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Pediatrics

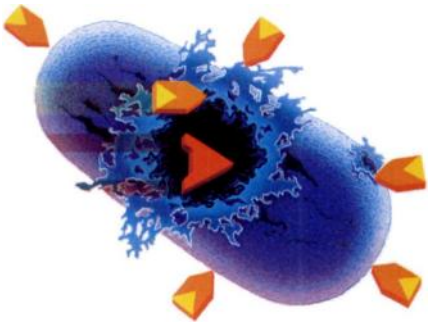
AMERICAN ACADEMY OF PEDIATRICS ELK GROVE VILLAGE IL 60009–0927

When otitis media advances beyond the reach of amoxicillin...

Prescribe

AUGMENTIN™

amoxicillin/clavulanate potassium



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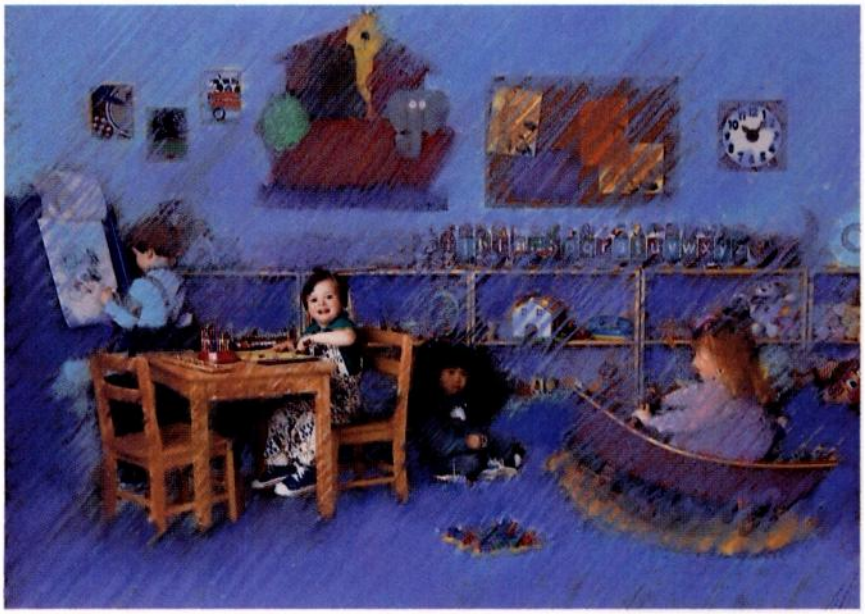
- Exceptional clinical response rate of 96%*
- The only oral antibiotic that destroys β-lactamase
- Safety profile characteristic of a penicillin
- Available in pleasant-tasting oral suspension and chewable tablets



The right choice for persistent otitis media

*Data on file, Beecham Laboratories.

Please see brief summary of prescribing information on adjacent page.

Brief Summary of Prescribing Information

AUGMENTIN™ amoxicillin clavulanate potassium

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 amoxicillin. 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 ten (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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Mutaz B. Habal, MD, FAAP
A. Michael Sadove, MD, FAAP
Jeffrey L. Marsh, MD, FAAP
Richard E. Albin, MD, FAAP
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1. Starzl TE, Klintmalm GBG, Porter KA, et al. Liver transplantation with use of cyclosporin A and prednisone. *N Engl J Med.* 1981;305:266–269

Book

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

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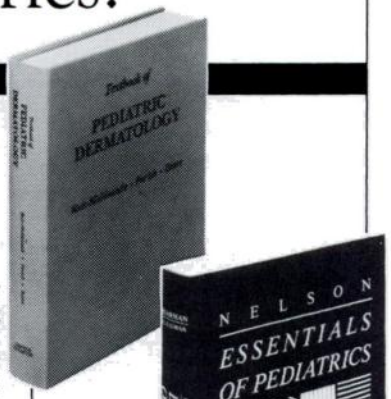

