bottles. Store below 86°F (30°C). Protect from light.

Tablets: Alupent is supplied in two dosage strengths as scored, round white tablets in bottles of 100. Tablets of 10 mg coded BI/74. Tablets of 20 mg coded BI/72.

Storage for bottles: Store below 86°F (30°C). Protect from light.

Storage for blister samples: Store below 77°F (25°C). Protect from light.

Consult package insert before prescribing.

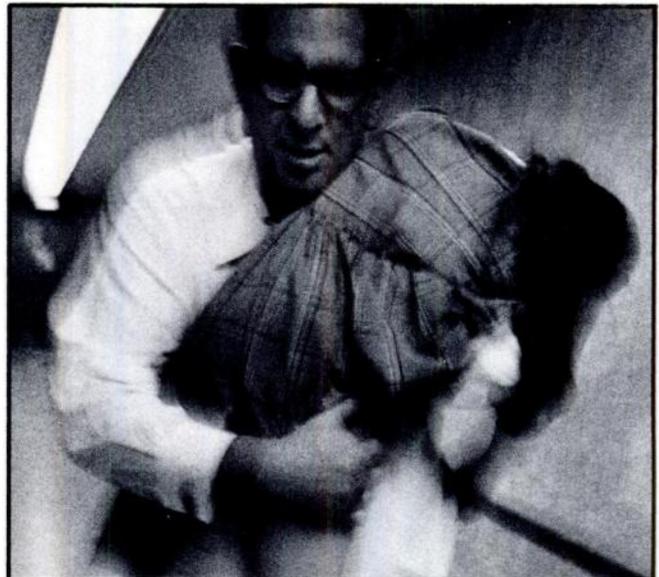
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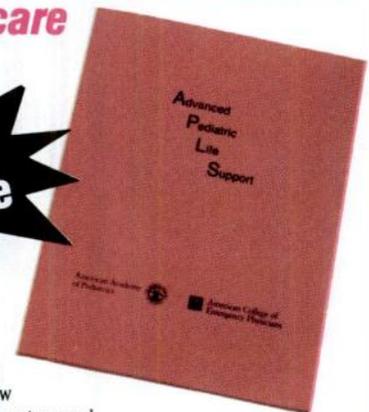
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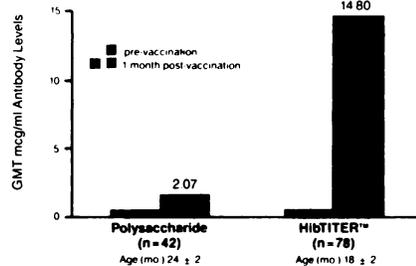
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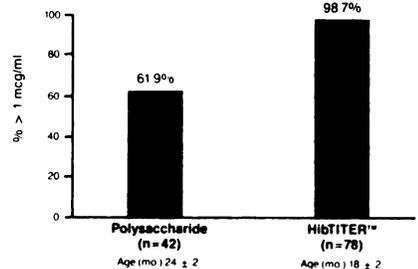
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Immunogenicity of HibTITER™ and Haemophilus b Polysaccharide Vaccines*



*Pediatr Res 23 380A Abstr 1073 1988

Percent of Subjects Vaccinated with HibTITER™ or Haemophilus b Polysaccharide Vaccines with Antibody Levels > 1 mcg/ml One Month Post-Vaccination*



*Pediatr Res 23 380A Abstr 1073 1988

HiBTITER™ HAEMOPHILUS b CONJUGATE VACCINE (Diphtheria CRM₁₉₇ Protein Conjugate)

DESCRIPTION

HiBTITER™ Haemophilus b Conjugate Vaccine (Diphtheria CRM₁₉₇ Protein Conjugate) is a sterile solution of a conjugate of oligosaccharides of the capsular antigen of *Haemophilus influenzae* type b (Haemophilus b) and diphtheria CRM₁₉₇ protein (CRM₁₉₇) dissolved in 0.9% sodium chloride. The oligosaccharides are derived from highly purified capsular polysaccharide, polyribosylribitol phosphate (PRP), isolated from Haemophilus b strain Eagan grown in a chemically defined medium, and coupled by reductive amination directly to highly purified CRM₁₉₇. CRM₁₉₇ is a non-toxic variant of diphtheria toxin isolated from cultures of *Corynebacterium diphtheriae* C7 (1917) grown in a caseinase acid and yeast extract based medium that is ultrafiltered before use. The conjugate is purified to remove unreacted protein, oligosaccharides, and reagents; sterilized by filtration; and filled into vials. HiBTITER is intended for intramuscular use.

The vaccine is a clear, colorless solution. Each single dose of 0.5 ml is formulated to contain 10 µg of purified Haemophilus b saccharide and approximately 25 µg of CRM₁₉₇ protein. Multidose vials contain thimerosal (mercurial derivative) 1:10,000 as a preservative.

CLINICAL PHARMACOLOGY

Haemophilus influenzae type b (Haemophilus b) is the most common cause of invasive bacterial disease, including meningitis, in young children in the United States. Although non-encapsulated *Haemophilus influenzae* are common and six capsular polysaccharide types are known, strains with the type b capsule cause most of the invasive Haemophilus diseases.¹ Haemophilus b diseases occur primarily in children under five years of age. In the United States, the cumulative risk of developing invasive Haemophilus b disease during the first five years of life is about 1 in 200. Approximately 60% of cases are meningitis; 40%, cellulitis, epiglottitis, pericarditis, pneumonia, sepsis or septic arthritis. An estimated 12,000 cases of Haemophilus b meningitis occur annually.¹⁻³ The mortality rate can be 5%, and neurologic sequelae have been observed in up to 38% of survivors.⁴

The incidence of invasive Haemophilus b disease peaks between six months and 1 year of age. However, at least 30% of Haemophilus b disease occurs in children 18 months of age and older.¹⁻³ Inter-personal transmission of Haemophilus b occurs, and risk of invasive disease is increased in children younger than 4 years of age who are exposed in the household to a primary case of disease.⁵ Clusters of cases in children in day care have been reported, and recent studies suggest that the rate of secondary cases may also be increased among children exposed to a primary case in the day care setting.^{6,7}

The incidence of invasive Haemophilus b diseases is increased in certain children, such as those who are Native Americans, black, or from lower socio-economic status and those with medical conditions such as asplenia, sickle-cell disease, malignancies associated with immunosuppression and antibody deficiency syndromes.^{1,2,8}

The protective activity of antibody to PRP was (1) inferred from the protection produced by antibody passively administered to animals before challenge with Haemophilus b and to children with agammaglobulinemia or with Haemophilus b disease,⁹ and (2) demonstrated by the efficacy of Haemophilus b Polysaccharide Vaccine.¹⁰ A randomized, controlled trial of highly purified Haemophilus b Polysaccharide Vaccine was conducted in Finland in 1974. Approximately 98,000 children were studied, about half of whom received the vaccine. Among children of 18-71 months of age, the protective efficacy in preventing invasive Haemophilus b disease through a four year follow up was 90% (95% confidence interval, 55%-96%).¹⁰ Data from other antibody studies indicate that a pre-existing titer of antibody to PRP of 0.15 µg/ml correlates with protection.¹¹ Data from the Finnish field trial indicate that a titer of ≥ 1.0 µg/ml three weeks after vaccination is associated with long term protection.¹²

The characteristics of an immune response depend on the type of cells producing the response and the antigens stimulating the process. Certain antigens, such as proteins, induce B lymphocytes to produce antibody aided by thymus derived lymphocytes called T helper (T_H) cells. These antigens are called thymus dependent or TD antigens. The immune response is potentially boostable, and IgG antibody predominates.¹⁴ In contrast, polysaccharide antigens stimulate B cells without T cell help, producing a non-boostable response of both IgG and IgM antibodies. These antigens are known as thymus independent or TI antigens. Linkage of Haemophilus b saccharides to CRM₁₉₇ can convert the TI saccharide to a TD antigen, and result in an enhanced antibody response to the saccharide that is boostable and predominantly of the IgG isotype.¹⁵ Laboratory evidence indicates that the native state of the CRM₁₉₇ protein and the use of oligosaccharides in the formulation of HiBTITER™ Haemophilus b Conjugate Vaccine (Diphtheria CRM₁₉₇ Protein Conjugate) enhances its T_H potential and thus its immunogenicity.¹⁶⁻¹⁹

The immunogenicity of HiBTITER has been evaluated in 287 children of 15-23 months of age in 5 centers in the United States. Total antibody activity of coded samples was quantitated in one laboratory by a radioimmuno assay that produces results that correlate with the assay used by the National Public Health Institute of Finland.^{12, 19} One month after immunization, the geometric mean titer (GMT) of anti-Haemophilus b antibody was 13.42 µg/ml; all children had an antibody rise \geq two fold and 98.7% of the children had titers ≥ 1 µg/ml. The antibody was predominantly of the IgG isotype and of the IgG₁ sub-class.¹⁹ A long-term study of 28 children vaccinated at 15-22

months of age demonstrated a GMT of 13.95 µg/ml one month, 8.89 µg/ml six months, and 3.88 µg/ml 17-27 months post-vaccination. Titers of ≥ 1 µg/ml were found in all children at one and six months, and in 25 of 28 at 17-22 months post-vaccination, respectively.

A study of the anti-Haemophilus b polysaccharide antibody level in 11 adults and 6 children of 18-23 months of age at 0, 1, 3, 7, 14 and 28 days post-vaccination indicated that vaccination with HiBTITER did not reduce significantly the pre-existing titer.¹⁹ Furthermore, analysis before and at 1, 3, 7 and 10 days after vaccination with HiBTITER indicated that none of the 10 children studied had detectable antigenuria.

Table 1 summarizes a study that compared the immunogenicity of HiBTITER and Haemophilus b Polysaccharide Vaccine in a single center.

TABLE 1
Immunogenicity of HiBTITER and Haemophilus b Polysaccharide (HiBP) Vaccine*
Anti-HbPs Antibody Activity

Vaccine	Age (mo.)	GMT (µg/ml)		Fold		% ≥ 1 µg/ml		% BC**		
		No.	Pre	Post	Rise	Pre	Post	Pre	Post	
HiBPs	24	2	42	0.13	2.07	15.9	0	61.9	2.4	47.6
HiBTITER	18	2	78	0.13	14.8	113.8	0	98.7	0	92.2

Statistical Analysis

T Test, p value — HiBTITER vs. HiBPs

0.83 0.001 0.001 0.0001 0.32 0.001

*Only subjects with pre-immunization titers ≤ 0.6 µg/ml were included in the analysis.

**Percent of subjects with complement-mediated bactericidal activity.¹⁹

The data indicate that HiBTITER is more immunogenic than Haemophilus b Polysaccharide Vaccine, even in a younger aged group.

HiBTITER has been found to be immunogenic in children with medical conditions that increase susceptibility to Hib disease. In studies of 28 infants of 22 months to 5 years of age with recurrent infections and a deficiency in antibody response to Haemophilus b Polysaccharide Vaccine, some of whom also had deficiencies in IgA or IgG subclass antibodies, one dose of HiBTITER was immunogenic in all 28 and generated titers of ≥ 1 µg/ml in 27 of the 28 infants.¹⁹

INDICATIONS AND USAGE

HiBTITER™ Haemophilus b Conjugate Vaccine (Diphtheria CRM₁₉₇ Protein Conjugate) is indicated for the immunization of children 18 months to 5 years of age against invasive diseases caused by *Haemophilus influenzae* type b. As with other vaccines, antibody levels correlated with protection are attained only several days after administration of HiBTITER.

The Immunization Practices Advisory Committee (ACIP) of the U.S. Department of Health and Human Services²⁰ and the Infectious Disease Committee of the American Academy of Pediatrics²¹ have recommended the use of Haemophilus b conjugate vaccines, including HiBTITER for all children at 18 months of age. According to the ACIP recommendations,²⁰ physicians may wish to vaccinate previously healthy children between 2 and 5 years of age to prevent the disease that can occur in this group, although the risk of disease decreases with increasing age. The Infectious Disease Committee also recommended that healthy children 19 months of age through the 5th year of life who have not yet been vaccinated with Haemophilus b Polysaccharide Vaccine should receive conjugate vaccine²¹. Both groups recommended vaccination for those children 18 months of age and older considered at high risk for Haemophilus b disease, such as those in day care, and those who had invasive Haemophilus b disease when less than 24 months of age.^{20,21}

The need for a booster dose of HiBTITER has not been established and is not recommended at this time.

HiBTITER will not protect against *Haemophilus influenzae* other than type b strains or other microorganisms that cause meningitis or septic disease.

No impairment of the antibody response to the individual antigens was demonstrated when HiBTITER was given at the same time at separate sites as Diphtheria and Tetanus Toxoid and Pertussis Vaccine Adorbed (DTP). Because the efficacy of HiBTITER has not been established in children less than 18 months of age, HiBTITER is not indicated for use in this age group at this time. Studies to establish the efficacy of HiBTITER in children less than 18 months of age are ongoing.

HiBTITER IS NOT RECOMMENDED FOR USE IN CHILDREN YOUNGER THAN 18 MONTHS OF AGE.

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine, including diphtheria toxoid or thimerosal in the multi-dose presentation, is a contraindication to use of HiBTITER.

WARNINGS

If the vaccine is used in persons deficient in producing antibody, whether due to genetic defect or to immunosuppressive therapy, the expected immune response may not be obtained. As with any vaccine, HiBTITER may not protect 100% of individuals receiving the vaccine.

PRECAUTIONS

As with the injection of any biological material, Epinephrine injection (1:1000) should be available for immediate use should an anaphylactic or other allergic reaction occur.

GENERAL

As with the injection of any biological material, Epinephrine injection (1:1000) should be available for immediate use should an anaphylactic or other allergic reaction occur.

Prior to an injection of any vaccine, all reasonable precautions should be taken to prevent adverse reactions. Any febrile illness or active infection is reason for delaying use of HiBTITER™ Haemophilus b Conjugate Vaccine (Diphtheria CRM₁₉₇ Protein Conjugate).

As reported with Haemophilus b Polysaccharide Vaccine, cases of Haemophilus b disease may occur in the week after vaccination, prior to the onset of the protective effects of the vaccine.^{22,23}

The vaccine should not be injected intradermally or intravenously, since the safety and efficacy of these routes have not been evaluated. The vaccine should be given intramuscularly. Special care should be taken to ensure that the injection does not enter a blood vessel.

A separate, sterile syringe and needle or a sterile disposable unit should be used for each patient to prevent transmission of infectious agents from one person to another.

ALTHOUGH SOME ANTIBODY RESPONSE TO DIPHTHERIA TOXIN OCCURS, IMMUNIZATION WITH HiBTITER DOES NOT SUBSTITUTE FOR ROUTINE DIPHTHERIA IMMUNIZATION.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

HiBTITER has not been evaluated for its carcinogenic, mutagenic potential or impairment of fertility.

PREGNANCY REPRODUCTION STUDIES—PREGNANCY CATEGORY C:

Animal reproduction studies have not been conducted with HiBTITER. It is also not known whether HiBTITER can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. HiBTITER is NOT recommended for use in a pregnant woman.

ADVERSE REACTIONS

Adverse reactions associated with HiBTITER have been evaluated in 1197 infants of 1-23 months of age given 2751 doses independent of DTP vaccine. Observations were made during the day of vaccination and days 1 and 2 post-vaccination. A temperature $> 38.3^{\circ}\text{C}$ was recorded at least once during the observation period following 2.4% of the vaccinations. Local erythema, warmth or swelling (≥ 2 cm) was observed following 2.2% of vaccinations. The incidence of temperature $> 38.3^{\circ}\text{C}$ was greater during the first post-vaccination day than during the day of vaccination or the second post-vaccination day. The incidence of local erythema, warmth or swelling was similar during the day of vaccination and the first post-vaccination day; it was lower during the second post-vaccination day.

Table 2 summarizes the subset of this data that details the reactions associated with a single vaccination of HiBTITER given (without DTP) to infants of 15-23 months of age.

TABLE 2
Selected Adverse Reactions* in Infants of 15-23 Months of Age Following Vaccination with HiBTITER™ Haemophilus b Conjugate Vaccine (Diphtheria CRM₁₉₇ Protein Conjugate)

Adverse Reaction	No. of Subjects	Reaction (%) Post-Vaccination	
		24 hrs.	48 hrs.
Fever $> 38.3^{\circ}\text{C}$	268	0.75	0.75
Erythema	268	1.9	—
Swelling	268	0.75	—
Tenderness	268	1.9	0.4

*The following complaints were reported following vaccination of these 268 infants in the indicated number of children: diarrhea (4), vomiting (4), prolonged crying (> 4 hours) (2), rash (1).

Additional safety data of HiBTITER are available from ongoing efficacy studies being conducted in young infants. To date, approximately 40,000 doses have been given to 18,000 infants at 2, 4 and 6 months in California at the same time as oral polio vaccine and at a separate site as DTP; approximately 80,000 doses have been given to 45,000 infants at 4 and 6 months in Finland in a separate site, but at the same time as a combined DTP and inactivated polio vaccine (IPV). The rate and type of reaction associated with the vaccinations were no different from those seen when DTP or DTP-IPV was administered alone. These included fever, local reactions, rash and one hypersensitive episode with a transient seizure.¹⁹

Following the use of Haemophilus b Polysaccharide Vaccine, reports of the following types of associated adverse reactions were recorded by passive reporting²⁴ and post-marketing surveillance methods:^{19,25} fever $> 38.3^{\circ}\text{C}$, local erythema, swelling and tenderness, rash, hives, convulsions, vomiting/diarrhea. A cause and effect relationship between these side effects and the vaccination was not established.

DOSEAGE AND ADMINISTRATION

Any parenteral drug product should be inspected visually for extraneous particulate matter and/or discoloration prior to administration whenever solution and container permit. If these conditions exist, HiBTITER should not be administered.

HiBTITER is indicated for children 18 months to 5 years of age. The immunizing dose is a single injection of 0.5 ml given intramuscularly, preferably in the outer

aspect of the vastus lateralis (mid-thigh), or in the deltoid muscle.

Each dose of 0.5 ml is formulated to contain 10 µg of purified Haemophilus b saccharide and approximately 25 µg of CRM₁₉₇ protein.

Before injection, the skin over the site to be injected should be cleaned with a suitable germicide. After insertion of the needle, aspirate to ensure that the needle has not entered a blood vessel.

DO NOT INJECT INTRAVENOUSLY.

STORAGE

Stability studies indicate that HiBTITER can be shipped at ambient temperatures and stored at 2°-8°C (35°-46°F). DO NOT FREEZE.

HOW SUPPLIED

Vial, 1 Dose (4 per package)—Product No. 53124-201-01

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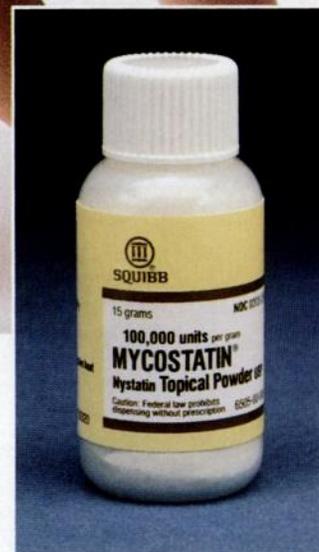
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CONTRAINDICATIONS: Mycostatin topical preparations are contraindicated in patients with a history of hypersensitivity to any of their components.

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ADVERSE REACTIONS: Nystatin is virtually nontoxic and nonsensitizing and is well tolerated by all age groups including debilitated infants, even on prolonged administration. If irritation on topical application should occur, discontinue medication.

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HOW SUPPLIED: Mycostatin Cream (Nystatin Cream) is supplied in tubes providing 100,000 units Nystatin USP per gram in an aqueous, perfumed vanishing cream base.