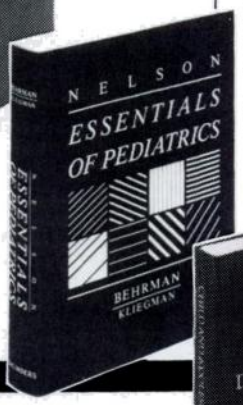

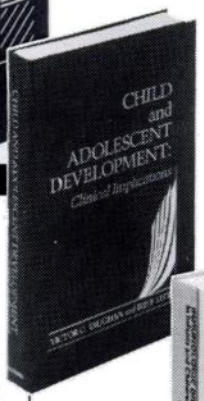

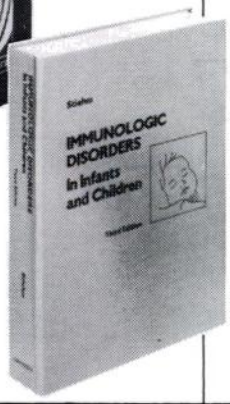

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ANNUAL MEETINGS

1989
Chicago
October 21–26

1990
Boston
October 5–10

1991
New Orleans
October 26–31

1992
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October 10–15

SPRING SESSIONS

1990
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1991
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Scottsdale, Arizona
October 6–8

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Williamsburg, Virginia
December 15–17

1990

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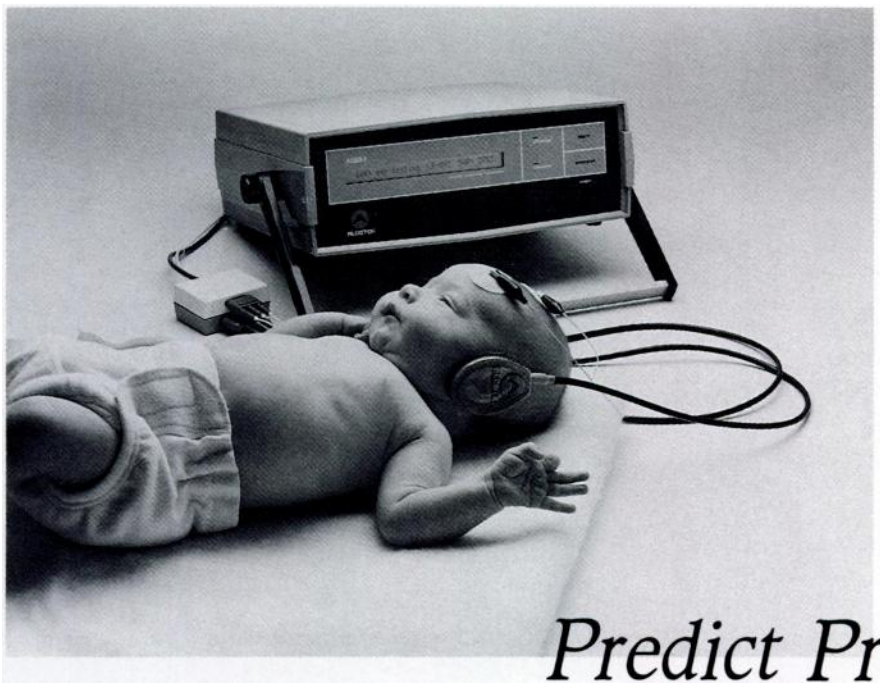

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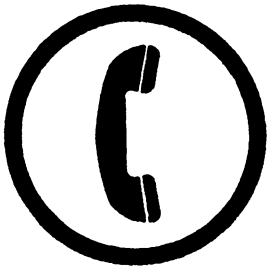