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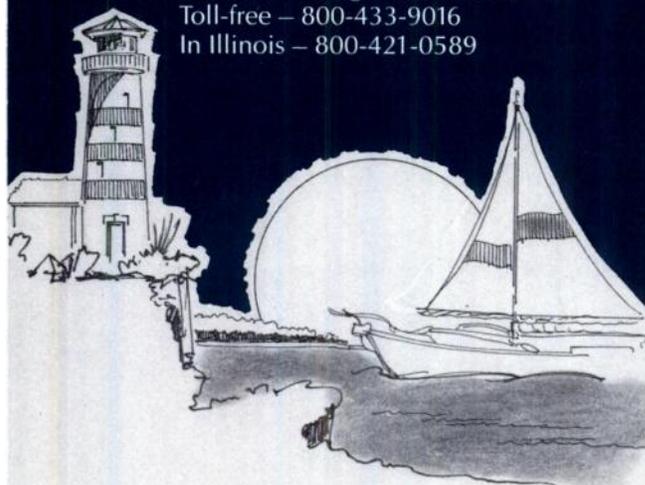
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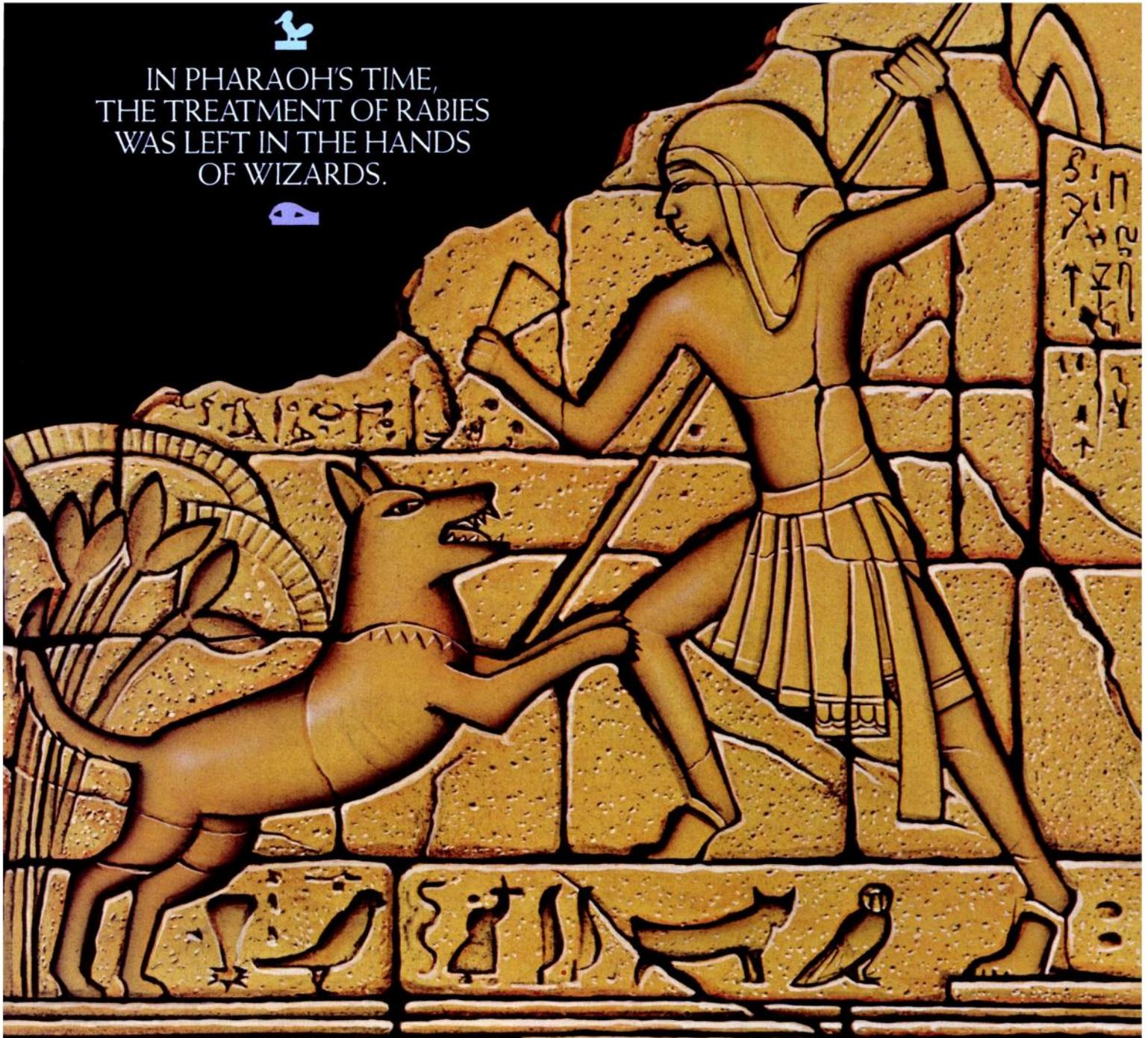
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Rabies Immune Globulin
U.S.P. (Human)



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Modern Solutions to Ancient Problems

*"Immune complex-like" reactions may occur in approximately 6% of persons receiving booster vaccines and much less frequently in persons receiving primary immunization. MMWR July 20, 1984. There have been reports of suboptimal response and possible vaccine failure when the vaccine has been administered in the gluteal area. NEJM May 14, 1987; MMWR Nov. 27, 1987.

Please see next page for brief summary prescribing information, symptoms and treatment.

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RABIES VACCINE U.S.P. (HUMAN DIPLOID CELL) IMOVAX® RABIES

DESCRIPTION: The IMOVAX RABIES Vaccine produced by Institut Merieux is a sterile, stable, freeze-dried suspension of rabies virus prepared from strain PM-1503-3M obtained from the Wistar Institute, Philadelphia, PA.

The virus is harvested from infected human diploid cells, MRC-5 strain, concentrated by ultrafiltration and is inactivated by beta propiolactone. One dose of reconstituted vaccine contains less than 100 mg albumin, less than 150 µg neomycin sulfate and 20 µg of phenol red indicator. This vaccine must only be used intramuscularly and as a single dose vial.

The vaccine contains no preservative or stabilizer. It should be used immediately after reconstitution, and if not administered promptly, discard contents.

The potency of one dose (1.0 ml) Merieux IMOVAX RABIES Vaccine is equal to or greater than 2.5 international units of rabies antigen.

CONTRAINDICATIONS: For post-exposure treatment, there are no known specific contraindications to the use of Merieux IMOVAX RABIES Vaccine. In cases of pre-exposure immunization, there are no known specific contraindications other than situations such as developing febrile illness, etc.

WARNINGS: Rabies Vaccine in this package is a unit dose to be delivered intramuscularly in the deltoid area.¹ This vaccine must not be used intradermally or as a multiple dose dispensing unit. In both pre-exposure and post-exposure immunization, the full 1.0 ml dose should be given intramuscularly.

In the case of pre-exposure immunization, recently a significant increase has been noted in "immune complex-like" reactions in persons receiving booster doses of HDCV.² The illness characterized by onset 2-21 days post-booster, presents with a generalized urticaria and may also include arthralgia, arthritis, angioedema, nausea, vomiting, fever, and malaise. In no cases were the illnesses life-threatening. Preliminary data suggest this "immune complex-like" illness may occur in up to 6% of persons receiving booster doses and much less frequently in persons receiving primary immunization. Additional information with this vaccine is needed to define more clearly the risk of these adverse reactions.^{1,3}

Two cases of neurologic illness resembling Guillain-Barré syndrome,^{4,5} a transient neuromyolytic illness, that resolved without sequelae in 12 weeks and a focal subacute central nervous system disorder temporally associated with HDCV, have been reported.⁶

All serious systemic neuromyolytic or anaphylactic reactions

to a rabies vaccine should be immediately reported to the state health department or Merieux Institute, Inc., at (800) 327-2842 or (305) 593-9577.¹

PRECAUTIONS: IN ADULTS AND CHILDREN THE VACCINE SHOULD BE INJECTED INTO THE DELTOID MUSCLE. IN INFANTS AND SMALL CHILDREN THE MID-LATERAL ASPECT OF THE THIGH MAY BE PREFERABLE.

General—When a person with a history of hypersensitivity must be given rabies vaccine, antihistamines may be given; epinephrine (1:1000) should be readily available to counteract anaphylactic reactions, and the person should be carefully observed after immunization.

While the concentration of antibiotics in each dose of vaccine is extremely small, persons with known hypersensitivity to any of these agents could manifest an allergic reaction. While the risk is small, it should be weighed in light of the potential risk of contracting rabies.

Drug Interactions—Corticosteroids, other immunosuppressive agents, and immunosuppressive illnesses can interfere with the development of active immunity and predispose the patient to developing rabies. Immunosuppressive agents should not be administered during post-exposure therapy, unless essential for the treatment of other conditions. When rabies post-exposure prophylaxis is administered to persons receiving steroids or other immunosuppressive therapy, it is especially important that serum be tested for rabies antibody to ensure that an adequate response has developed.¹

Usage in Pregnancy—Pregnancy Category C. Animal reproduction studies have not been conducted with IMOVAX RABIES Vaccine. It is also not known whether the product can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Rabies vaccine should be given to a pregnant woman only if clearly needed.

Because of the potential consequences of inadequately treated rabies exposure and limited data that indicate that fetal abnormalities have not been associated with rabies vaccination, pregnancy is not considered a contraindication to post-exposure prophylaxis.^{1,7} If there is substantial risk of exposure to rabies, pre-exposure prophylaxis may also be indicated during pregnancy.¹

Pediatric Use—Both safety and efficacy in children have been established.

ADVERSE REACTIONS: ALSO SEE WARNINGS AND CONTRAINDICATIONS SECTIONS FOR

ADDITIONAL STATEMENTS. Once initiated, rabies prophylaxis should not be interrupted or discontinued because of local or mild systemic adverse reactions to rabies vaccine. Usually such reactions can be successfully managed with anti-inflammatory and antipyretic agents (e.g. aspirin). Reactions after vaccination with HDCV are less common than with previously available vaccines.^{2,3,8} In a study using five doses of HDCV, local reactions, such as pain, erythema, and swelling or itching at the injection site were reported in about 25% of recipients of HDCV, and mild systemic reactions such as headache, nausea, abdominal pain, muscle aches and dizziness were reported in about 20% of recipients.¹

Serious systemic anaphylactic or neuromyolytic reactions occurring during the administration of rabies vaccines pose a dilemma for the attending physician. A patient's risk of developing rabies must be carefully considered before deciding to discontinue vaccination. Moreover, the use of corticosteroids to treat life-threatening neuromyolytic reactions carries the risk of inhibiting the development of active immunity to rabies. It is especially important in these cases that the serum of the patient be tested for rabies antibodies. Advice and assistance on the management of serious adverse reactions in persons receiving rabies vaccines may be sought from the state health department or Merieux Institute, Inc.

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8. Greenberg M, Childress J. Vaccination against rabies with duck-embryo and Semple vaccines. *JAMA* 173:333-7 (1960).

RABIES IMMUNE GLOBULIN (HUMAN) U.S.P. IMOGRAM® RABIES

DESCRIPTION: Rabies Immune Globulin (Human) IMOGRAM® RABIES is a sterile solution of antirabies immunoglobulin (10-18% protein) for intramuscular administration. It is prepared by cold alcohol fractionation from pooled venous plasma of individuals immunized with Rabies Vaccine prepared from human diploid cells (HDCV). The product is stabilized with 0.3 M glycine and contains 1:10,000 sodium ethylmercurithiosalicylate (thimerosal) as a preservative. The globulin solution has a pH of 6.8±0.4 adjusted with sodium hydroxide or hydrochloric acid. The product is standardized against the U.S. Standard Rabies Immune Globulin. The U.S. unit of potency is equivalent to the International Unit (I.U.) for rabies antibody. The product is prepared from units of human plasma that have been tested and found negative for hepatitis B surface antigen (HBsAg) by FDA-required tests.

CONTRAINDICATIONS: Rabies Immune Globulin (Human) should not be administered in repeated doses once vaccine treatment has been initiated. Repeating the dose may interfere with maximum active immunity expected from the vaccine.

WARNINGS: Rabies Immune Globulin (Human) should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immune globulin preparations or those individuals allergic to thimerosal.

Persons with specific IgA deficiency have increased potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products containing IgA.^{1,2}

PRECAUTIONS: General—Rabies Immune Globulin (Human) should not be administered intravenously because of the potential for serious reactions. Injection should be made intramuscularly and care should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel. Although systemic reactions to immunoglobulin preparations are rare, epinephrine should be available for treatment of acute anaphylactoid symptoms. As with all preparations given intramuscularly, bleeding complications may be encountered in patients with bleeding disorders.

Drug Interactions—Live virus vaccines such as measles vaccines should not be given close to the time of Rabies Immune Globulin (Human) administration because antibodies in the globulin preparation may interfere with the immune response to the vaccination. Immunization with live vaccines should not be given within three months after Rabies Immune Globulin (Human) administration.

Pregnancy Category C—Animal reproduction studies have not been conducted with Rabies Immune Globulin (Human). It is also not known whether RIG(H) can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. RIG(H) should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS: Local or mild systemic adverse reactions to the globulin after intramuscular injections are uncommon^{3,4} and may be treated symptomatically. Local tenderness, soreness or stiffness of the muscles may occur at the injection site and may persist for several hours after injection. Urticaria and angioedema may occur. Anaphylac-

tic reactions, although rare, have been reported following injection of human immune globulin preparations.

REFERENCES:

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Issued March 1988

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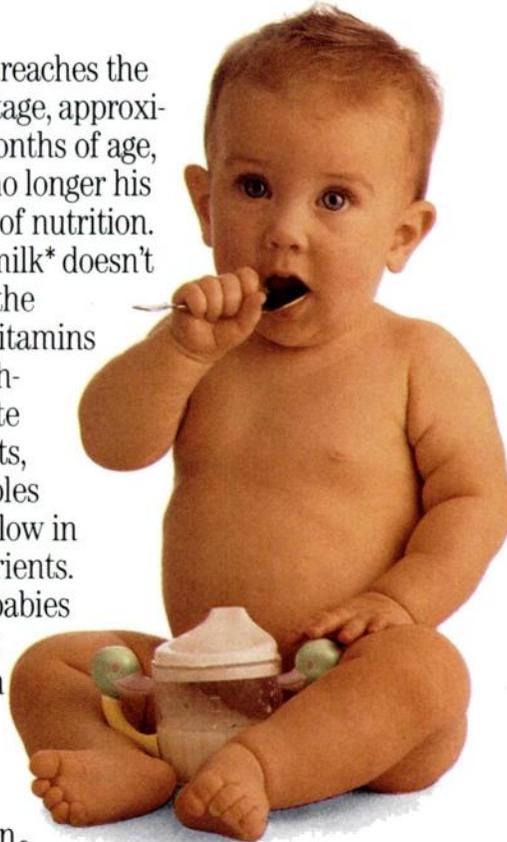
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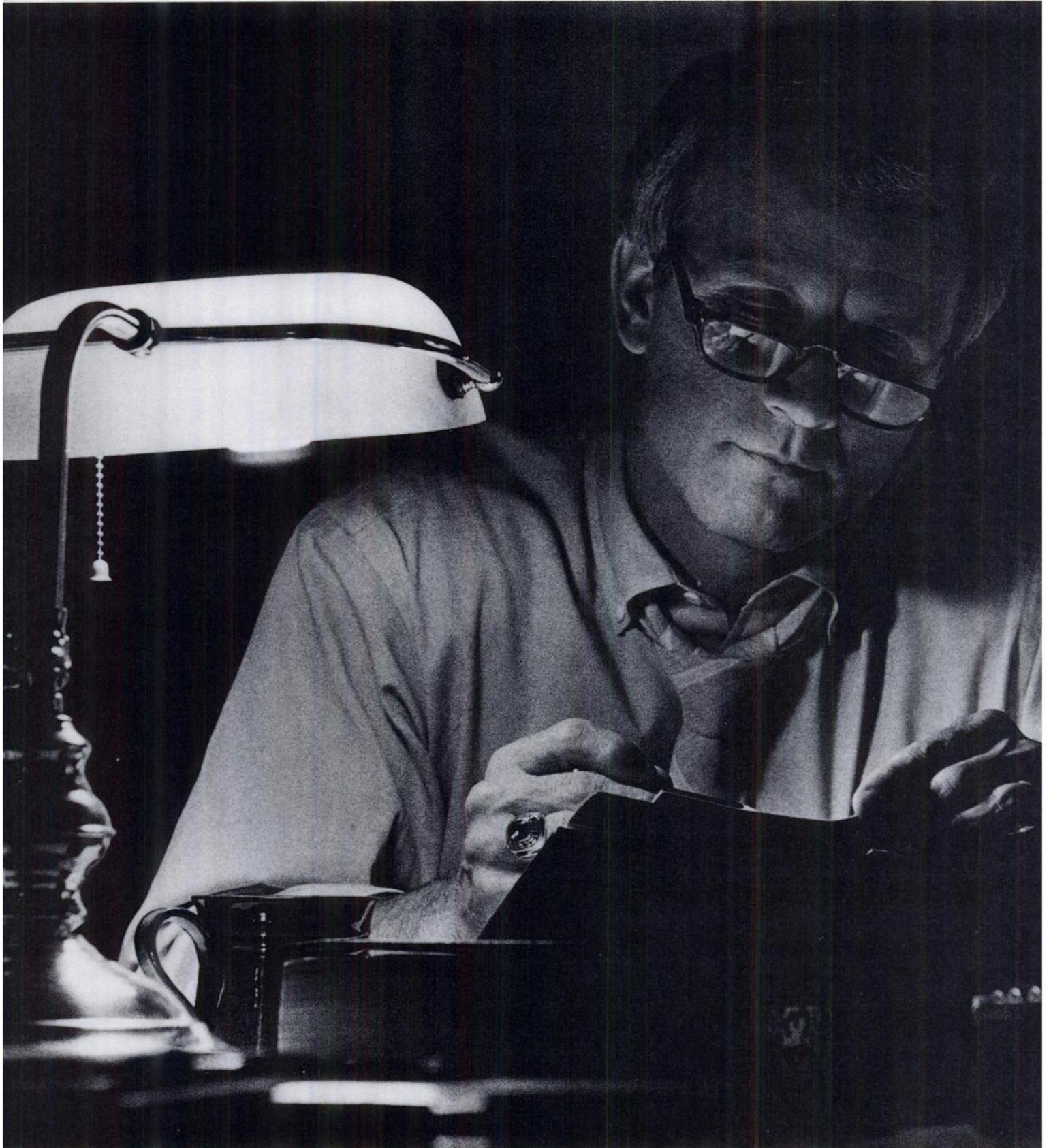


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provides 14-day protection against reinfestation—*with one application*—and no evidence of CNS toxicity as reported with lindane overexposure.⁵

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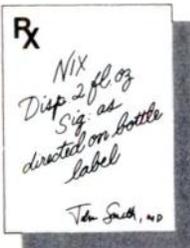


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Nix FOR LICE®

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permethrin 1%



PEDICULICIDAL/OVICIDAL ACTIVITIES: *In vitro* data indicate that permethrin has pediculicidal and ovicidal activity against *Pediculus humanus var. capitis*. The high cure rate (97-99%) of Nix in patients with head lice demonstrated at 14 days following a single application is attributable to a combination of its pediculicidal and ovicidal activities and its residual persistence on the hair which may also prevent reinfestation.

INDICATIONS AND USAGE: Nix is indicated for the single-application treatment of infestation with *Pediculus humanus var. capitis* (the head louse) and its nits (eggs). Retreatment for recurrences is required in less than 1% of patients since the ovicidal activity may be supplemented by residual persistence in the hair. If live lice are observed after at least seven days following the initial application, a second application can be given.

CONTRAINDICATIONS: Nix is contraindicated in patients with known hypersensitivity to any of its components, to any synthetic pyrethroid or pyrethrin, or to chrysanthemums.

WARNING: If hypersensitivity to Nix occurs, discontinue use.

PRECAUTIONS:

General: Head lice infestation is often accompanied by pruritus, erythema, and edema. Treatment with Nix may temporarily exacerbate these conditions.

Information for Patients: Patients with head lice should be advised that itching, redness, or swelling of the scalp may occur after application of Nix. If irritation persists, they should consult their physician. Nix is not irritating to the eyes; however, patients should be advised to avoid contact with eyes during application and to flush with water immediately if Nix gets in the eyes. In order to prevent accidental ingestion by children, the remaining contents of Nix should be discarded after use.

Combing of nits following treatment with Nix is not necessary for effective treatment. However, patients may do so for cosmetic or other reasons. The nits are easily combed from the hair treated with Nix after drying.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Six carcinogenicity bioassays were evaluated with permethrin, three each in rats and mice. No tumorigenicity was seen in the rat studies. However, species-specific increases in pulmonary adenomas, a common benign tumor of mice of high spontaneous background incidence, were seen in the three mouse studies. In one of these studies there was an increased incidence of pulmonary alveolar-cell carcinomas and benign liver adenomas only in female mice when permethrin was given in their food at a concentration of 5000 ppm. Mutagenicity assays, which give useful correlative data for interpreting results from carcinogenicity bioassays in rodents, were negative. Permethrin showed no evidence of mutagenic potential in a battery of *in vitro* and *in vivo* genetic toxicity studies. Permethrin did not have any adverse effect on reproductive function at a dose of 180 mg/kg/day orally in a three-generation rat study.

Pregnancy: Teratogenic Effects: Pregnancy Category B: Reproduction studies have been performed in mice, rats, and rabbits (200-400 mg/kg/day orally) and have revealed no evidence of impaired fertility or harm to the fetus due to permethrin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the evidence for tumorigenic potential of permethrin in animal studies, consideration should be given to discontinuing nursing temporarily or withholding the drug while the mother is nursing.

Pediatric Use: Nix is safe and effective in children two years of age and older. Safety and effectiveness in children less than two years of age have not been established.

ADVERSE REACTIONS: The most frequent adverse reaction to Nix is pruritus. This is usually a consequence of head lice infestation itself, but may be temporarily aggravated following treatment with Nix. 5.9% of patients in clinical studies experienced mild temporary itching; 3.4% experienced mild transient burning/stinging, tingling, numbness, or scalp discomfort; and 2.1% experienced mild transient erythema, edema, or rash of the scalp.

DOSAGE AND ADMINISTRATION:

Adults and Children: Nix is intended for use after the hair has been washed with shampoo, rinsed with water and towel dried. Apply a sufficient volume of Nix to saturate the hair and scalp (especially behind the ears and on nape of the neck). Nix should remain on the hair for 10 minutes before being rinsed off with water. A single treatment is sufficient to eliminate head lice infestation. Combing of nits is not required for therapeutic efficacy, but may be done for cosmetic reasons or to meet school 'no nit' policies. A nit comb is provided.

SHAKE WELL BEFORE USING.

HOW SUPPLIED: Nix (Permethrin) 1% (wt./wt.) Creme Rinse is supplied in plastic squeeze bottles that contain 2 fl. oz. weighing 56 g. (NDC-0081-0780-81)

Store at 15°-25°C (59°-77°F).

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A Brief Summary

Please see package insert for full description, directions for use, and references.

INDICATIONS: For prevention of poliomyelitis caused by Poliovirus Types 1, 2, and 3.

CONTRAINDICATIONS: Under no circumstances should this vaccine be administered parenterally.

Administration of the vaccine should be postponed or avoided in those experiencing any acute illness and in those with any advanced debilitated condition or persistent vomiting or diarrhea.

ORIMUNE must not be administered to patients with immune deficiency diseases such as combined immunodeficiency, hypogammaglobulinemia, and agammaglobulinemia. Further, ORIMUNE must not be administered to patients with altered immune states, such as those occurring in thymic abnormalities, leukemia, lymphoma, or generalized malignancy or by lowered resistance from therapy with corticosteroids, alkylating drugs, antimetabolites, or radiation. ORIMUNE should also not be given to members of a household in which there is a family history of immunodeficiency until the immune status of all members is determined to be normal. All persons with altered immune status should avoid close household-type contact with recipients of the vaccine for at least six to eight weeks. Inactivated poliovirus vaccine (IPV) is preferred for immunizing all persons in the above described circumstances.

WARNINGS: Under no circumstances should this vaccine be administered parenterally.

Administration of the vaccine should be postponed or avoided in those experiencing any acute illness and in those with any advanced debilitated condition or persistent vomiting or diarrhea.

Other viruses (including poliovirus and other enteroviruses) may interfere with the desired response to this vaccine, since their presence in the intestinal tract may interfere with the replication of the attenuated strains of poliovirus in the vaccine.

PRECAUTIONS: Preliminary data indicate that immune globulin (Human) (IG) does not appear to interfere with immunization with poliovirus vaccine live oral trivalent (OPV). However, until more data are available, it would seem prudent not to administer OPV shortly after IG, unless such a procedure is unavoidable, for example, with unexpected travel to or contact with epidemic areas or endemic areas. If OPV is given with or shortly after IG, the dose should probably be repeated after three months if immunization is still indicated.

The vaccine is not effective in modifying or preventing cases of existing and/or incubating poliomyelitis.

NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986 (as amended in 1987)

Manufacturer and lot number of vaccine administered must be recorded by health care provider in vaccine recipient's permanent record, along with date of administration and name, address, and title of person administering vaccine.

Health care provider must report to a health department or to the FDA the occurrence following immunization of any event set forth in the Vaccine Injury Table including: paralytic poliomyelitis—in a nonimmunodeficient recipient within 30 days of vaccination—in an immunodeficient recipient within 6 months of vaccination; any vaccine-associated community case of paralytic poliomyelitis; or any acute complication or sequela (including death) of above events.

Use in Pregnancy: Pregnancy Category C. Animal reproduction studies have not been conducted with Poliovirus vaccine live oral trivalent. It is also not known whether OPV can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Although there is no convincing evidence documenting adverse effects of either OPV or IPV on the developing fetus or pregnant woman, it is prudent on theoretical grounds to avoid vaccinating pregnant women. However, if immediate protection against poliomyelitis is needed, OPV is recommended. (See **CONTRAINDICATIONS** and **ADVERSE REACTIONS**.)

ADVERSE REACTIONS: Paralytic disease following the ingestion of live poliovirus vaccines has been, on rare occasion, reported in individuals receiving the vaccine (see, for example, **CONTRAINDICATIONS**), and in persons who were in close contact with vaccinees. The vaccine viruses are shed in the vaccinee's stools for at least six to eight weeks as well as via the pharyngeal route. Most reports of paralytic disease following ingestion of the vaccine or contact with a recent vaccinee are based on epidemiological analysis and temporal association between vaccination or contact and the onset of symptoms. Most authorities believe that a causal relationship exists. Prior to administration of the vaccine, the attending physician should warn or specifically direct personnel acting under his authority to convey the warnings to the vaccinee, parent, guardian, or other responsible person of the possibility of vaccine-associated paralysis, particularly to susceptible family members and other close personal contacts.

The Centers for Disease Control report that during the years 1973 through 1984 approximately 274.1 million OPV doses were distributed in the US. During this same period, 105 vaccine-associated cases were reported (1 case per 2.6 million doses distributed). Of these 105 cases, 35 occurred in vaccine recipients (1 case per 7.8 million doses distributed), 50 occurred in household and nonhousehold contacts of vaccinees (1 case per 5.5 million doses distributed), 14 occurred in immunodeficient recipients or contacts, and 6 occurred in persons with no history of vaccine exposure, from whom vaccine-like viruses were isolated.

Thirty-three (94%) of the recipient cases, 41 (82%) of the contact cases, and 5 (36%) of the immunodeficient cases were associated with the recipient's first dose of OPV. Because most cases of vaccine-associated paralysis have occurred in association with the first dose, the CDC has estimated the likelihood of paralysis in association with first v subsequent doses of OPV, using the number of births during 1973-1984 to estimate the number of first doses distributed, and subtracting this from the total distribution to estimate the number of subsequent doses distributed. This method estimates a frequency of paralysis for recipients of 1 case per 1.2 million first doses v 1 case per 116.5 million subsequent doses; for contacts one case per 1 million first doses v 25.9 million subsequent doses; with an overall frequency of 1 case per 520,000 first doses v 1 case per 12.3 million subsequent doses.

Other methods of estimating the likelihood of paralysis in association with OPV have been described. Because the number of susceptible vaccine recipients or contacts of recipients is not known, the true risk of vaccine-associated poliomyelitis is impossible to determine precisely.

When the attenuated vaccine strains are to be introduced into a household with adults who have not been adequately vaccinated or whose immune status cannot be determined, the risk of vaccine-associated paralysis can be reduced by giving these adults one dose of IPV per month for three months before the children receive Poliovirus vaccine live oral trivalent ORIMUNE. The children may receive the first dose of ORIMUNE at the same visit that the adult receives the third dose of IPV. The CDC reports that no paralytic reactions to IPV are known to have occurred since the 1955 cluster of poliomyelitis cases caused by vaccine that contained live polioviruses that had escaped inactivation.

The ACIP states: "Because of the overriding importance of ensuring prompt and complete immunization of the child and the extreme rarity of OPV-associated disease in contacts, the Committee recommends the administration of OPV to a child regardless of the poliovirus-vaccine status of adult household contacts. This is the usual practice in the United States. The responsible adult should be informed of the small risk involved. An acceptable alternative, if there is a strong assurance that ultimate, full immunization of the child will not be jeopardized or unduly delayed, is to immunize adults according to the schedule outlined above before giving OPV to the child."

The ACIP has concluded that "Oral polio vaccine remains the vaccine of choice for primary immunization of children."

Rev. 7/89



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RSV can be life threatening

The burden of bronchiolitis and pneumonia in infants is serious enough. But recent estimates show that of the 91,000 annual cases of hospitalized children 4 years and younger with respiratory syncytial virus (RSV), up to 5% may die from disease complications.²

Who will become severely ill?

Even in the absence of underlying cardiac or respiratory disease, clinical data available at the time of admission were shown to be non-predictive of disease severity and length of hospital stay³—a finding that underscores the urgency for decisive action.

Prompt treatment speeds recovery

Patients hospitalized with RSV should receive standard supportive respiratory and fluid management. In addition, clinical evidence and experience with over 35,000 patients confirm that early treatment of appropriate patients with **Virazole® (ribavirin) Aerosol**

- improves disease symptoms safely and rapidly^{4,7}
- can help reduce the need for supplemental oxygen and mechanical ventilation^{8,9}
- may shorten hospitalization^{3,8}



RSV

patients

serious enough
to hospitalize
•
serious enough
to consider
treatment

References:

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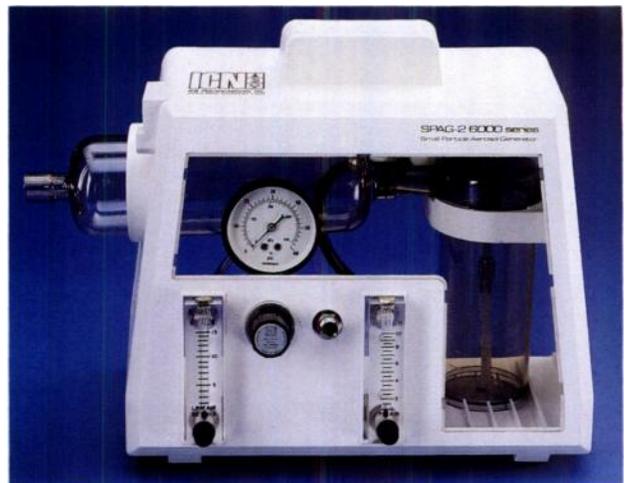
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Small Particle Aerosol Generator (SPAG™-2)

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Virazole®
(ribavirin)

lyophilized for aerosol administration

PRESCRIBING INFORMATION

WARNING: RIBAVIRIN AEROSOL SHOULD NOT BE USED FOR INFANTS REQUIRING ASSISTED VENTILATION BECAUSE PRECIPITATION OF THE DRUG IN THE RESPIRATORY EQUIPMENT MAY INTERFERE WITH SAFE AND EFFECTIVE VENTILATION OF THE PATIENT. Conditions for safe use with a ventilator are still in development.

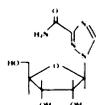
Deterioration of respiratory function has been associated with ribavirin use in infants, and in adults with chronic obstructive lung disease or asthma. Respiratory function should be carefully monitored during treatment. If initiation of ribavirin aerosol treatment appears to produce sudden deterioration of respiratory function, treatment should be stopped and re-instituted only with extreme caution and continuous monitoring.

Although ribavirin is not indicated in adults, the physician should be aware that it is teratogenic in animals (see CONTRAINDICATIONS).

DESCRIPTION:

Virazole® (ribavirin) Aerosol, an antiviral drug, is a sterile, lyophilized powder to be reconstituted for aerosol administration. Each 100 ml glass vial contains 6 grams of ribavirin, and when reconstituted to the recommended volume of 300 ml with sterile water for injection or sterile water for inhalation (no preservatives added), will contain 20 mg/ml ribavirin, pH approximately 5.5. Aerosolization is to be carried out in a SPAG-2 nebulizer only.

Ribavirin is 1-beta-D-ribofuranosyl-1,2,4-triazole-3-carboxamide, with the following structural formula:



Ribavirin, a synthetic nucleoside, is a stable, white, crystalline compound with a maximum solubility in water of 142 mg/ml at 25°C and with only a slight solubility in ethanol. The empirical formula is C₈H₁₂N₄O₅ and the molecular weight is 244.2 Daltons.

CLINICAL PHARMACOLOGY:

Antiviral effects:

Ribavirin has antiviral inhibitory activity (in vitro against respiratory syncytial virus,¹ influenza virus, and herpes simplex virus). Ribavirin is also active against respiratory syncytial virus (RSV) in experimentally infected cotton rats.²

In cell cultures, the inhibitory activity of ribavirin for RSV is selective. The mechanism of action is unknown. Reversal of the in vitro antiviral activity by guanosine or xanthosine suggests ribavirin may act as an analogue of these cellular metabolites.

Immunologic effects:

Neutralizing antibody responses to RSV were decreased in ribavirin treated compared to placebo treated infants.³ The clinical significance of this observation is unknown. In rats, ribavirin resulted in lymphoid atrophy of thymus, spleen, and lymph nodes. Humoral immunity was reduced in guinea pigs and ferrets. Cellular immunity was also mildly depressed in animal studies.

Microbiology:

Several clinical isolates of RSV were evaluated for ribavirin susceptibility by plaque reduction in tissue culture. Plaques were reduced 85-98% by 16 µg/ml; however, plaque reduction varies with the test system. The clinical significance of these data is unknown.

Pharmacokinetics:

Assay for ribavirin in human materials is by a radioimmunoassay which detects ribavirin and at least one metabolite.

Ribavirin administered by aerosol is absorbed systemically. Four pediatric patients inhaling ribavirin aerosol administered by face mask for 2.5 hours each day for

3 days had plasma concentrations ranging from 0.44 to 1.55 µM, with a mean concentration of 0.76 µM. The plasma half-life was reported to be 9.5 hours. Three pediatric patients inhaling ribavirin aerosol administered by face mask or mist tent for 20 hours each day for 5 days had plasma concentrations ranging from 1.5 to 14.3 µM, with a mean concentration of 6.6 µM.

It is likely that the concentration of ribavirin in respiratory tract secretions is much higher than plasma concentrations in view of the route of administration.

The bioavailability of ribavirin aerosol is unknown and may depend on the mode of aerosol delivery. After aerosol treatment, peak plasma concentrations are less than the concentration that reduced RSV plaque formation in tissue culture by 85 to 98%. After aerosol treatment, respiratory tract secretions are likely to contain ribavirin in concentrations many fold higher than those required to reduce plaque formation. However, RSV is an intracellular virus and serum concentrations may better reflect intracellular concentrations in the respiratory tract than respiratory secretion concentrations.

In man, rats, and rhesus monkeys, accumulation of ribavirin and/or metabolites in the red blood cells has been noted, platelet in red cells in man in about 4 days and gradually declining with an apparent half-life of 40 days. The extent of accumulation of ribavirin following inhalation therapy is not well defined.

INDICATIONS AND USAGE:

Ribavirin aerosol is indicated in the treatment of carefully selected hospitalized infants and young children with severe lower respiratory tract infections due to respiratory syncytial virus (RSV). In two placebo controlled trials in infants hospitalized with RSV lower respiratory tract infection, ribavirin aerosol treatment had a therapeutic effect, as judged by the reduction by treatment day 3 of severity of clinical manifestations of disease.^{3,4} Virus titers in respiratory secretions were also significantly reduced with ribavirin in one of these studies.⁴

Only severe RSV lower respiratory tract infection is to be treated with ribavirin aerosol. The vast majority of infants and children with RSV infection have no lower respiratory tract disease or have disease that is mild, self-limited, and does not require hospitalization or antiviral treatment. Many children with mild lower respiratory tract involvement will require shorter hospitalization than would be required for a full course of ribavirin aerosol (3 to 7 days) and should not be treated with the drug. Thus the decision to treat with ribavirin aerosol should be based on the severity of the RSV infection.

The presence of an underlying condition such as prematurity or cardiopulmonary disease may increase the severity of the infection and its risk to the patient. High risk infants and young children with these underlying conditions may benefit from ribavirin treatment, although efficacy has been evaluated in only a small number of such patients.

Ribavirin aerosol treatment must be accompanied by and does not replace standard supportive respiratory and fluid management for infants and children with severe respiratory tract infection.

Diagnosis:

RSV infection should be documented by a rapid diagnostic method such as demonstration of viral antigen in respiratory tract secretions by immunofluorescence^{5,6} or ELISA⁷ before or during the first 24 hours of treatment. Ribavirin aerosol is indicated only for lower respiratory tract infection due to RSV. Treatment may be initiated while awaiting rapid diagnostic test results. However, treatment should not be continued without documentation of RSV infection.

CONTRAINDICATIONS:

Ribavirin is contraindicated in women or girls who are or may become pregnant during exposure to the drug. Ribavirin may cause fetal harm and respiratory syncytial virus infection is self-limited in this population. Ribavirin is not completely cleared from human blood even four weeks after administration. Although there are no pertinent human data, ribavirin has been found to be teratogenic and/or embryolethal in nearly all species in which it has been tested. Teratogenicity was evident after a single oral dose of 2.5 mg/kg in the hamster and after daily oral doses of 10 mg/kg in the rat. Malformations of skull, palate, eye, jaw, skeleton, and gastrointestinal tract were noted in animal studies. Survival of fetuses and offspring was reduced. The drug causes embryolethality in the rabbit at daily oral dose levels as low as 1 mg/kg.

WARNINGS:

Ribavirin administered by aerosol produced cardiac lesions in mice and rats after 30 and 36 mg/kg, respectively, for 4 weeks, and after oral administration in monkeys at 120 and rats at 154 to 200 mg/kg for 1 to 6 months. Ribavirin aerosol administered to developing ferrets at 60 mg/kg for 10 or 30 days resulted in inflammatory and possibly emphysematous changes in the lungs. Proliferative changes were seen at 131 mg/kg for 30 days. The significance of these findings

to human administration is unknown.

Ribavirin lyophilized in 6 gram vials is intended for use as an aerosol only.

PRECAUTIONS:

General:

Patients with lower respiratory tract infection due to respiratory syncytial virus require optimum monitoring and attention to respiratory and fluid status.

Drug Interactions:

Interactions of ribavirin with other drugs such as digoxin, bronchodilators, other antiviral agents, antibiotics, or anti-metabolites has not been evaluated. Interference by ribavirin with laboratory tests has not been evaluated.

Carcinogenesis, mutagenesis, impairment of fertility:

Ribavirin induces cell transformation in an in vitro mammalian system (BalbC 3T3 cell line). However, in vivo carcinogenicity studies are incomplete. Results thus far, though inconclusive, suggest that chronic feeding of ribavirin to rats at dose levels in the range of 16-60 mg/kg body weight can induce benign mammary, pancreatic, pituitary and adrenal tumors.

Ribavirin is mutagenic to mammalian (L5178Y) cells in culture. Results of microbial mutagenicity assays and a dominant lethal assay (mouse) were negative.

Ribavirin causes testicular lesions (tubular atrophy) in adult rats at oral dose levels as low as 16 mg/kg/day (lower doses not tested), but fertility of ribavirin-treated animals (male or female) has not been adequately investigated.

Pregnancy:

Teratogenic Effects: Pregnancy Category X. See "Contraindications" section.

Nursing Mothers: Use of ribavirin aerosol in nursing mothers is not indicated because RSV infection is self-limited in this population. Ribavirin is toxic to lactating animals and their offspring. It is not known whether the drug is excreted in human milk.

ADVERSE REACTIONS:

Approximately 200 patients have been treated with ribavirin aerosol in controlled or uncontrolled clinical studies.

Pulmonary function significantly deteriorated during ribavirin aerosol treatment in six of six adults with chronic obstructive lung disease and in four of six asthmatic adults. Dyspnea and chest soreness were also reported in the latter group. Minor abnormalities in pulmonary function were also seen in healthy adult volunteers.

Several serious adverse events occurred in severely ill infants with life-threatening underlying diseases, many of whom required assisted ventilation. The role of ribavirin aerosol in these events is indeterminate. The following events were associated with ribavirin use:

Pulmonary: Worsening of respiratory status, bacterial pneumonia, pneumothorax, apnea, and ventilator dependence.