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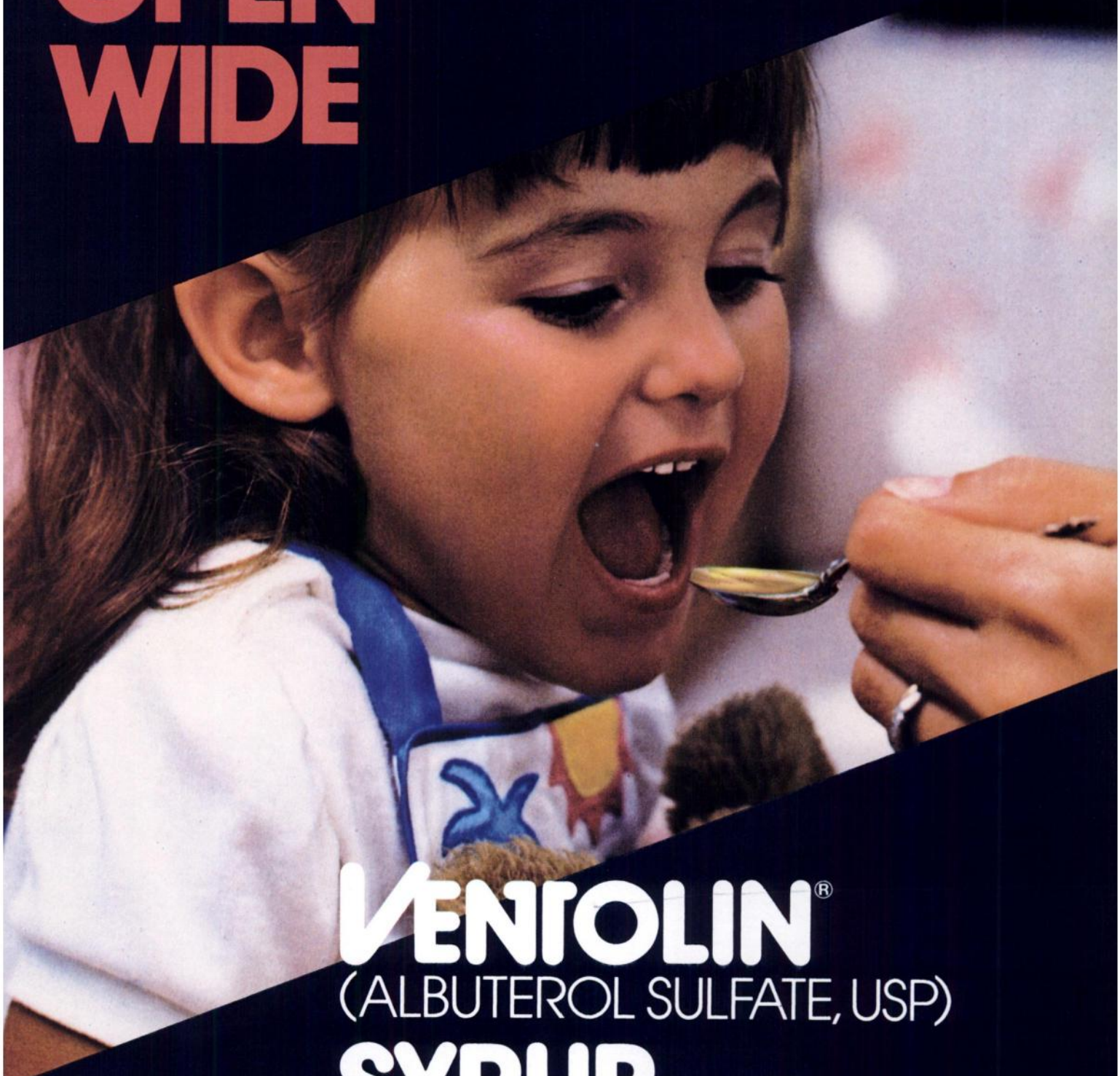

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Unsurpassed bronchodilator therapy for children 2 years of age and older...flavorful taste enhances compliance...a simple tid regimen helps provide all-day and all-night control in most patients.

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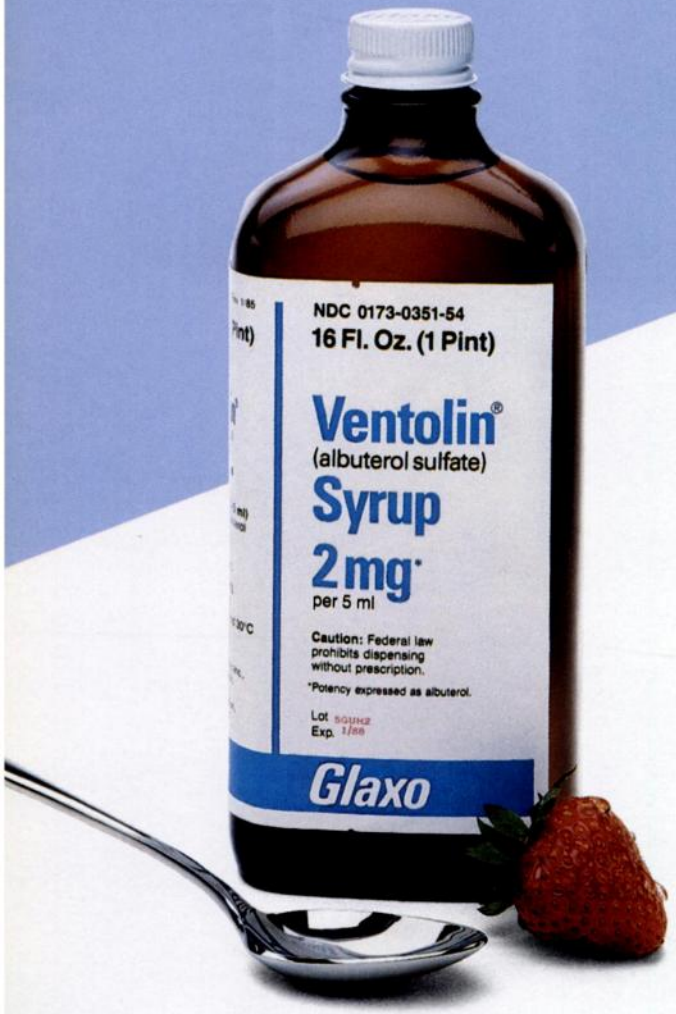
*Potency expressed as albuterol
Please consult following page for Brief Summary of Prescribing Information