Cardiovascular: Cardiac arrest, hypotension, and digitalis toxicity.

There were 7 deaths during or shortly after treatment with ribavirin aerosol. No death was attributed to ribavirin aerosol by the investigators.

Some subjects requiring assisted ventilation have experienced serious difficulties, which may jeopardize adequate ventilation and gas exchange. Precipitation of drug within the ventilatory apparatus, including the endotracheal tube, has resulted in increased positive end expiratory pressure and increased positive inspiratory pressure. Accumulation of fluid in tubing ("rainout") has also been noted.

Although anemia has not been reported with use of the aerosol, it occurs frequently with oral and intravenous ribavirin, and most infants treated with the aerosol have not been evaluated 1 to 2 weeks post-treatment when anemia is likely to occur. Reticulocytosis has been reported with aerosol use.

Rash and conjunctivitis have been associated with the use of ribavirin aerosol.

Overdosage:

No overdosage with ribavirin by aerosol administration has been reported in the human. The LD₅₀ in mice is 2 gm orally. Hypoactivity and gastrointestinal symptoms occurred. In man, ribavirin is sequestered in red blood cells for weeks after dosing.

DOSEAGE AND ADMINISTRATION:

Before use, read thoroughly the Viratek Small Particle Aerosol Generator (SPAG) Model SPAG-2 Operator's Manual for small particle aerosol generator operating instructions.

Treatment was effective when instituted within the first 3 days of respiratory syncytial virus lower respiratory tract infection.³ Treatment early in the course of severe lower respiratory tract infection may be necessary to achieve efficacy.

Treatment is carried out for 12-18 hours per day for at least 3 and no more than 7 days, and is part of a total treatment program. The aerosol is delivered to an infant oxygen hood

from the SPAG-2 aerosol generator. Administration by face mask or oxygen tent may be necessary if a hood cannot be employed (see SPAG-2 manual). However, the volume of distribution and condensation area are larger in a tent and efficacy of this method of administering the drug has been evaluated in only a small number of patients. Ribavirin aerosol is not to be administered with any other aerosol generating device together with other aerosolized medications. Ribavirin aerosol should not be used for patients requiring simultaneous assisted ventilation (see Boxed Warnings).

Virazole is supplied as 6 grams of lyophilized drug per 100 ml vial for aerosol administration only. By sterile technique, solubilize drug with sterile USP water for injection or inhalation in the 100 ml vial. Transfer to the clean, sterilized 500 ml wide-mouth Erlenmeyer flask (SPAG-2 Reservoir) and further dilute to a final volume of 300 ml with sterile USP water for injection or inhalation. The final concentration should be 20 mg/ml. **Important:** This water should not have had any antimicrobial agent or other substance added. The solution should be inspected visually for particulate matter and discoloration prior to administration. Solutions that have been placed in the SPAG-2 unit should be discarded at least every 24 hours and when the liquid level is low before adding newly reconstituted solution.

Using the recommended drug concentration of 20 mg/ml ribavirin as the starting solution in the drug reservoir of the SPAG unit, the average aerosol concentration for a 12 hour period would be 190 micrograms/liter (0.19 mg/l) of air.

HOW SUPPLIED:

Virazole® (ribavirin) Aerosol is supplied in 100 ml glass vials with 6 grams of sterile, lyophilized drug which is to be reconstituted with 300 ml sterile water for injection or sterile water for inhalation (no preservatives added) and administered only by a small particle aerosol generator (SPAG-2). Vials containing the lyophilized drug powder should be stored in a dry place at 15-25°C (59-78°F). Reconstituted solutions may be stored, under sterile conditions, at room temperature (20-30°C, 68-86°F) for 24 hours. Solutions which have been placed in the SPAG-2 unit should be discarded at least every 24 hours.

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January 1986
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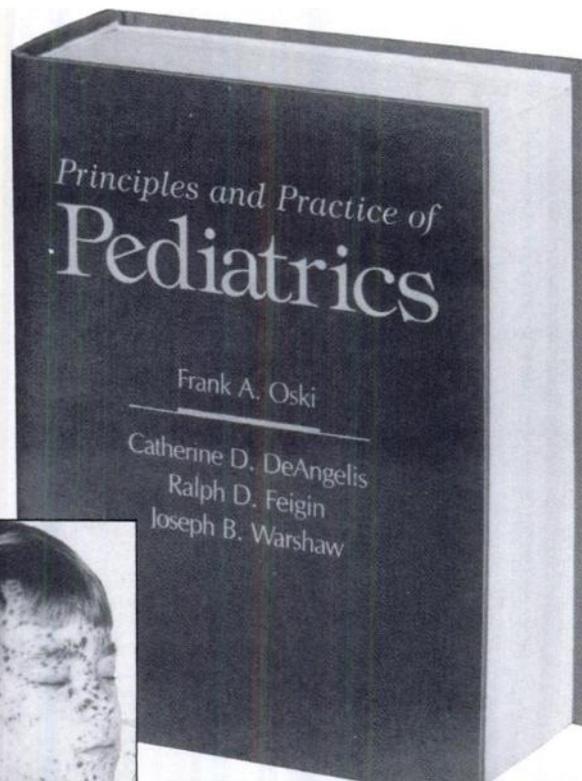


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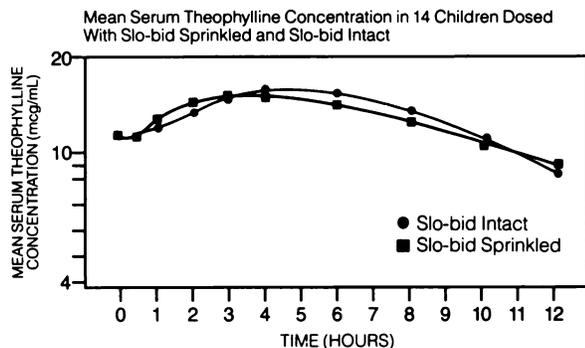
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References: 1. Saccar CL, Gawchik S, Spitzer I, et al: Steady-state evaluation of sustained-release theophylline administered in apple-sauce in asthmatic children. *Immunol Allergy Pract* 1987;9:462-466. 2. Consumer attitudes toward solid forms of medication. Capsugel, Division of Warner-Lambert Company, March 1983.

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BRIEF SUMMARY

DESCRIPTION: Slo-bid™ Gyrocaps® contain 50 mg, 75 mg, 100 mg, 125 mg, 200 mg, or 300 mg theophylline, anhydrous in the form of long acting beads within a dye-free hard gelatin capsule and are intended for oral administration. Slo-bid Gyrocaps can be administered with a 12-hour dosing interval for a majority of patients and a 24-hour dosing interval for selected patients (see DOSAGE AND ADMINISTRATION section in full prescribing information for description of appropriate patient population).

INDICATIONS AND USAGE: For relief and/or prevention of symptoms from asthma and reversible bronchospasm associated with chronic bronchitis and emphysema.

CONTRAINDICATIONS: Slo-bid is contraindicated in individuals who have shown hypersensitivity to any of the components of this product. It is also contraindicated in patients with active peptic ulcer disease and in individuals with underlying seizure disorders (unless receiving appropriate anticonvulsant medication).

WARNINGS: Serum levels above 20 µg/mL are rarely found after appropriate administration of the recommended doses. However, in individuals in whom theophylline plasma clearance is reduced for any reason, even conventional doses may result in increased serum levels and potential toxicity. Reduced theophylline clearance has been documented in the following readily identifiable groups: 1) patients with impaired renal or liver function; 2) patients over 65 years of age, particularly males and those with chronic lung disease; 3) those with cardiac failure from any cause; 4) patients with sustained high fever; 5) neonates and infants under 1 year of age; and 6) those patients taking certain drugs (see PRECAUTIONS, Drug Interactions). Frequently, such patients have markedly prolonged theophylline serum levels following discontinuation of the drug.

Reduction of dosage and laboratory monitoring is especially appropriate in the above individuals.

Serious side effects such as ventricular arrhythmias, convulsions, or even death may appear as the first sign of toxicity without any previous warning. Less serious signs of theophylline toxicity (i.e., nausea and restlessness) may occur frequently when initiating therapy but are usually transient; when such signs are persistent during maintenance therapy, they are often associated with serum concentrations above 20 µg/mL. Stated differently, serious toxicity is not reliably preceded by less severe side effects. A serum concentration measurement is the only reliable method of identifying a potential for life-threatening toxicity.

Many patients who require theophylline exhibit tachycardia due to their underlying disease process, so the cause/effect relationship to elevated serum theophylline concentrations may not be appreciated.

Theophylline products may cause dysrhythmias and/or worsen preexisting arrhythmias and any significant change in rate and/or rhythm warrants monitoring and further investigation.

Studies in laboratory animals (minkipigs, rodents, and dogs) recorded the occurrence of cardiac arrhythmias and sudden death (with histologic evidence of myocardial necrosis) when beta agonists and methylxanthines were administered concurrently. The significance of these findings when applied to humans is currently unknown.

PRECAUTIONS: General: On the average, theophylline half-life is shorter in cigarette and marijuana smokers than in nonsmokers, but smokers can have half-lives as long as nonsmokers. Theophylline should not be administered concurrently with other xanthine preparations. Use with caution in patients with hypoxemia, hypertension or with a history of peptic ulcer. Theophylline may occasionally act as a local irritant to the GI tract, although GI symptoms are more commonly centrally mediated and associated with serum drug concentrations over 20 µg/mL.

Information for Patients:

The physician should reinforce the importance of taking only the prescribed dose at the prescribed time intervals. The patient should alert the physician if symptoms occur repeatedly, especially near the end of a dosing interval. When prescribing administration by the sprinkle method, details of the proper technique should be explained to the patient.

Laboratory Test: Serum levels should be monitored periodically to determine the theophylline levels associated with observed clinical response and to identify the potential for toxicity. For such measurements, the serum sample should be obtained at the time of peak concentration, approximately 5-9 hours after the morning dose. It is important that the patient has not missed or taken additional doses during the previous 48 hours and that dosing intervals have been reasonably equally spaced.

DOSE ADJUSTMENT BASED ON SERUM THEOPHYLLINE MEASUREMENTS WHEN THESE INSTRUCTIONS HAVE NOT BEEN FOLLOWED MAY RESULT IN RECOMMENDATIONS THAT PRESENT RISK OF TOXICITY TO THE PATIENT.

Drug Interactions:

Drug-Drug: Toxic synergism with ephedrine has been documented and may occur with some other sympathomimetic bronchodilators. In addition, the following drug interactions have been demonstrated:

Theophylline with:	Increased serum theophylline levels
Allopurinol (high dose)	Increased serum theophylline levels
Cimetidine	Increased serum theophylline levels
Erythromycin, Troleandomycin	Increased serum theophylline levels
Lithium carbonate	Increased renal excretion of lithium
Oral contraceptives	Increased serum theophylline levels
Phenitoin	Decreased theophylline and phenitoin serum levels
Rifampin	Decreased serum theophylline levels

Drug-Food: Taking Slo-bid immediately after a high-fat content meal such as 8 ounces whole milk, 2 fried eggs, 2 strips bacon, one bran muffin with butter, 2 ounces hash brown potatoes (about 789 calories, including approximately 49 gm of fat) may result in a decrease in the rate of absorption, but with no significant difference in the extent of absorption (see CLINICAL PHARMACOLOGY, Pharmacokinetics). The influence of the type and amount of other foods, as well as the time interval between drug and food, has not been studied.

Drug/Laboratory Test Interactions: Currently available analytic methods, including high-pressure liquid chromatography and immunoassay techniques, for measuring serum theophylline levels are specific. Metabolites and other drugs generally do not affect the results. Other new analytic methods are also now in use. The physician should be aware of the laboratory method used and whether other drugs will interfere with the assay for theophylline.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term carcinogenicity studies have not been performed with theophylline.

Chromosome-breaking activity was detected in human cell cultures at concentrations of theophylline up to 50 times the therapeutic serum concentrations in humans. Theophylline was not mutagenic in the dominant lethal assay in male mice given theophylline intraperitoneally in doses up to 30 times the maximum daily human oral dose.

Studies to determine the effect on fertility have not been performed with theophylline.

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

Nursing Mothers: Theophylline is distributed into breast milk and may cause irritability or other signs of toxicity in nursing infants. Because of the potential for serious adverse reactions in nursing infants from theophylline, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use:

Safety and effectiveness of Slo-bid Gyrocaps administered:

1. Every 24 hours in children under 12 years of age, have not been established.
2. Every 12 hours in children under 6 years of age, have not been established.

ADVERSE REACTIONS: The following adverse reactions have been observed, but there has not been enough systematic collection of data to support an estimate of their frequency. The most consistent adverse reactions are usually due to overdosage.

Gastrointestinal: nausea, vomiting, epigastric pain, hematemesis, diarrhea

Central Nervous System: headaches, irritability, restlessness, insomnia, reflex hyperexcitability, muscle twitching, clonic and tonic generalized convulsions

Cardiovascular: palpitation, tachycardia, extrasystoles, flushing, hypotension, circulatory failure, ventricular arrhythmias

Respiratory: tachypnea

Renal: potentiation of diuresis

Other: alopecia, hyperglycemia, inappropriate ADH syndrome, rash

CAUTION: Federal (U.S.A.) law prohibits dispensing without prescription. Keep this and all medications out of the reach of children.

HOW SUPPLIED: Slo-bid Gyrocaps are identified as follows:

- 50 mg—Clear (cap) and opaque white (body) capsule with 50 printed in red
- 75 mg—Opaque white (cap) and clear (body) capsule with 75 printed in red
- 100 mg—Clear capsule with 100 printed in red
- 125 mg—Opaque white (cap) and opaque white (body) capsule with 125 printed in red
- 200 mg—Opaque white (cap) and clear (body) capsule with 200 printed in red
- 300 mg—Opaque white capsule with 300 printed in red

Slo-bid Gyrocaps 50 mg are available in bottles of 100 (NDC 0075-0057-00), bottles of 1000 (NDC 0075-0057-99) and in unit dose 10 x 10 (NDC 0075-0057-62). Slo-bid Gyrocaps 75 mg are available in bottles of 100 (NDC 0075-1075-00), bottles of 1000 (NDC 0075-1075-99) and in unit dose 10 x 10 (NDC 0075-0057-62). Slo-bid Gyrocaps 100 mg are available in bottles of 100 (NDC 0075-0100-00), bottles of 1000 (NDC 0075-0100-99) and in unit dose 10 x 10 (NDC 0075-0100-62). Slo-bid Gyrocaps 125 mg are available in bottles of 100 (NDC 0075-1125-00), bottles of 1000 (NDC 0075-1125-99) and in unit dose 10 x 10 (NDC 0075-1125-62). Slo-bid Gyrocaps 200 mg are available in bottles of 100 (NDC 0075-0200-00), bottles of 1000 (NDC 0075-0200-99) and in unit dose 10 x 10 (NDC 0075-0200-62), and Slo-bid Gyrocaps 300 mg are available in bottles of 100 (NDC 0075-0300-00), bottles of 1000 (NDC 0075-0300-99) and in unit dose 10 x 10 (NDC 0075-0300-62), and are manufactured by



ROREER PHARMACEUTICALS

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CONTINUING MEDICAL EDUCATION COURSE #3

Pediatric Update

December 15-17, 1989

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Experience this very special time of year in the winter splendor of Colonial Williamsburg. An overview of the most current topics in pediatrics will be presented in these subspecialty areas: behavioral pediatrics, gastroenterology, infectious diseases, neonatology, and virology.

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Neonatology

Gerald B. Merenstein, MD, FAAP

Virology

Richard J. Whitley, MD, FAAP

Course Monitor

Errol R. Alden, MD, FAAP

AMA Category I Credit: 16 Hours

PREP Credit: 10 Hours

To register or for program information contact:
Department of Education, CME Registration

American Academy of Pediatrics

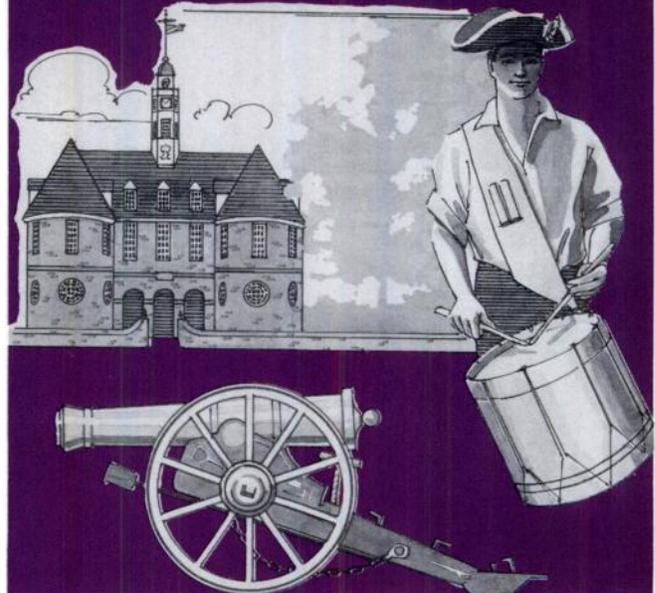


P.O. Box 927

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Toll-free — 800-433-9016

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The Playtex® Baby Nurser— Proven better than bottles

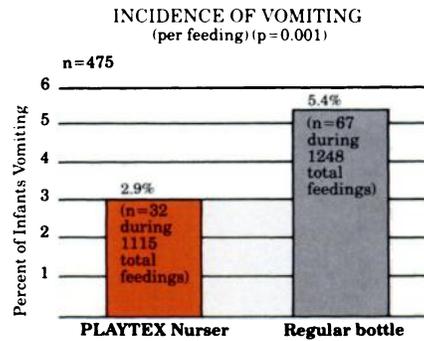
**Significantly “less vomiting” than
with “a standard glass bottle.”¹**

Its collapsible sac contracts like a breast to deliver milk—not air. So babies swallow less air, develop less gas.² And, as proven in a clinical comparative study, the PLAYTEX Nurser actually causes less spitting up and significantly less vomiting than “standard glass bottles”¹—so babies stay happier, and more comfortable.

**“More physiologic feeding”¹—Less spitting up, to help
smooth the transition from the breast.**

With its special collapsible nurser design and Natural Action® nipple that’s shaped like mother’s, the PLAYTEX Nurser is closest to breastfeeding.

So for an easier adjustment—for both mother and baby, during supplementation or weaning—recommend the best: recommend the PLAYTEX Baby Nurser.



for less spitting up, less regurgitation.¹

References:

1. Keitel HG, Yadav V: Benign regurgitation in newly born infants: Etiologic and preventive factors. *Med Sci* November, 1965; 48-56.
2. Meyer HF: *Infant Foods and Feeding Practices*, Charles C. Thomas, 1960; chapter seven.

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playtex®

Baby Nurser



Discover Eucerin®..

Unsurpassed therapy for dry skin

**Why Eucerin® is ideal for your
patients... and your practice**

When you recommend Eucerin Creme or Lotion, you've got two things going for you.

First, you're recommending a clinically tested unique water-in-oil formulation for long lasting effectiveness.

Second, you're avoiding unwanted problems, because Eucerin Creme and Eucerin Lotion are free of any known skin irritants, such as perfumes, colorings, and free lanolin. Both products are also non-comedogenic.

And when you recommend Eucerin, you're in good company. In surveys of physicians and pharmacists, Eucerin consistently places first as the moisturizer of choice.*

Another good choice for your patients—and yourself, too—is Eucerin Cleansing Bar. This non-soap cleanser, with a pH of 5.5, has been clinically demonstrated to be among the mildest bars available.

Avoid problems and go with the winner. Eucerin. Clinically tested, gentle, and safe. Good for your patients, and your practice.