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Unsurpassed bronchodilator therapy that goes down easy

■ Effective relief within 30 minutes...lasts as long as 6 hours

■ Promotes compliance with a flavorful taste and simple starting dosage regimen:

2 to 6 years—0.1 mg/kg body weight tid not to exceed 1 tsp (2 mg) tid
6 to 14 years—1 tsp (2 mg) tid or qid
14 years and older—1 to 2 tsp (2 to 4 mg) tid or qid

Please consult complete Prescribing Information for dosage adjustment.

■ Free of undesirable additives—no sulfites, sugar, alcohol, or tartrazine (yellow dye #5)

Side effects seen with VENTOLIN Syrup in older children and adults are similar to those of other sympathomimetic agents. In children 2 to 6 years old, excitement was noted in approximately 20% and nervousness in 15%.

*Potency expressed as albuterol.

VES 053 • Printed in USA • June 1989

Ventolin® (albuterol sulfate, USP)
Syrup

BRIEF SUMMARY

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

CONTRAINDICATIONS: Ventolin® 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 beta$_2$-adrenoceptors of the cardiovascular system at the recommended dosage, *occasionally* the usual cardiovascular and central nervous system (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 pre-existing diabetes mellitus and ketoacidosis. Additionally albuterol and other beta-agonists 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® Syrup is unknown.

Information for Patients: The action of Ventolin 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 Ventolin 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 Ventolin 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 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 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.

Pregnancy: *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 that demonstrate that it will stop preterm labor or prevent labor at term. Therefore, cautious use of Ventolin® (albuterol sulfate, USP) 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 2 years of age have not yet been adequately demonstrated.

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

In young children 2 to 6 years of age, some adverse reactions were noted more frequently than in adults and older children. These include excitement (in 20% of patients); nervousness (15%); hyperkinesia (4%); insomnia, tachycardia, and gastrointestinal symptoms (2%); and anorexia, emotional lability, pallor, fatigue, and conjunctivitis (1%).

In addition, albuterol, like other sympathomimetic agents, can cause hypertension, angina, vomiting, vertigo, CNS 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® 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: Information concerning possible overdosage and its treatment appears in the full prescribing information.

HOW SUPPLIED: Ventolin® Syrup, a clear, orange-yellow liquid with a strawberry flavor, contains 2 mg of albuterol as the sulfate per 5 ml in bottles of 16 fluid ounces (one pint) (NDC 0173-0351-54).

Store between 2° and 30°C (36° and 86°F).

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RB2-507
March 1989

PEDIATRICS IN REVIEW: November 1989 Contents

BOOKS RECEIVED

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Catalog of Prenatally Diagnosed Conditions. D. D. Weaver. Baltimore, MD: The Johns Hopkins University Press; 1989 (price unavailable), 251 pp.

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Dyslexia: Theory and Practice of Remedial Instruction. D. B. Clark. Parkton, MD: York Press; 1988 (price unavailable), 240 pp.