*Among physicians, Leading Independent Audit Service, 1985, 1986, 1987
Among pharmacists, American Druggist Open Call Survey, 1984, 1985, 1986, 1987



Better ways to quicker healing

Beiersdorf

bmp
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medical
program

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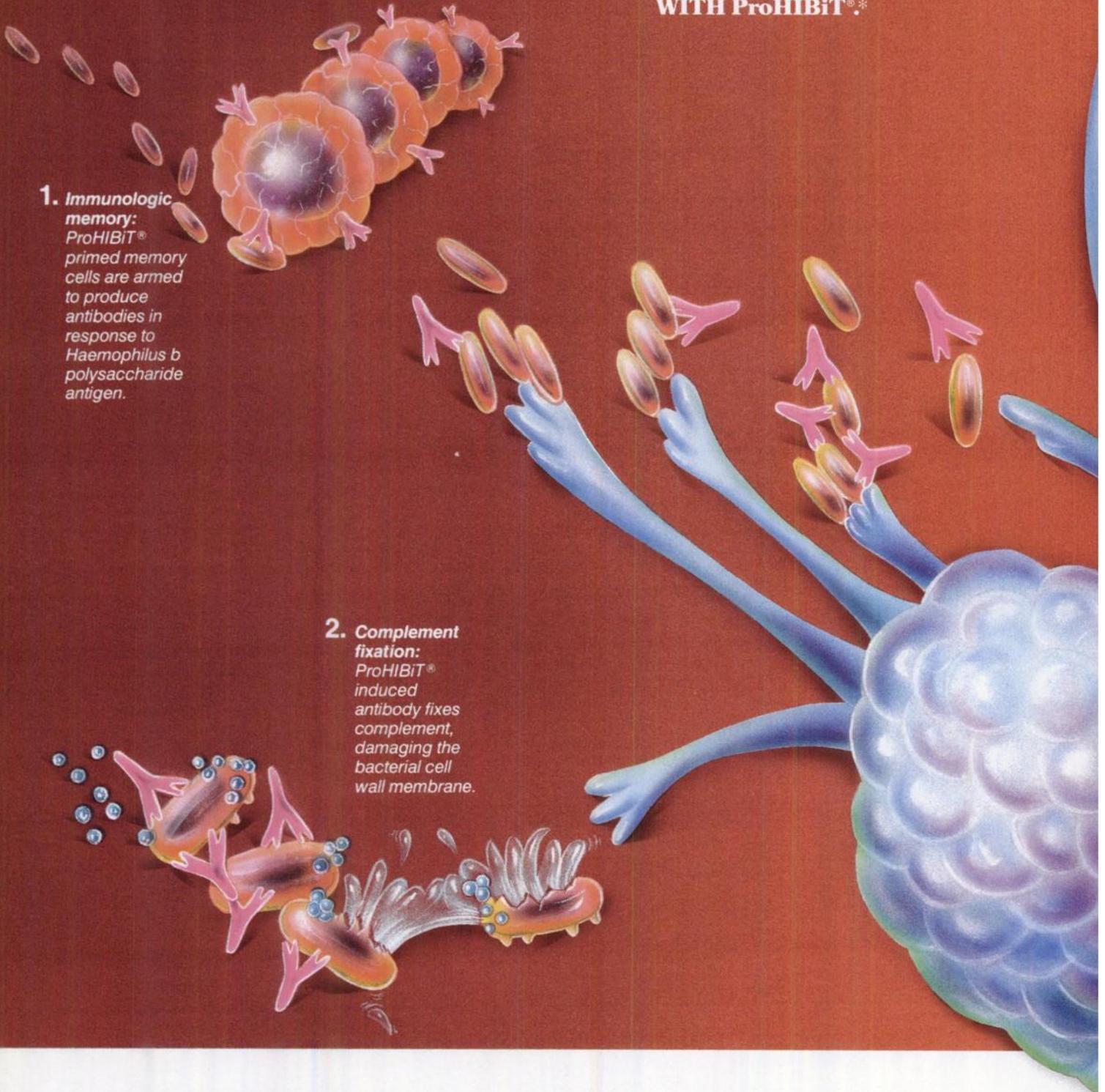
Beiersdorf Inc Norwalk CT 06856-5529

YOUR POWERFUL ALLY AGAINST

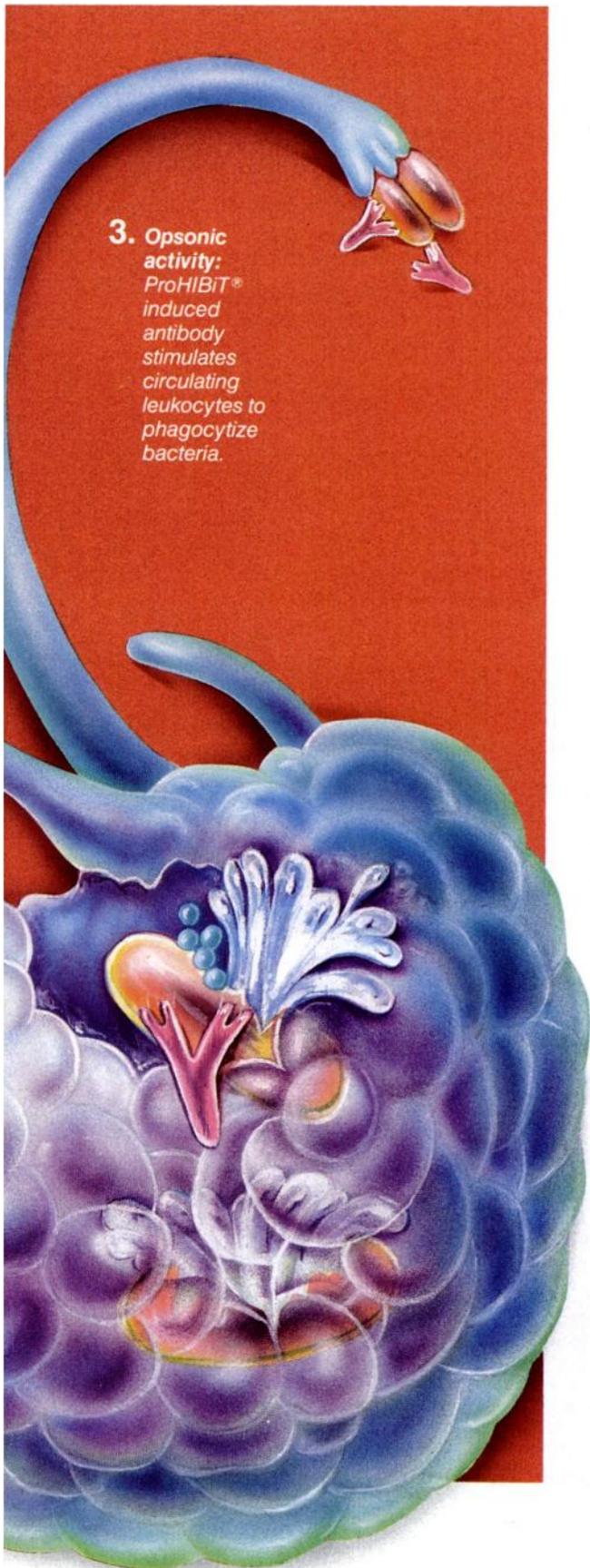
IMMUNE RESPONSE INCLUDES
FUNCTIONALLY IMPORTANT
ANTIBODY PRODUCTION
FOLLOWING IMMUNIZATION
WITH ProHIBiT®.*

**1. Immunologic
memory:**
ProHIBiT®
primed memory
cells are armed
to produce
antibodies in
response to
Haemophilus b
polysaccharide
antigen.

**2. Complement
fixation:**
ProHIBiT®
induced
antibody fixes
complement,
damaging the
bacterial cell
wall membrane.



HAEMOPHILUS b DISEASE.



3. Opsonic activity:
ProHIBiT® induced antibody stimulates circulating leukocytes to phagocytize bacteria.

DEFENDS

ProHIBiT® defends against Haemophilus b disease in three important ways:

1

PRIMES

THE IMMUNE SYSTEM

ProHIBiT® primes the immune system to produce memory cells that stimulate rapid production of antibodies when challenged^{1,2} with native polysaccharide.

2

PROMOTES

BACTERICIDAL ACTION

ProHIBiT® promotes bactericidal action² of the immune system to help your patients fight off infection.

3

ENHANCES

PHAGOCYTOSIS

ProHIBiT® induced antibody enhances phagocytosis² (opsonic activity).

If you wish to order ProHIBiT®, call the following toll-free number: 1-800-VACCINE (1-800-822-2463).



Connaught Laboratories, Inc.

ProHIBiT®

Haemophilus b Conjugate Vaccine (Diphtheria Toxoid-Conjugate)

**PROVEN SAFE AND WELL TOLERATED
AFTER MILLIONS OF IMMUNIZATIONS¹**

Please see brief summary of prescribing information on last page of this advertisement.¹

¹ProHIBiT® is currently indicated for children 18-60 months of age.

²Serious adverse experiences (seizures, Guillain-Barré syndrome), have been rarely reported in association with ProHIBiT® immunization.

ProHIBiT®

YOUR POWERFUL ALLY AGAINST HIB DISEASE

Haemophilus b Conjugate Vaccine (Diphtheria Toxoid-Conjugate)

Caution: Federal (U.S.A.) law prohibits dispensing without prescription.

BRIEF SUMMARY

INDICATIONS AND USAGE

ProHIBiT is indicated for the routine immunization of children 18 months to 5 years of age against invasive diseases caused by *Haemophilus influenzae* type b. As with other vaccines, several days following administration of ProHIBiT are required for protective levels of antibody to be attained.

A booster dose of ProHIBiT is *not* required.

ProHIBiT will not protect against *Haemophilus influenzae* other than type b or other microorganisms that cause meningitis or septic disease.

No impairment of the immune response to the individual antigens was demonstrated when ProHIBiT and Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (DTP) were given at the same time at separate sites.

Because the safety and efficacy of ProHIBiT have not been established in children less than 18 months of age, ProHIBiT is not indicated for use in this age group at this time. Studies to establish the safety and efficacy of ProHIBiT in children less than 18 months of age are ongoing.

ProHIBiT IS NOT RECOMMENDED FOR USE IN CHILDREN YOUNGER THAN 18 MONTHS OF AGE.

CONTRAINDICATIONS

HYPERSENSITIVITY TO ANY COMPONENT OF THE VACCINE, INCLUDING THIMEROSAL AND DIPHTHERIA TOXOID, IS A CONTRAINDICATION TO USE OF THIS VACCINE.

WARNINGS

If ProHIBiT is used in persons with malignancies or those receiving immunosuppressive therapy or who are otherwise immunocompromised, the expected immune response may not be obtained.

As with any vaccine, ProHIBiT may not protect 100% of individuals receiving the vaccine.

PRECAUTIONS

GENERAL

As with the injection of any biological material, Epinephrine Injection (1:1000) should be available for immediate use should an anaphylactic or other allergic reaction occur.

Prior to an injection of any vaccine, all known precautions should be taken to prevent adverse reactions. This includes a review of the patient's history with respect to possible hypersensitivity to the vaccine or similar vaccines.

Any febrile illness or acute infection is reason to delay the use of ProHIBiT.

As reported with *Haemophilus b* polysaccharide vaccine, cases of *Haemophilus b* disease may occur in the week after vaccination, prior to the onset of the protective effects of the vaccine.

Special care should be taken to ensure that the injection does not enter a blood vessel.

A separate, sterile syringe and needle or a sterile disposable unit should be used for each individual patient to prevent transmission of hepatitis or other infectious agents from one person to another.

ALTHOUGH SOME IMMUNE RESPONSE TO THE DIPHTHERIA TOXOID COMPONENT MAY OCCUR, IMMUNIZATION WITH ProHIBiT DOES NOT SUBSTITUTE FOR ROUTINE DIPHTHERIA IMMUNIZATION.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

ProHIBiT has not been evaluated for its carcinogenic, mutagenic potential or impairment of fertility.

PREGNANCY

REPRODUCTIVE STUDIES — PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with ProHIBiT. It is also not known whether ProHIBiT can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ProHIBiT is NOT recommended for use in a pregnant woman.

ADVERSE REACTIONS

When ProHIBiT alone was given to over 1,000 adults and children, no serious adverse reactions were observed. Thrombocytopenia was seen in one adult but a causative relationship was not established.

When ProHIBiT was given with DTP and Inactivated Poliovirus Vaccine to 30,000 young infants, the rate and extent of serious adverse reactions were not different from those seen when DTP was administered alone. Allergic reactions such as urticaria were infrequently observed.

Selected adverse reactions following vaccination with ProHIBiT (without DTP) in subjects 16-24 months of age are summarized in Table.

	No. of Subjects*	Reaction %		
		6 Hours	24 Hours	48 Hours
Fever >38.3°C	281	1.1	2.1	1.8
Erythema	285	—	2.5	0.4
Induration	285	—	1.0	0.4
Tenderness	285	—	4.6	0.7

*Not all subjects had measurements at all time periods.

Other adverse reactions temporally associated with administration of ProHIBiT included diarrhea, vomiting, and crying and occurred at a frequency of ≤1.2%.

Adverse reactions in clinical evaluations among 689 children, 7-14 months of age, 24 hours after receiving a single dose of ProHIBiT, were observed and compared to 139 children who received a saline placebo. There were no significant differences in the reaction rates for fever, erythema, induration, and tenderness between the two groups.

DOSAGE AND ADMINISTRATION

Parenteral drug products should be inspected visually for extraneous particulate matter and/or discoloration prior to administration whenever solution and container permit. If these conditions exist, vaccine should not be administered.

ProHIBiT is indicated for children 18 months to 5 years of age. The immunizing dose is a single injection of 0.5 ml given intramuscularly in the outer aspect area of the vastus lateralis (mid-thigh) or deltoid.

Each 0.5 ml dose contains 25 mcg of purified capsular polysaccharide and 18 mcg of conjugated diphtheria toxoid protein.

Before injection, the skin over the site to be injected should be cleansed with a suitable germicide. After insertion of the needle, aspirate to ensure that the needle has not entered a blood vessel.

DO NOT INJECT INTRAVENOUSLY.

HOW SUPPLIED

Vial, 1 Dose (5 per package) — Product No. 49281-541-01

Vial, 5 Dose — Product No. 49281-541-05

Vial, 10 Dose — Product No. 49281-541-10

STORAGE

Store between 2°-8°C (35°-46°F). DO NOT FREEZE.

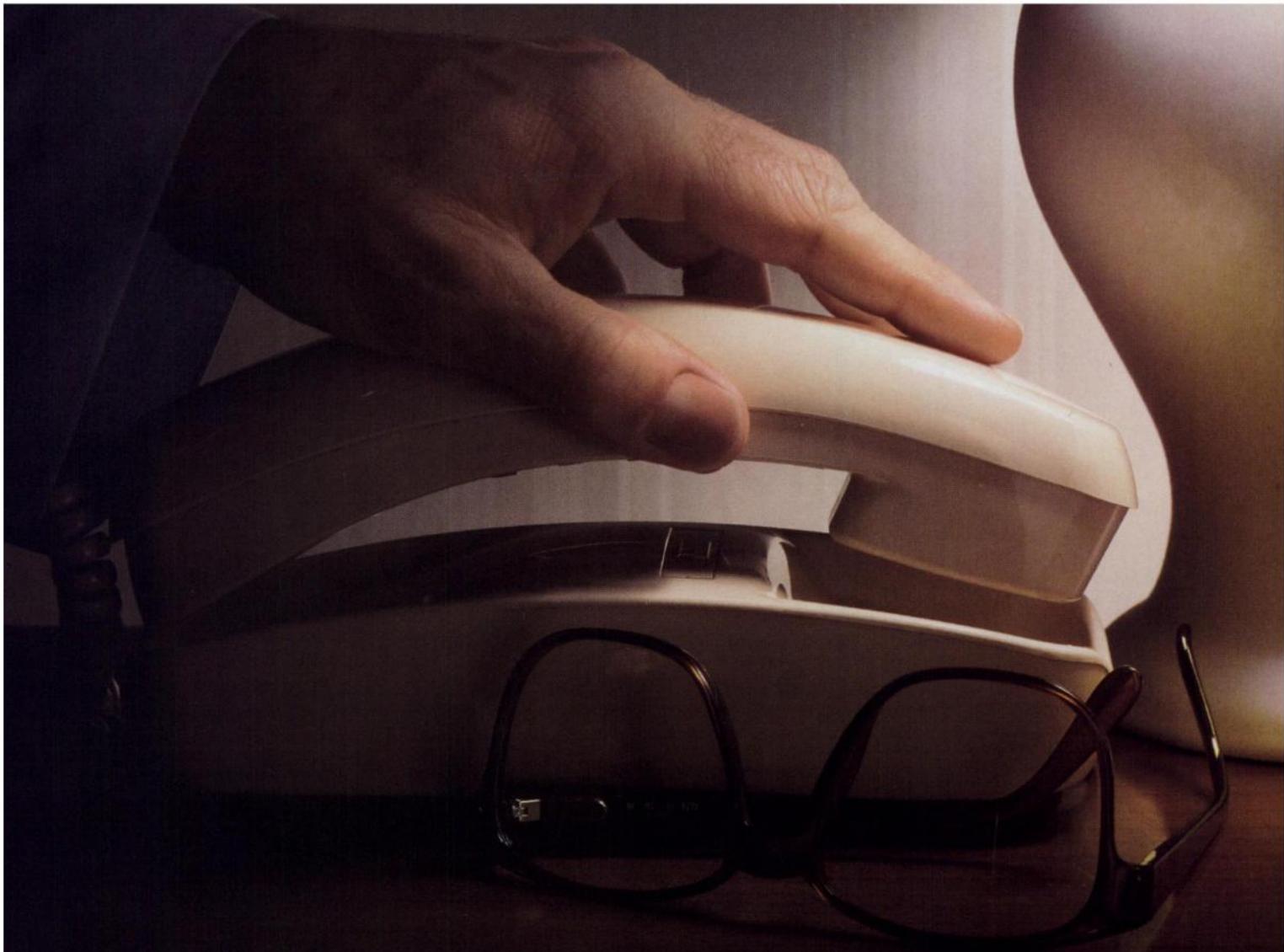
REFERENCES: 1. Data on file, Connaught Laboratories, Inc. 2. Weinberg GA, Granoff DM: Polysaccharide-protein conjugate vaccines for the prevention of *Haemophilus influenzae* type b disease. *J Pediatr* 1988;113:621-631.

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 **CONNAUGHT
LABORATORIES, INC.**

Specialist in vaccines and biologicals

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Swiftwater, Pennsylvania 18370



How many times have you heard...

“Doctor I’m having a terrible time with my child’s constipation what should I do?”

Fleet® BabyLax® is the answer. Fleet BabyLax is the safe, effective medically correct solution for occasional childhood constipation that’s easier on both child and mother.

Babylax, from the makers of Fleet enema, is a unique, ready-to-use disposable applicator that contains 4 ml of liquid glycerin. Babylax takes just seconds to use. The parent simply removes the protective shield, inserts the pre-lubricated applicator and squeezes the bulb



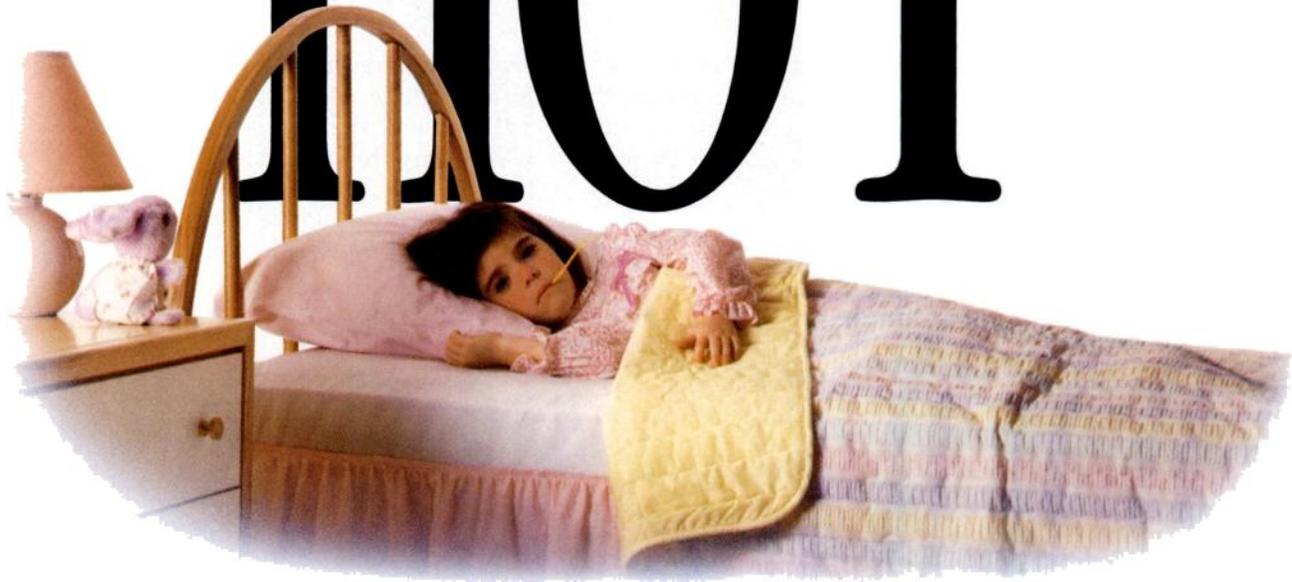
dispensing the glycerin. Then the applicator is removed and discarded. A normal bowel movement should occur within 30 minutes.

Babylax eliminates all the problems of suppositories: messy insertion, lengthy melting time and discomfort for the child.

Babylax is available in most drug and food stores, in handy boxes of six disposable units.

Babylax. Another healthy innovation from C. B. Fleet Company.

“HOT”



Cool her fever with the brand that offers the most dosage choices

When your patients need fever relief, Children's **TYLENOL**[®] acetaminophen should be your first choice. **TYLENOL**[®] offers you more dosage choices than any other acetaminophen brand, so your patients get the right medicine in a form and flavor that's right for every child's needs:

- Alcohol-free Infants' Drops
- Alcohol-free Children's Elixir in Cherry and *New Grape* flavors
- Children's 80 mg Chewables in *both* Grape and Fruit flavors
- Easy-to-swallow 160 mg Junior Strength Coated Caplets for 6- to 14-year-olds

Remember, **TYLENOL**[®] is clinically proven as effective an antipyretic as aspirin, with a superior safety profile.^{1,2} And parents can easily find your recommendation, because **TYLENOL**[®] products are more widely available in food and drug stores than any other brand.³ So next time a little patient is "Hot!" with fever, make your first choice **TYLENOL**[®] acetaminophen.

References: 1. Tarlin L, et al: *Am J Dis Child* 1972;124:880-882. 2. Aspirin or paracetamol? *Lancet* 1981;ii:287-289. 3. Data on file, McNeil Consumer Products Company.

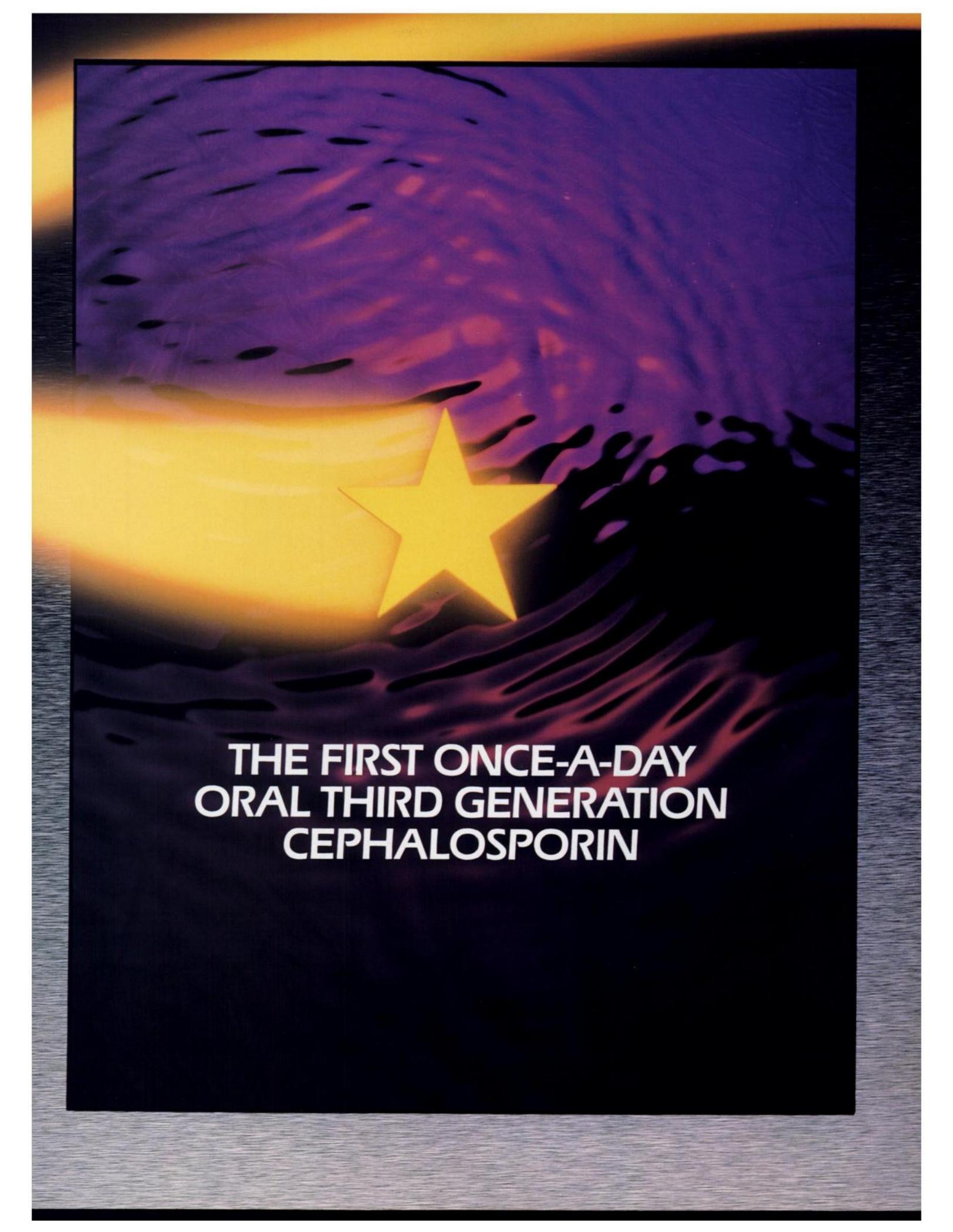
Children's and Junior Strength

TYLENOL[®]

acetaminophen

First choice for fever and pain relief





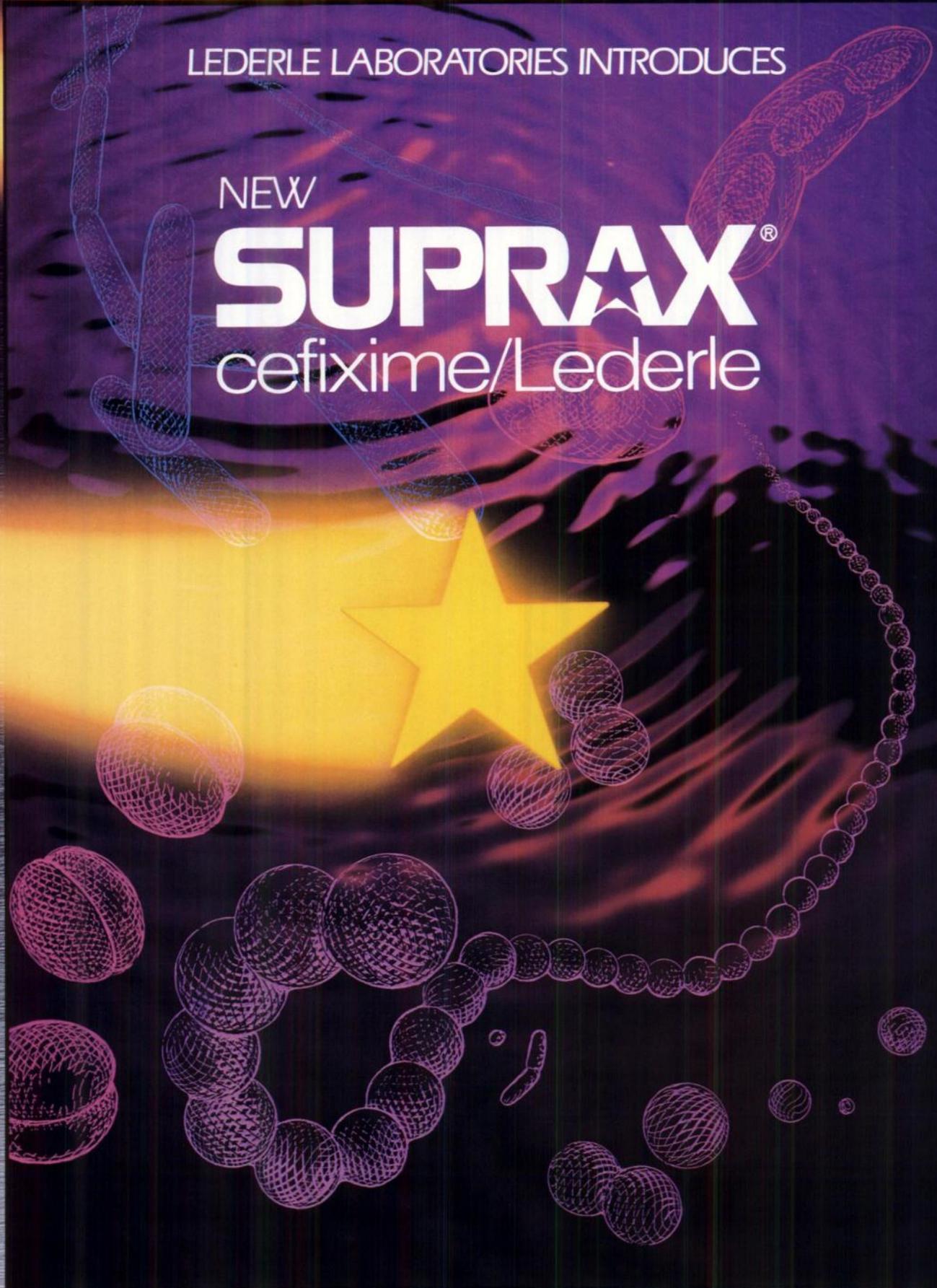
**THE FIRST ONCE-A-DAY
ORAL THIRD GENERATION
CEPHALOSPORIN**

LEDERLE LABORATORIES INTRODUCES

NEW

SUPRAX[®]

cefixime/Lederle



THIRD GENERATION SPECTRUM AND POTENCY FOR RESPIRATORY TRACT INFECTIONS

Once-a-Day Therapy for the Treatment of:

- Otitis media
- Acute bronchitis
- Acute exacerbations of chronic bronchitis
- Pharyngitis
- Tonsillitis

Effective qd or bid Regardless of Severity of Infection

**The Only Oral Cephalosporin Indicated for
 β -Lactamase Producing Strains of Haemophilus influenzae
and Branhamella catarrhalis**

**Potent In Vitro Activity* Against Major Pathogens Isolated in
Respiratory Tract Infections**

Beta-Lactamase Stability Superior to Ceclor[†] and Keflex^{†1-3}

Easy Dosing Regimen: 400 mg/day in adults, given once daily, or if preferred, in divided doses bid; 8 mg/kg/day in children, given qd, or bid if preferred.

*Although a useful guide, in vitro activity does not necessarily correlate with clinical results.

[†] Ceclor is a registered trademark of Eli Lilly and Co. Keflex is a registered trademark of Dista Products Co.

Reach for a Star  NEW
SUPRAX[®]
cefixime/Lederle

Please see brief summary of
Prescribing Information on last page.

NEW

SUPRAX[®]

cefixime/Lederle



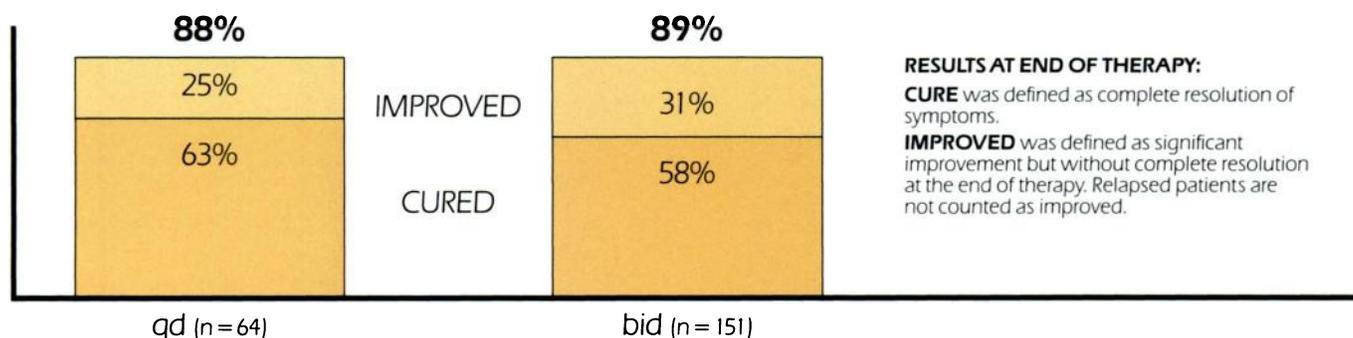
THE FIRST ORAL THIRD GENERATION CEPHALOSPORIN FOR OTITIS MEDIA*

Once-Daily Dosing Maintains Inhibitory Drug Concentrations Against Important Pathogens in Otitis Media

SUPRAX Oral Suspension Provides Outstanding Clinical and Bacteriologic Success in Otitis Media^{4,5}

Excellent Clinical Success in Otitis Media†

191 of 215 Patients Effectively Treated qd or bid With 10-Day Course of SUPRAX Oral Suspension‡

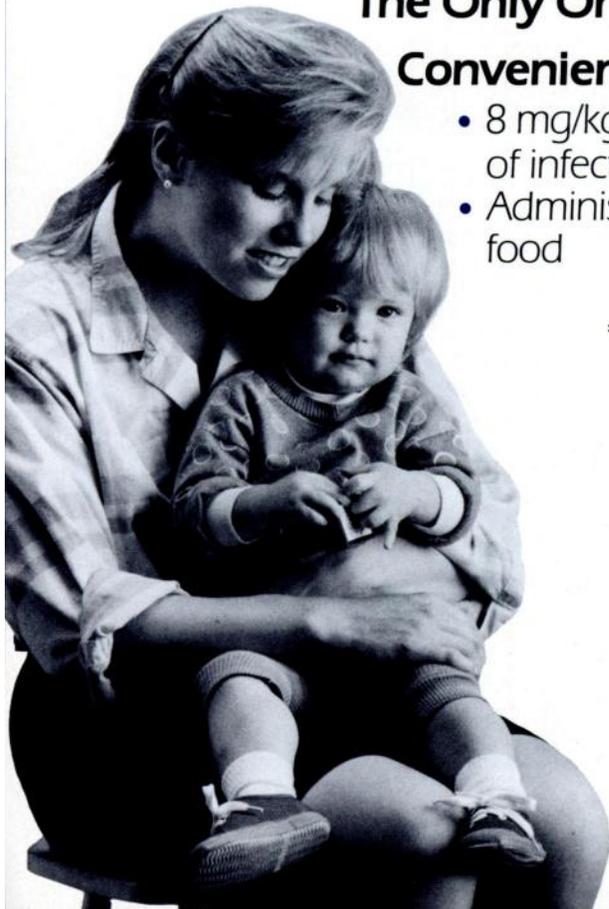


The Only Cephalosporin Indicated for β -Lactamase Producing Strains of Haemophilus influenzae and Branhamella catarrhalis

The Only Once-a-Day for Otitis Media

Convenient Dosing and Flexibility

- 8 mg/kg per day in children regardless of severity of infection
- Administered once or twice daily with or without food



* Due to susceptible organisms. Please consult **Clinical Studies** section of brief summary for limitations on usage.

† Results of clinical trials in infections due to *Haemophilus influenzae*, *Branhamella catarrhalis*, *Streptococcus pyogenes*, and *Streptococcus pneumoniae*. Please consult **Clinical Studies** section of brief summary for limitations on usage.

‡ Tablets should not be substituted for suspension in otitis media.

Reach for a Star



NEW

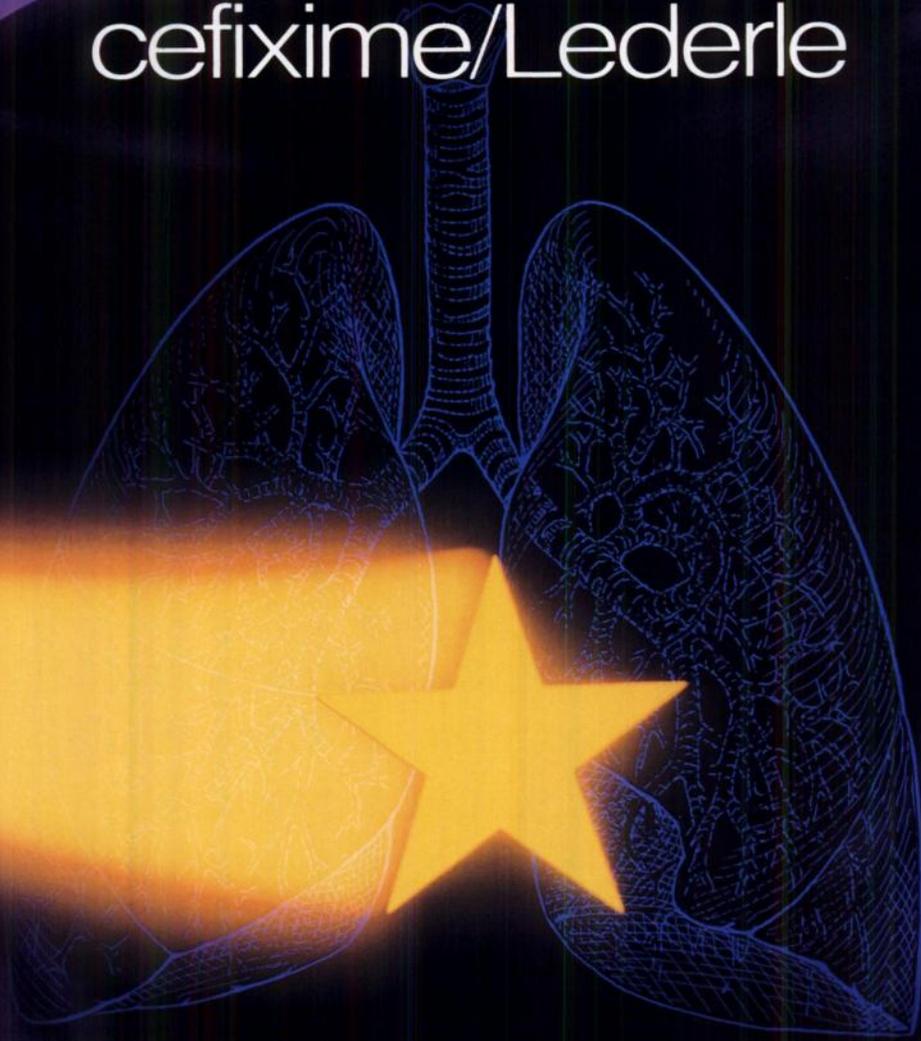
SUPRAX[®]
cefixime/Lederle

Please see brief summary of Prescribing Information on last page.