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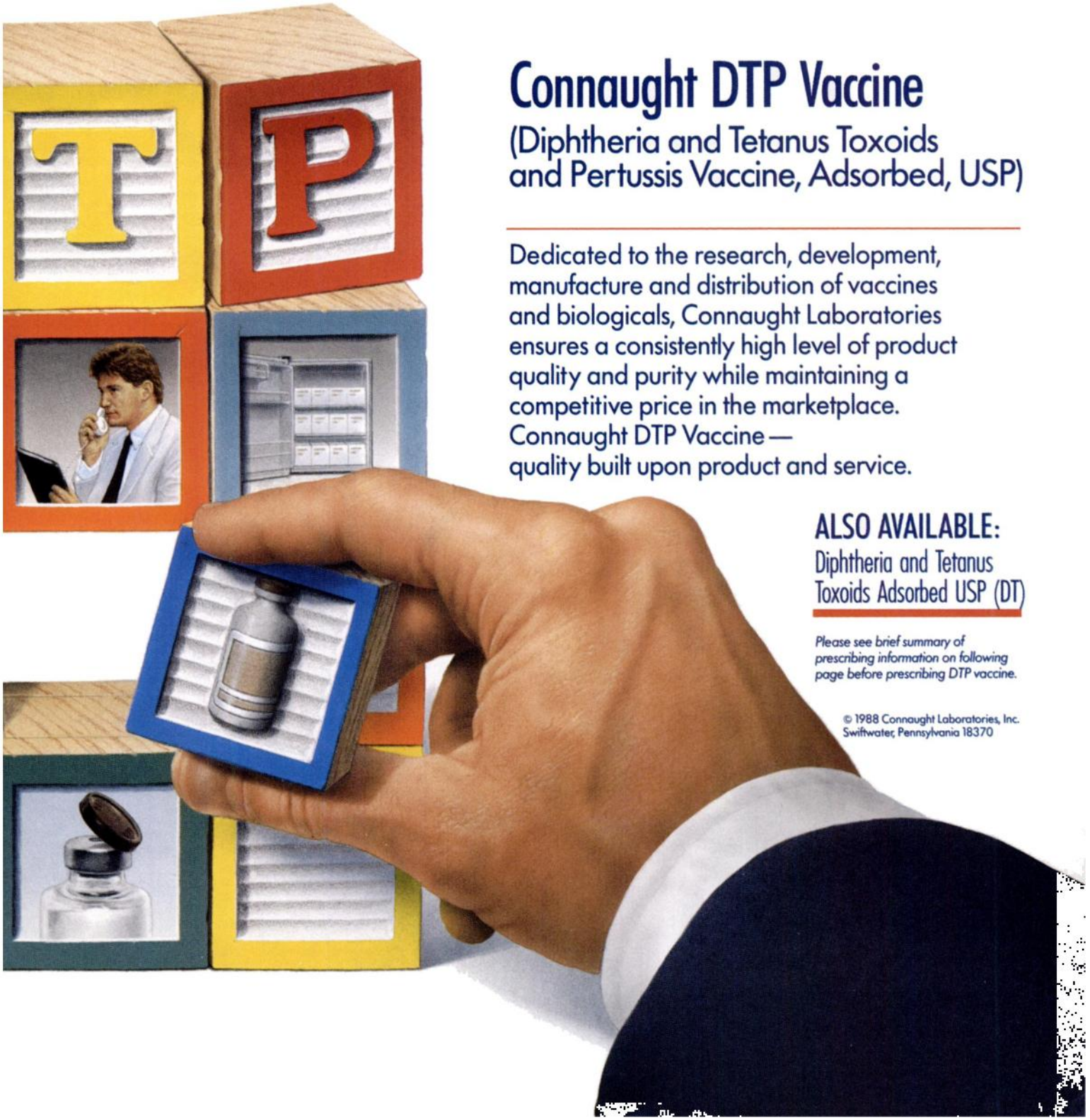


Connaught DTP Vaccine

(Diphtheria and Tetanus Toxoids and Pertussis Vaccine, Adsorbed, USP)

Dedicated to the research, development, manufacture and distribution of vaccines and biologicals, Connaught Laboratories ensures a consistently high level of product quality and purity while maintaining a competitive price in the marketplace. Connaught DTP Vaccine — quality built upon product and service.

ALSO AVAILABLE:
Diphtheria and Tetanus Toxoids Adsorbed USP (DT)

Please see brief summary of prescribing information on following page before prescribing DTP vaccine.

Connaught DTP Vaccine

(Diphtheria and Tetanus Toxoids and Pertussis Vaccine, Adsorbed, USP)

BRIEF SUMMARY
Before prescribing, please consult the complete package circular.

INDICATIONS AND USAGE: For active immunization of infants and children to age 7 years against diphtheria, tetanus and pertussis (whooping chough) simultaneously. DTP is recommended for primary immunization of infants and children up to 7 years of age. However, in instances where the pertussis vaccine component is contraindicated, or where the physician decides that pertussis vaccine is not to be administered, Diphtheria and Tetanus Toxoids Adsorbed (For Pediatric Use) should be used. Immunization should be started at 6 weeks to 2 months of age and be completed before the seventh birthday.

CONTRAINDICATIONS: *Persons 7 years of age and older must NOT be immunized with Pertussis Vaccine.*

Absolute contraindications.

1. Allergic hypersensitivity to any component of the vaccine.
2. Fever of 40.5°C (105°F) or greater within 48 hours.
3. Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours.
4. Persisting, inconsolable crying lasting 3 hours or more or an unusual, high-pitched cry occurring within 48 hours.
5. Convulsion(s) with or without fever occurring within 7 days.
6. Encephalopathy occurring within 7 days; this includes severe alterations in consciousness with generalized or local neurologic signs.

The presence of a neurologic condition characterized by changing developmental or neurologic findings, regardless of whether a definitive diagnosis has been made, is also considered an absolute contraindication to receipt of pertussis vaccine, because administration of DTP may coincide with or possibly even aggravate manifestations of the disease. Such disorders include uncontrolled epilepsy, infantile spasms, and progressive encephalopathy.

Use of this product is also contraindicated if the child has a personal or family history of a seizure disorder. However, the ACIP does not accept family histories of convulsions or other central nervous system disorders as contraindications to pertussis vaccination.

IT IS ALSO A CONTRAINDICATION TO ADMINISTER DTP TO INDIVIDUALS KNOWN TO BE SENSITIVE TO THIMEROSAL. IN ANY CASE, EPINEPHRINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE SHOULD AN ACUTE ANAPHYLACTIC REACTION OCCUR DUE TO ANY COMPONENT OF THE VACCINE.

Elective immunization procedures should be deferred during an outbreak of poliomyelitis.

WARNINGS: *This vaccine must NOT be used for immunizing persons 7 years of age and older.*

IMMUNIZATION SHOULD BE DEFERRED DURING THE COURSE OF ANY ACUTE ILLNESS. THE OCCURRENCE OF ANY TYPE OF NEUROLOGICAL SYMPTOMS OR SIGNS, INCLUDING ONE OR MORE CONVULSIONS (SEIZURES) FOLLOWING ADMINISTRATION OF THIS PRODUCT IS AN ABSOLUTE CONTRAINDICATION TO FURTHER USE. USE OF THIS PRODUCT IS ALSO CONTRAINDICATED IF THE CHILD HAS A PERSONAL OR FAMILY HISTORY OF A SEIZURE DISORDER.

THE PRESENCE OF ANY EVOLVING OR CHANGING DISORDER AFFECTING THE CENTRAL NERVOUS SYSTEM IS A CONTRAINDICATION TO ADMINISTRATION OF DTP REGARDLESS OF WHETHER THE SUSPECTED NEUROLOGICAL DISORDER IS ASSOCIATED WITH OCCURRENCE OF SEIZURE ACTIVITY OF ANY TYPE.

The administration of DTP to children with proven or suspected underlying neurological disorders, must be decided on an individual basis. Please refer to ACIP recommendations for the following categories of patients:

1. **Infants as yet unimmunized who are suspected of having underlying neurologic disease.**
2. **Infants and children with neurologic events temporally associated with DTP.**
3. **Incompletely immunized children with neurologic events occurring between doses.**
4. **Infants and children with stable neurologic conditions.**
5. **Children with resolved or corrected neurologic disorders.**

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune response to vaccines. Short-term (less than 2 weeks) corticosteroid therapy or intra-articular, bursal, or tendon injections with corticosteroids should not be immunosuppressive. Although no specific studies with pertussis vaccine are available, if immunosuppressive therapy will be discontinued shortly, it would be reasonable to defer immunization until the patient has been off therapy for one month, otherwise, the patient should be vaccinated while still on therapy.

Persons receiving immunosuppressive therapy, a recent injection of immune globulin, or having an immunodeficiency disorder, may not generate an adequate immunologic response to the DTP vaccine.

DTP should not be given to infants or children with any coagulation disorder that would contraindicate intramuscular injection, unless the potential benefit clearly outweighs the risk of administration.

The simultaneous administration of DTP, oral polio virus vaccine (OPV), and/or measles-mumps-rubella vaccine (MMR) has resulted in seroconversion rates and rates of side effects similar to those observed when the vaccines are administered separately. Please refer to ACIP recommendations.

PRECAUTIONS

GENERAL

Epinephrine injection (1:1000) must be immediately available should an acute anaphylactic reaction occur due to any component of the vaccine.