NEW

SUPRAX[®]

cefixime/Lederle



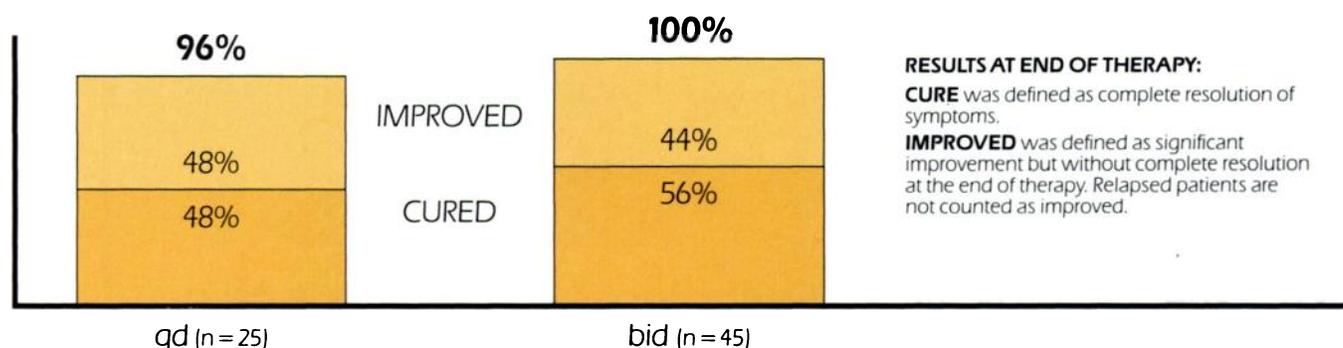
THIRD GENERATION SPECTRUM AND POTENCY FOR BRONCHITIS*

The Only Oral Agent Indicated for Once-Daily Therapy in the Treatment of Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis

Active Against Important Pathogens Isolated in Bronchitis

99% Clinical Success in Bronchitis⁴

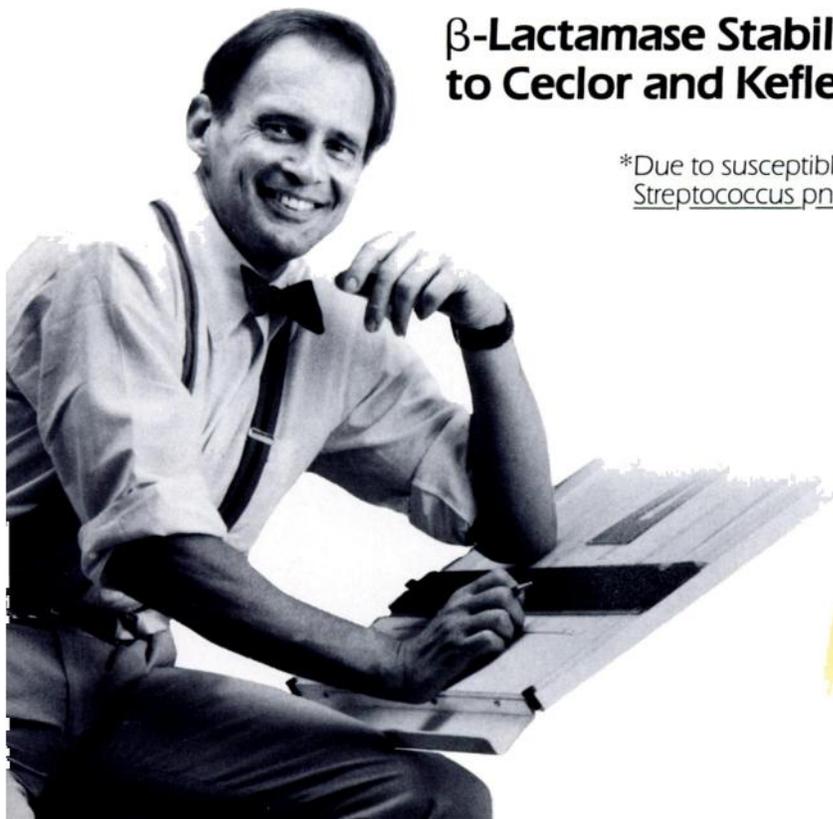
69 of 70 Patients Treated qd or bid Were Either Cured or Significantly Improved



The Only Oral Cephalosporin Indicated for β -Lactamase Producing Strains of Haemophilus influenzae in the Treatment of Bronchitis

β -Lactamase Stability Superior to Ceclor and Keflex¹⁻³

*Due to susceptible organisms, Haemophilus influenzae and Streptococcus pneumoniae



Reach for a Star
NEW

SUPRAX[®]
cefixime/Lederle

Please see brief summary of Prescribing Information on last page.

NEW
SUPRAX[®]
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THIRD GENERATION THERAPY FOR RESPIRATORY TRACT INFECTIONS

The Only Once-a-Day Oral Antibiotic Indicated for the Treatment of Otitis Media and Bronchitis*

- The recommended adult dose is 400 mg given once daily. Or, if preferred, 400 mg in divided doses, bid.
- The recommended dose for children is 8 mg/kg daily, qd or bid. Children weighing more than 50 kg or older than 12 years should be treated with the recommended adult dose. The tablet should not be substituted for the suspension in the treatment of otitis media.

Suspension Needs No Refrigeration After Reconstitution— Stable for 14 Days

Most Adverse Reactions Are Mild and Transient in Nature

- Fewer than one in three patients experienced any type of gastrointestinal effects: diarrhea (16%), nausea (7%), loose or frequent stools (6%), abdominal pain (3%), dyspepsia (3%), and flatulence (4%). Only 5% of patients discontinued treatment due to drug-related adverse effects.
- As with other drugs of this class, pseudomembranous colitis has been reported. SUPRAX is contraindicated in patients with known allergy to the cephalosporin group of antibiotics. The safety and effectiveness of cefixime in children aged less than 6 months have not been established.

Great Tasting



Please see brief summary of
Prescribing Information on last page.

*Due to susceptible organisms. Please consult **Clinical Studies** section of brief summary for limitations on usage.

Reach for a Star



SUPRAX® cefixime/Lederle

BRIEF SUMMARY. Please see package insert for full Prescribing Information

INDICATIONS AND USAGE

Otitis Media caused by *Haemophilus influenzae* (beta-lactamase positive and negative strains), *Moraxella (Branhamella) catarrhalis*, (most of which are beta-lactamase positive), and *Streptococcus pyogenes*.*

Note: For information on otitis media caused by *Streptococcus pneumoniae*, see

CLINICAL STUDIES

Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis caused by *Streptococcus pneumoniae* and *Haemophilus influenzae* (beta-lactamase positive and negative strains).

Perform culture and susceptibility studies to determine causative organism and its susceptibility to SUPRAX. Therapy may begin while waiting for study results and may be adjusted when results are known.

Pharyngitis and Tonsillitis caused by *Streptococcus pyogenes*.

Note: Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* infections, including the prophylaxis of rheumatic fever. SUPRAX is generally effective in the eradication of *S pyogenes* from the nasopharynx; however, data establishing the efficacy of SUPRAX in the subsequent prevention of rheumatic fever are not available.

Uncomplicated Urinary Tract Infections caused by *Escherichia coli* and *Proteus mirabilis*.

*Efficacy for this organism was studied in fewer than ten patients with otitis media.

CLINICAL STUDIES

In clinical trials of otitis media in nearly 400 children between the ages of 6 months to 10 years, *Streptococcus pneumoniae* was isolated from 47% of the patients, *Haemophilus influenzae* from 34%, *Moraxella (Branhamella) catarrhalis* from 15%, and *Streptococcus pyogenes* from 4%.

The overall response rate of *Streptococcus pneumoniae* to cefixime was approximately 10% lower and that of *Haemophilus influenzae* or *Moraxella (Branhamella) catarrhalis* approximately 7% higher (12% when beta-lactamase positive strains of *H influenzae* are included) than the response rates of these organisms to the active control drugs.

In these studies, patients were randomized and treated with either cefixime at dose regimens of 4 mg/kg bid or 8 mg/kg qd, or with a standard antibiotic regimen. Sixty-nine to 70% of the patients in each group had resolution of signs and symptoms of otitis media when evaluated two to four weeks posttreatment, but persistent effusion was found in 15% of the patients. When evaluated at the completion of therapy, 17% of patients receiving cefixime and 14% of patients receiving effective comparative drugs (18% including those patients who had *Haemophilus influenzae* resistant to the control drug and who received the control antibiotic) were considered to be treatment failures. By the two- to four-week follow-up, a total of 30%-31% of patients had evidence of either treatment failure or recurrent disease.

Bacteriological Outcome of Otitis Media at Two- to Four-Weeks Posttherapy Based on Repeat Middle Ear Fluid Culture or Extrapolation from Clinical Outcome

Organism	Cefixime ^(a) 4 mg/kg bid	Cefixime ^(a) 8 mg/kg qd	Control ^(a) drugs
<i>Streptococcus pneumoniae</i>	48/70 (69%)	18/22 (82%)	82/100 (82%)
<i>Haemophilus influenzae</i> beta-lactamase negative	24/34 (71%)	13/17 (76%)	23/34 (68%)
<i>Haemophilus influenzae</i> beta-lactamase positive	17/22 (77%)	9/12 (75%)	1/1 ^(b)
<i>Moraxella (Branhamella)</i> <i>catarrhalis</i>	26/31 (84%)	5/5	18/24 (75%)
<i>Streptococcus pyogenes</i>	5/5	3/3	6/7
All Isolates	120/162 (74%)	48/59 (81%)	130/166 (78%)

^(a) Number eradicated/number isolated.

^(b) An additional 20 beta-lactamase positive strains of *Haemophilus influenzae* were isolated, but were excluded from this analysis because they were resistant to the control antibiotic. In nineteen of these the clinical course could be assessed, and a favorable outcome occurred in 10. When these cases are included in the overall bacteriological evaluation of therapy with the control drugs, 140/185 (76%) of pathogens were considered to be eradicated.

Tablets should not be substituted for suspension when treating otitis media.

CONTRAINDICATIONS

Known allergy to cephalosporins.

WARNINGS

BEFORE THERAPY WITH SUPRAX IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF THIS PRODUCT IS TO BE GIVEN TO PENICILLIN-SENSITIVE PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE CROSS-HYPERSENSITIVITY AMONG BETA-LACTAM ANTIBIOTICS HAS BEEN CLEARLY DOCUMENTED AND MAY OCCUR IN UP TO 10% OF PATIENTS WITH A HISTORY OF PENICILLIN ALLERGY. IF AN ALLERGIC REACTION TO SUPRAX OCCURS, DISCONTINUE THE DRUG. SERIOUS, ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE AND OTHER EMERGENCY MEASURES, INCLUDING OXYGEN, INTRAVENOUS FLUIDS, INTRAVENOUS ANTIHISTAMINES, CORTICOSTEROIDS, PRESSOR AMINES, AND AIRWAY MANAGEMENT, AS CLINICALLY INDICATED.

Administer cautiously to allergic patients.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is a primary cause of severe antibiotic-associated diarrhea including pseudomembranous colitis. Pseudomembranous colitis has been reported with the use of SUPRAX and other broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins). It is important to consider this diagnosis in patients who develop diarrhea in association with antibiotic use. Symptoms of pseudomembranous colitis may occur during or after antibiotic treatment and may range in severity from mild to life threatening. Mild cases usually respond to drug discontinuation alone. Moderate-to-severe cases should be managed with fluid, electrolyte, and protein supplementation. When the colitis is not relieved by drug discontinuation, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C difficile*. Other causes of colitis should be excluded.

PRECAUTIONS

General: Prolonged use may result in overgrowth of nonsusceptible organisms. If superinfection occurs, take appropriate measures.

Carefully monitor patients on dialysis. Adjust dosage of SUPRAX in patients with renal impairment and those undergoing continuous ambulatory peritoneal dialysis and hemodialysis. (See **DOSAGE AND ADMINISTRATION**.)

Prescribe cautiously in patients with a history of gastrointestinal disease, particularly colitis.

Drug Interactions: No significant drug interactions have been reported to date.

Drug/Laboratory Test Interactions: A false-positive reaction for ketones in the urine may occur with tests using nitroprusside but not with those using nitroferricyanide.

SUPRAX cefixime administration may result in a false-positive reaction for glucose in the urine using Clinitest[®]***, Benedict's solution, or Fehling's solution. Use glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix[®]** or Tes-Tape[®]**).

A false-positive direct Coombs test has been reported during treatment with other cephalosporin antibiotics; therefore, it should be recognized that a positive Coombs test may be due to the drug.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Although no lifetime animal studies have been conducted to evaluate carcinogenic potential, no mutagenic potential of SUPRAX was found in standard laboratory tests. Reproductive studies revealed no fertility impairment in rats at doses up to 125 times the adult therapeutic dose.

Usage in Pregnancy: Pregnancy Category B: Reproduction studies have been performed in mice and rats at doses up to 400 times the human dose and have revealed no evidence of harm to the fetus due to SUPRAX.

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery: SUPRAX has not been studied for use during labor and delivery. Treatment should only be given if clearly needed.

Nursing Mothers: It is not known whether SUPRAX is excreted in human milk. Consider discontinuing nursing temporarily during treatment with this drug.

Pediatric Use: Safety and effectiveness of SUPRAX in children aged less than 6 months have not been established.

The incidence of gastrointestinal adverse reactions, including diarrhea and loose stools, in pediatric patients receiving the suspension, was comparable to adult patients receiving tablets.

ADVERSE REACTIONS

Most adverse reactions observed in clinical trials were of a mild and transient nature. Five percent (5%) of patients in the US trials discontinued therapy because of drug-related adverse reactions. Commonly seen adverse reactions in US trials of the tablet formulation were gastrointestinal events, which were reported in 30% of adult patients on either the bid or the qd regimen. Clinically mild gastrointestinal side effects occurred in 20% of all patients, moderate events occurred in 9% of all patients, and severe adverse reactions occurred in 2% of all patients. Individual event rates included diarrhea 16%, loose or frequent stools 6%, abdominal pain 3%, nausea 7%, dyspepsia 3%, and flatulence 4%. The incidence of gastrointestinal adverse reactions, including diarrhea and loose stools, in pediatric patients receiving the suspension was comparable to adult patients receiving tablets.

Symptoms usually responded to symptomatic therapy or ceased when SUPRAX was discontinued.

Several patients developed severe diarrhea and/or documented pseudomembranous colitis, and a few required hospitalization.

The following adverse reactions have been reported following the use of SUPRAX. Incidence rates were less than 1 in 50 (less than 2%), except as noted above for gastrointestinal events.

Gastrointestinal: Diarrhea, loose stools, abdominal pain, dyspepsia, nausea, and vomiting. Several cases of documented pseudomembranous colitis were identified during the studies. The onset of pseudomembranous colitis symptoms may occur during or after therapy.

Hypersensitivity Reactions: Skin rashes, urticaria, drug fever, and pruritus.

Hepatic: Transient elevations in SGPT, SGOT, and alkaline phosphatase.

Renal: Transient elevations in BUN or creatinine.

Central Nervous System: Headaches or dizziness.

Hemic and Lymphatic Systems: Transient thrombocytopenia, leukopenia, and eosinophilia. Prolongation in prothrombin time was seen rarely.

Other: Genital pruritus, vaginitis, candidiasis.

The following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics:

Adverse Reactions: Allergic reactions including anaphylaxis, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, superinfection, renal dysfunction, toxic nephropathy, hepatic dysfunction, including cholestasis, aplastic anemia, hemolytic anemia, hemorrhage.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced (see **DOSAGE AND ADMINISTRATION** and **OVERDOSAGE**). If seizures associated with drug therapy occur, discontinue drug. Administer anticonvulsant therapy if clinically indicated.

Abnormal Laboratory Tests: Positive direct Coombs test, elevated bilirubin, elevated LDH, pancytopenia, neutropenia, agranulocytosis.

OVERDOSAGE

Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2 g of SUPRAX did not differ from the profile seen in patients treated at the recommended doses.

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Why send an antitussive to do a bronchodilator's job?

- Asthma is the most common cause of persistent episodic cough in children.^{1,2}
- PROVENTIL Syrup has been proven to reduce nighttime cough symptoms due to asthma as much as 50%.³
- Starts within 30 minutes—lasts up to 6 hours.
- Safe enough for 2 year olds.
- Completely free of sugar, alcohol, tartrazine (yellow dye No. 5), and bisulfites.
- Pleasant tasting and easy to take.

References: 1. Cloutier MM: The coughing child: Etiology and treatment of a common symptom. *Postgrad Med* 1983;73:169-175. 2. Miser WF: Variant forms of asthma. *Am Fam Physician* 1987;35(6):89-96. 3. Rachelefsky GS, Katz RM, Siegel SC: Albuterol syrup in the treatment of the young asthmatic child. *Ann Allergy* 1981;47:143-146.

Proven
Proventil[®]
(albuterol sulfate) **Syrup**
2 mg albuterol per 5 ml
Stops coughs asthma starts.

Please see next page for brief summary of prescribing information.

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PS-045/14568409



Proven Proventil[®] (albuterol sulfate) Syrup

2 mg albuterol per 5 ml

INDICATIONS AND USAGE PROVENTIL Syrup is indicated for the relief of bronchospasm in adults and in children 2 years of age and older with reversible obstructive airway disease.

In controlled clinical trials in patients with asthma, the onset of improvement in pulmonary function, as measured by maximal midexpiratory flow rate (MMEF) and forced expiratory volume in one second (FEV₁), was within 30 minutes after a dose of PROVENTIL Syrup. Peak improvement of pulmonary function occurred between 2 to 3 hours. In a controlled clinical trial involving 55 children, clinically significant improvement (defined as maintenance of mean values over baseline of 15% or 20% or more in the FEV₁, and MMEF respectively) continued to be recorded up to 6 hours. No decrease in the effectiveness was reported in one uncontrolled study of 32 children who took PROVENTIL Syrup for a 3-month period.

CONTRAINDICATIONS PROVENTIL Syrup is contraindicated in patients with a history of hypersensitivity to any of its components.

PRECAUTIONS **General:** Although albuterol usually has minimal effects on the beta₁-adrenoceptors of the cardiovascular system at the recommended dosage, occasionally the usual cardiovascular and CNS stimulatory effects common to all sympathomimetic agents have been seen with patients treated with albuterol necessitating discontinuation. Therefore, albuterol should be used with caution in patients with cardiovascular disorders, including coronary insufficiency and hypertension, in patients with hyperthyroidism or diabetes mellitus, and in patients who are unusually responsive to sympathomimetic amines.

Large doses of intravenous albuterol have been reported to aggravate preexisting diabetes mellitus and ketoacidosis. Additionally, albuterol and other beta-agonists, when given intravenously, may cause a decrease in serum potassium, possibly through intracellular shunting. The decrease is usually transient, not requiring supplementation. The relevance of these observations to the use of PROVENTIL Syrup is unknown.

Information for Patients: The action of PROVENTIL Syrup may last up to six hours and therefore it should not be taken more frequently than recommended. Do not increase the dose or frequency of medication without medical consultation. If symptoms get worse, medical consultation should be sought promptly.

Drug Interactions: The concomitant use of PROVENTIL Syrup and other oral sympathomimetic agents is not recommended since such combined use may lead to deleterious cardiovascular effects. This recommendation does not preclude the judicious use of an aerosol bronchodilator of the adrenergic stimulant type in patients receiving PROVENTIL Syrup. Such concomitant use, however, should be individualized and not given on a routine basis. If regular coadministration is required, then alternative therapy should be considered.

Albuterol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, since the action of albuterol on the vascular system may be potentiated. Beta-receptor blocking agents and albuterol inhibit the effect of each other.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Albuterol sulfate, like other agents in its class, caused a significant dose-related increase in the incidence of benign leiomyomas of the mesovarium in a 2-year study in the rat, at doses corresponding to 2, 9, and 46 times the maximum human (child weighing 21 kg) oral dose. In another study this effect was blocked by the coadministration of propranolol. The relevance of these findings to humans is not known. An 18-month study in mice and a lifetime study in hamsters revealed no evidence of tumorigenicity. Studies with albuterol revealed no evidence of mutagenesis. Reproduction studies in rats revealed no evidence of impaired fertility.

Teratogenic Effects—Pregnancy Category C: Albuterol has been shown to be teratogenic in mice when given subcutaneously in doses corresponding to 0.2 times the maximum human (child weighing 21 kg) oral dose. There are no adequate and well-controlled studies in pregnant women. Albuterol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. A reproduction study in CD-1 mice with albuterol showed cleft palate formation in 5 of 111 (4.5%) fetuses at 0.25 mg/kg and in 10 of 108 (9.3%) fetuses at 2.5 mg/kg; none was observed at 0.025 mg/kg. Cleft palate also occurred in 22 of 72 (30.5%) fetuses treated with 2.5 mg/kg isoproterenol (positive control). A reproduction study in Stride Dutch rabbits revealed cranioschisis in 7 of 19 (37%) fetuses at 50 mg/kg, corresponding to 46 times the maximum human (child weighing 21 kg) oral dose of albuterol sulfate.

Labor and Delivery: Oral albuterol has been shown to delay preterm labor in some reports. There are presently no well-controlled studies which demonstrate that it will stop preterm labor or prevent labor at term. Therefore, cautious use of PROVENTIL Syrup is required in pregnant patients when given for relief of bronchospasm so as to avoid interference with uterine contractility. Use in such patients should be restricted to those patients in whom the benefits clearly outweigh the risks.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because of the potential for tumorigenicity shown for albuterol in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

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

ADVERSE REACTIONS The adverse reactions to albuterol are similar in nature to those of other sympathomimetic agents. The most frequent adverse reactions to PROVENTIL Syrup in adults and older children were tremor, 10 of 100 patients; nervousness and shakiness, each 9 of 100 patients. Other reported adverse reactions were headache, 4 of 100 patients; dizziness and increased appetite, each 3 of 100 patients; hyperactivity and excitement, each 2 of 100 patients; tachycardia, epistaxis, irritable behavior, and sleeplessness, each 1 of 100 patients. The following adverse effects occurred in less than 1 of 100 patients each: muscle spasm, disturbed sleep, epigastric pain, cough, palpitations; stomach ache; irritable behavior, dilated pupils; sweating; chest pain; weakness.

In young children 2 to 6 years of age, some adverse reactions were noted more frequently than in adults and older children. Excitement was noted in approximately 20% of patients and nervousness in 15%. Hyperkinesia occurred in 4% of patients; insomnia, tachycardia, and gastrointestinal symptoms in 2% each. Anorexia, emotional lability, pallor, fatigue, and conjunctivitis were seen in 1%.

In addition, albuterol, like other sympathomimetic agents, can cause adverse reactions such as hypertension, angina, vomiting, vertigo, central nervous system stimulation, unusual taste, and drying or irritation of the oropharynx.

The reactions are generally transient in nature, and it is usually not necessary to discontinue treatment with PROVENTIL Syrup. In selected cases, however, dosage may be reduced temporarily; after the reaction has subsided, dosage should be increased in small increments to the optimal dosage.

OVERDOSAGE Manifestations of overdosage include anginal pain, hypertension, hypokalemia, and exaggeration of the effects listed in **ADVERSE REACTIONS**.

The oral LD₅₀ in rats and mice was greater than 2,000 mg/kg. Dialysis is not appropriate treatment for overdosage of PROVENTIL Syrup. The judicious use of a cardioselective beta-receptor blocker, such as metoprolol tartrate, is suggested, bearing in mind the danger of inducing an asthmatic attack.

For more complete details, consult package insert or Schering literature available from your Schering representative or Professional Services Department, Schering Corporation, Kenilworth, NJ 07033.

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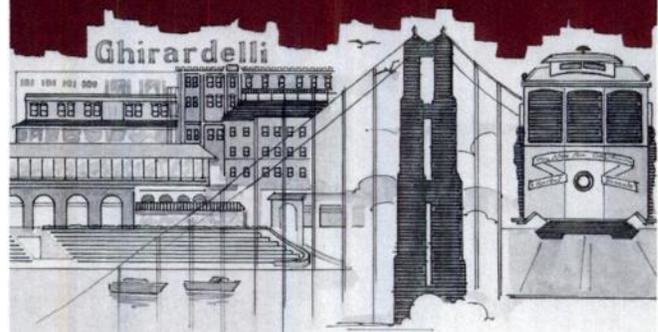
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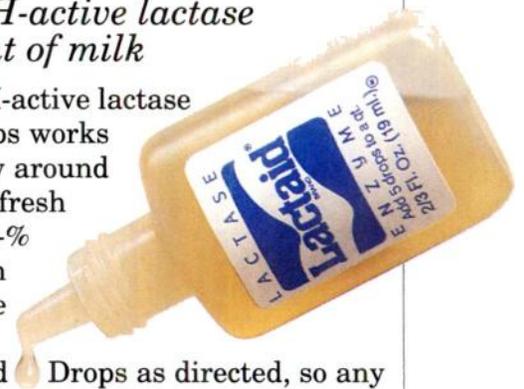
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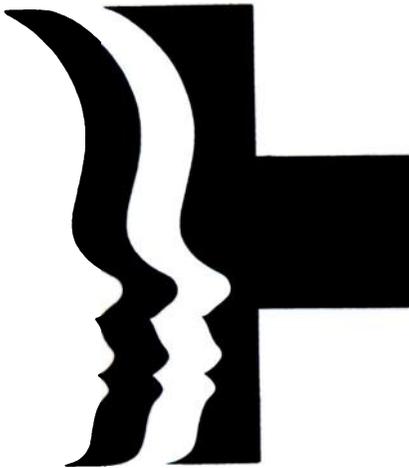
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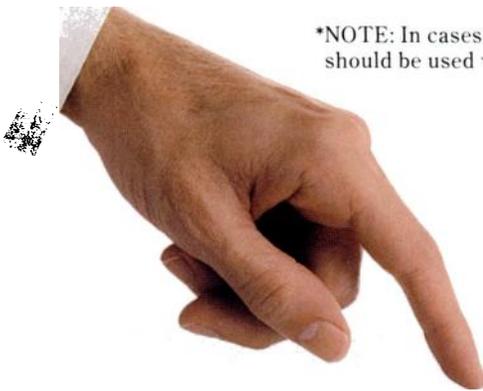
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1. Chandra RK, Singh G, Shridhara B. Effect of feeding whey hydrolysate, soy and conventional cow milk formulas on incidence of atopic disease in high risk infants. *Ann Allergy*. 1989;63(2):102-106.
2. Vandenplas Y, Deneeyer M, Sacre L, Loeb H. Preliminary data in a field study with a new hypo-allergic formula. *Eur J Pediatr*. 1988;148:274-277.

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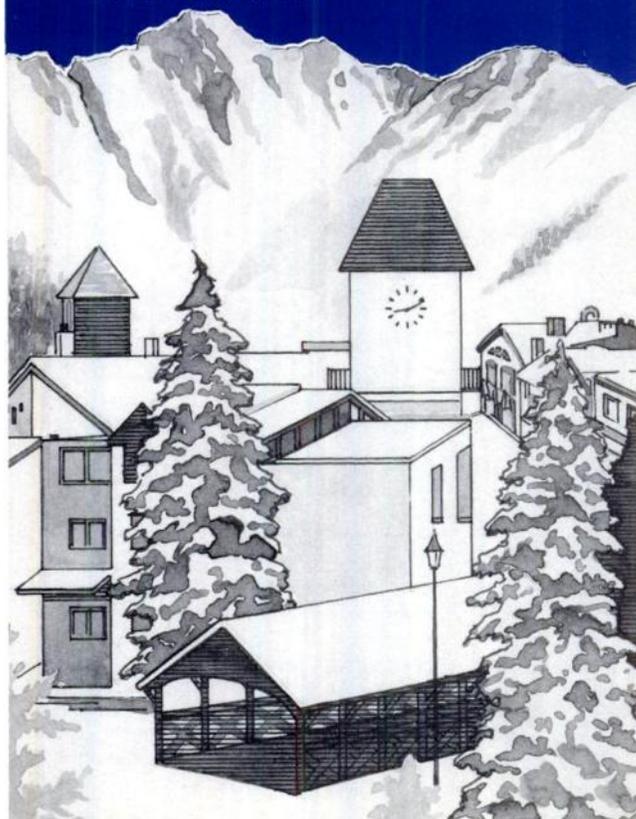


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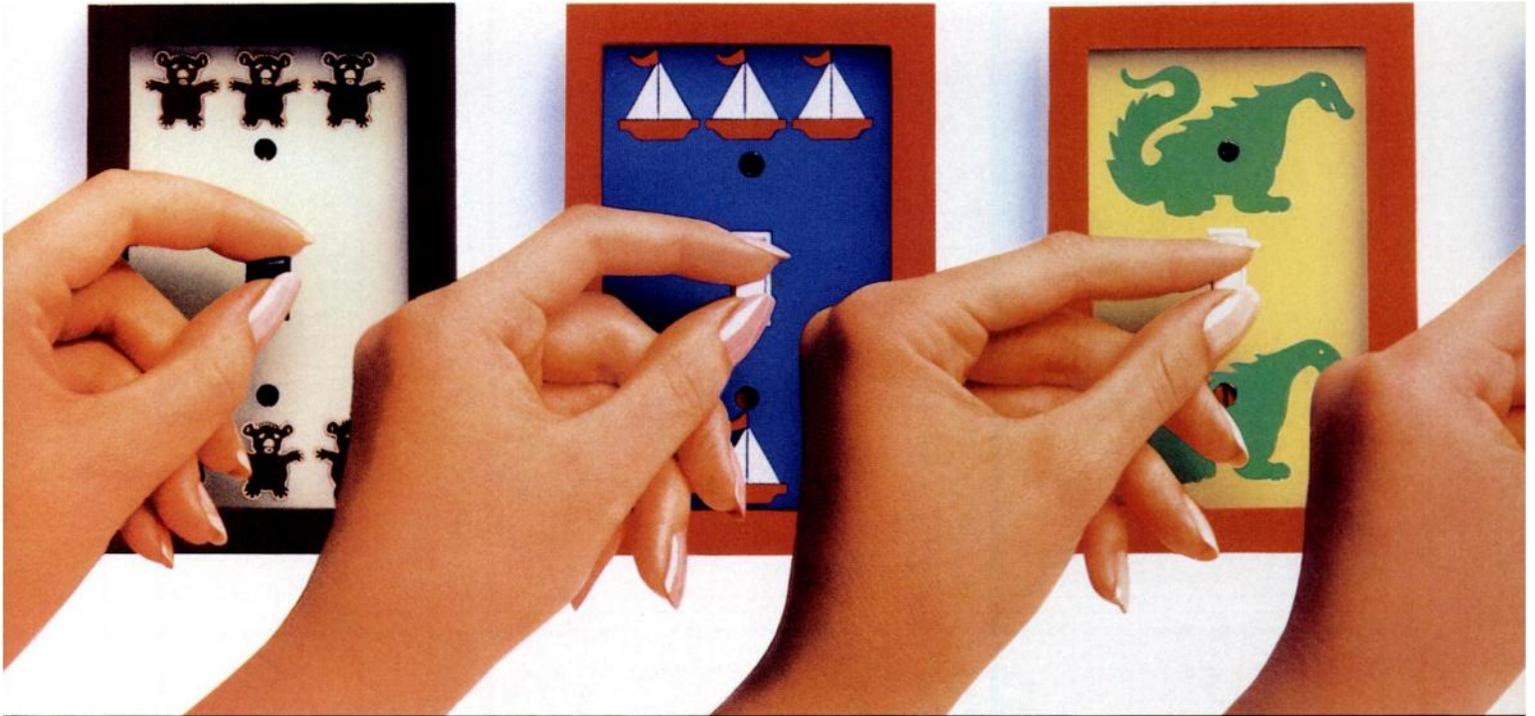


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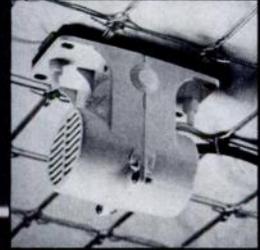
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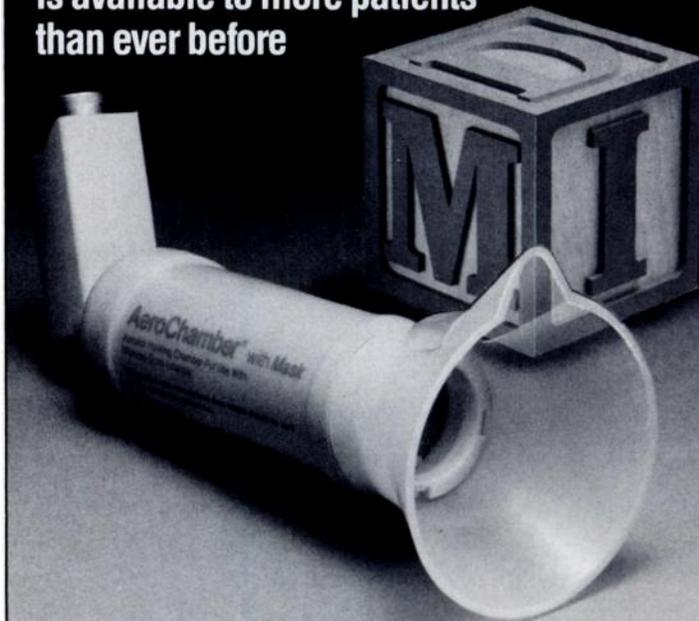
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Neonatologist

The University of Calgary and the Foothills Hospital invite applications for the position of Neonatologist. Applicants must have a strong interest in clinical care and neonatal/perinatal research; and should have FRCP(C) or equivalent, at least two years' specialized training in Neonatology and be eligible for licensure by the Alberta College of Physicians and Surgeons. Appointment will be at the rank of Assistant or Associate Professor. Remuneration will follow The University of Calgary guidelines.

The Foothills Hospital is the regional perinatal centre and has strong programs in obstetrical and neonatal care as well as regional education. The University of Calgary provides teaching at the undergraduate and graduate level and has well established investigators in neonatal/perinatal medicine.

In accordance with Canadian immigration requirements, priority will be given to Canadian citizens and permanent residents of Canada. The University of Calgary has an Employment Equity Program and encourages applications from all qualified candidates, including women, aboriginal people, visible minorities, and people with disabilities.

Applications, including a curriculum vitae, should be sent before October 31, 1989 to:

Dr. D.D. McMillan
Room C211, Foothills Hospital
1403 - 29 Street N.W.
Calgary, Alberta, Canada T2N 2T9



F O O T H I L L S H O S P I T A L

Clinical Neonatologist

The regional neonatal/perinatal care centre for approximately 19,000 annual births (4,000 at Foothills Hospital) includes a 36 bed NICU which operates in cooperation with the Alberta Children's Hospital, Rockyview Hospital and Peter Lougheed Centre of the Calgary General Hospital. Clinical responsibilities shared with neonatologists at the Foothills Hospital and other Calgary Hospitals include antenatal consultations, delivery room and neonatal intensive care with supervision of clinical assistants, residents and neonatal fellows. Educational involvement will occur in the undergraduate and postgraduate medical programs at the University of Calgary and in the Southern Alberta Perinatal Education Program.

Applicants should have FRCPC or equivalent, at least two years' specialized training in neonatology and be eligible for licensure by the Alberta College of Physicians and Surgeons. In accordance with Canadian Immigration regulations preference will be given to Canadian citizens and landed immigrants.

Employment includes attractive remuneration and a challenging career in a progressive environment.

Interested applicants may contact or send resume to:



**Foothills
Hospital**

Dr. D. McMillan, Chief of Neonatology
Department of Pediatrics, Room C211
Foothills Hospital
1403 - 29 Street N.W.
Calgary, Alberta, Canada T2N 2T9
Telephone (403) 270-1615

Closing Date: November 15, 1989

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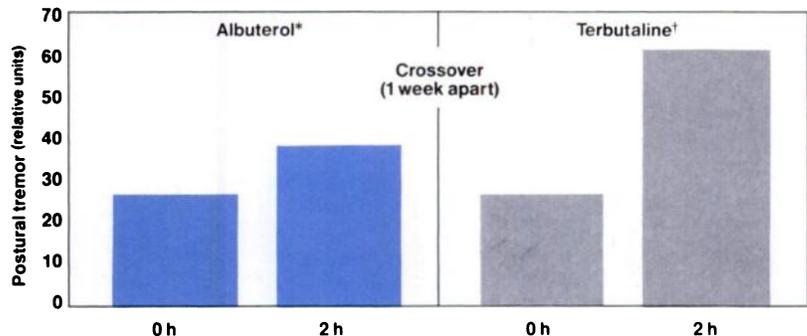
$P < 0.01$ between treatments.
*4 mg single dose of albuterol, $n = 20$.
†5 mg single dose of terbutaline, $n = 20$.

References: 1. Wolfe JD, Yamate M, Biederman AA, et al: Comparison of the acute cardiopulmonary effects of oral albuterol, metaproterenol, and terbutaline in asthmatics. *JAMA* 1985;253:2068-2072.
2. Rosen JP, Chervinsky P, Renard RL, et al: Duration of action of oral albuterol in an asthmatic population. *Ann Allergy* 1986;56:28-32.
3. Jenne JW, Valcarenghi G, Druz WS, et al: Comparison of tremor responses to orally administered albuterol and terbutaline. *Am Rev Respir Dis* 1986;134:708-713.

VENTOLIN® (ALBUTEROL SULFATE, USP) TABLETS 2 mg & 4 mg

- Symptomatic relief within 30 minutes...lasts for up to 8 hours^{1,2}
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- Wide therapeutic range—minimal metabolic variability
- Significantly less tremor early in therapy compared with terbutaline therapy^{1,3}

Mean postural tremor intensities before and after treatment in COPD patients upon first dose of a randomized crossover study³



Ventolin® (albuterol sulfate, USP) Tablets

BRIEF SUMMARY

The following is a brief summary only. Before prescribing, see complete prescribing information in Ventolin® Tablets product labeling.

CONTRAINDICATIONS: Ventolin® Tablets are contraindicated in patients with a history of hypersensitivity to any of their components.

WARNINGS: Immediate hypersensitivity reactions may occur after administration of albuterol, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, and oropharyngeal edema.

PRECAUTIONS: General: Albuterol, as with all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus; and in patients who are unusually responsive to sympathomimetic amines.

Large doses of intravenous albuterol have been reported to aggravate pre-existing diabetes mellitus and ketoacidosis. Additionally, beta-agonists, including albuterol, given intravenously may cause a decrease in serum potassium, possibly through intracellular shunting. The decrease is usually transient, not requiring supplementation. The relevance of these observations to the use of Ventolin® Tablets is unknown.

Information for Patients: The action of Ventolin Tablets may last for eight hours or longer, and therefore they should not be taken more frequently than recommended. Do not increase the dose or frequency of medication without medical consultation. If symptoms get worse, medical consultation should be sought promptly.

Drug Interactions: The concomitant use of Ventolin Tablets and other oral sympathomimetic agents is not recommended since such combined use may lead to deleterious cardiovascular effects. This recommendation does not preclude the judicious use of an aerosol bronchodilator of the adrenergic stimulant type in patients receiving Ventolin Tablets. Such concomitant use, however, should be individualized and not given on a routine basis. If regular coadministration is required, then alternative therapy should be considered.

Albuterol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants because the action of albuterol on the vascular system may be potentiated.

Beta-receptor blocking agents and albuterol inhibit the effect of each other.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Albuterol sulfate, like other agents in its class, caused a significant dose-related increase in the incidence of benign leiomyomas of the mesovarium in a two-year study in the rat, at doses corresponding to 3, 16, and 78 times the maximum human oral dose. In another study this effect was blocked by the coadministration of propranolol. The relevance of these findings to humans is not known. An 18-month study in mice and a lifetime study in hamsters revealed no evidence of tumorigenicity. Studies with albuterol revealed no evidence of mutagenesis. Reproduction studies in rats revealed no evidence of impaired fertility.

Pregnancy: Teratogenic Effects: Pregnancy Category C: Albuterol has been shown to be teratogenic in mice when given subcutaneously in doses corresponding to 0.4 times the maximum

human oral dose. There are no adequate and well-controlled studies in pregnant women. Albuterol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. A reproduction study in CD-1 mice given albuterol subcutaneously (0.025, 0.25, and 2.5 mg/kg, corresponding to 0.5, 5, and 52 times the maximum human oral dose, respectively) showed cleft palate formation in 5 of 111 (4.5%) fetuses at 0.25 mg/kg and in 10 of 108 (9.3%) fetuses at 2.5 mg/kg. None was observed at 0.025 mg/kg. Cleft palate also occurred in 22 of 72 (30.5%) fetuses treated with 2.5 mg/kg isoproterenol (positive control). A reproduction study with oral albuterol in Stride Dutch rabbits revealed cranioschisis in 7 of 19 (37%) fetuses at 50 mg/kg, 78 times the maximum human oral dose of albuterol.

Labor and Delivery: Oral albuterol has been shown to delay preterm labor in some reports. There are presently no well-controlled studies that demonstrate that it will stop preterm labor or prevent labor at term. Therefore, cautious use of Ventolin® (albuterol sulfate, USP) Tablets is required in pregnant patients when given for relief of bronchospasm so as to avoid interference with uterine contractility. Use in such patients should be restricted to those patients in whom the benefits clearly outweigh the risks.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because of the potential for tumorigenicity shown for albuterol in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children below 6 years of age have not been established.

ADVERSE REACTIONS: The adverse reactions to albuterol are similar to other sympathomimetic agents. The most frequent adverse reactions were nervousness and tremor (in approximately 20 of 100 patients); headache (7 of 100); tachycardia and palpitations (5 of 100); muscle cramps (3 of 100); insomnia, nausea, weakness, and dizziness (2 of 100); and drowsiness, flushing, restlessness, irritability, chest discomfort, and difficulty in micturition (less than 1 of 100).

Rare cases of urticaria, angioedema, rash, bronchospasm, and oropharyngeal edema have been reported after the use of albuterol.

In addition, albuterol, like other sympathomimetic agents, can cause hypertension, angina, vomiting, vertigo, central nervous system stimulation, unusual taste, and drying or irritation of the oropharynx.

The reactions are generally transient in nature, and it is usually not necessary to discontinue treatment with Ventolin Tablets. In selected cases, however, dosage may be reduced temporarily; after the reaction has subsided, dosage should be increased in small increments to the optimal dosage.

OVERDOSAGE: Information concerning possible overdosage and its treatment appears in the full prescribing information.

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RB2-314
March 1989