Prior to an injection of any vaccine, all known precautions should be taken to prevent side reactions. This includes a review of the patient's history with respect to possible sensitivity and any previous adverse reactions to the vaccine or similar vaccines (see CONTRAINDICATIONS), and a current knowledge of the literature concerning the use of the vaccine under consideration.

The vial of vaccine should be vigorously shaken to ensure a proper suspension of the antigen and adjuvant.

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.

ADVERSE REACTIONS

Not all adverse events following administration of DTP are causally related to DTP vaccine.

Adverse reactions which may be local and include pain, erythema, heat, edema and induration with or without tenderness, are common after the administration of vaccines containing diphtheria, tetanus, or pertussis antigens. Some data suggest that febrile reactions are more likely to occur in those who have experienced such responses after prior doses. However, these observations were not noted by Barkin, R.M., et al. Occasionally, a nodule may be palpable at the injection site of adsorbed products for several weeks. Sterile abscesses at the site of injection have been reported (6-10 per million doses).

Mild systemic reactions, such as fever, drowsiness, fretfulness, and anorexia, occur quite frequently. These reactions are significantly more common following DTP than following DT, are usually self-limited, and need no therapy other than, perhaps, symptomatic treatment (e.g., antipyretics). Rash, allergic reactions, and respiratory difficulties, including apnea, have been observed.

Moderate to severe systemic events, such as fever of 40.5°C (105°F) or higher, persistent, inconsolable crying lasting 3 hours or more, unusual high-pitched crying, collapse, or convulsions, occur relatively infrequently. More severe neurologic complications, such as a prolonged convulsion or an encephalopathy, occasionally fatal, have been reported to be associated with DTP administration.

Approximate rates for adverse events following receipt of DTP vaccine (regardless of dose number in the series) are indicated in Table 1.

TABLE 1. Adverse events occurring within 48 hours of DTP immunizations

Event	Frequency*
Local	
Redness	1/3 doses
Swelling	2/5 doses
Pain	1/2 doses
Mild/moderate systemic	
Fever >38°C (100.4°F)	1/2 doses
Drowsiness	1/3 doses
Fretfulness	1/2 doses
Vomiting	1/15 doses
Anorexia	1/5 doses
More serious systemic	
Persistent, inconsolable crying (duration ≥3 hours)	1/100 doses
High-pitched, unusual cry	1/900 doses
Fever ≥40.5°C (≥105°F)	1/330 doses
Collapse (hypotonic-hyporesponsive episode)	1/1,750 doses
Convulsions (with or without fever)	1/1,750 doses
Acute encephalopathy†	1/110,000 doses
Permanent neurologic deficit†	1/310,000 doses

*Number of adverse events per total number of doses regardless of dose number in DTP series.
†Occurring within 7 days of DTP immunization.

The frequency of local reactions and fever following DTP vaccination is significantly higher with increasing numbers of doses of DTP, while other mild to moderate systemic reactions (e.g., fretfulness, vomiting) are significantly less frequent. If local redness of 2.5 cm or greater occurs, the likelihood of recurrence after another DTP dose increases significantly.

Although there are uncertainties in the reported studies, recent data suggest that infants and young children who have had previous convulsions (whether febrile or nonfebrile) are more likely to have seizures following DTP than those without such histories.

Rarely, an anaphylactic reaction (i.e., hives, swelling of the mouth, difficulty breathing, hypotension, or shock) has been reported after receiving preparations containing diphtheria, tetanus, and/or pertussis antigens.

Sudden infant death syndrome (SIDS) has occurred in infants following administration of DTP. A large case-control study of SIDS in the United States showed that receipt of DTP was not causally related to SIDS. It should be recognized that the first three primary immunizing doses of DTP are usually administered to infants 2–6 months old and that approximately 85% of SIDS cases occur at ages 1–6 months, with the peak incidence occurring at 6 weeks–4 months of age. By chance alone, some SIDS victims can be expected to have recently received vaccine.

Onset of infantile spasms has occurred in infants who have recently received DTP or DT. Analysis of data from the NCES on children with infantile spasms showed that receipt of DTP or DT was not causally related to infantile spasms. The incidence of onset of infantile spasms increases at 3–9 months of age, the time period in which the second and third doses of DTP are generally given. Therefore, some cases of infantile spasms can be expected to be related by chance alone to recent receipt of DTP.

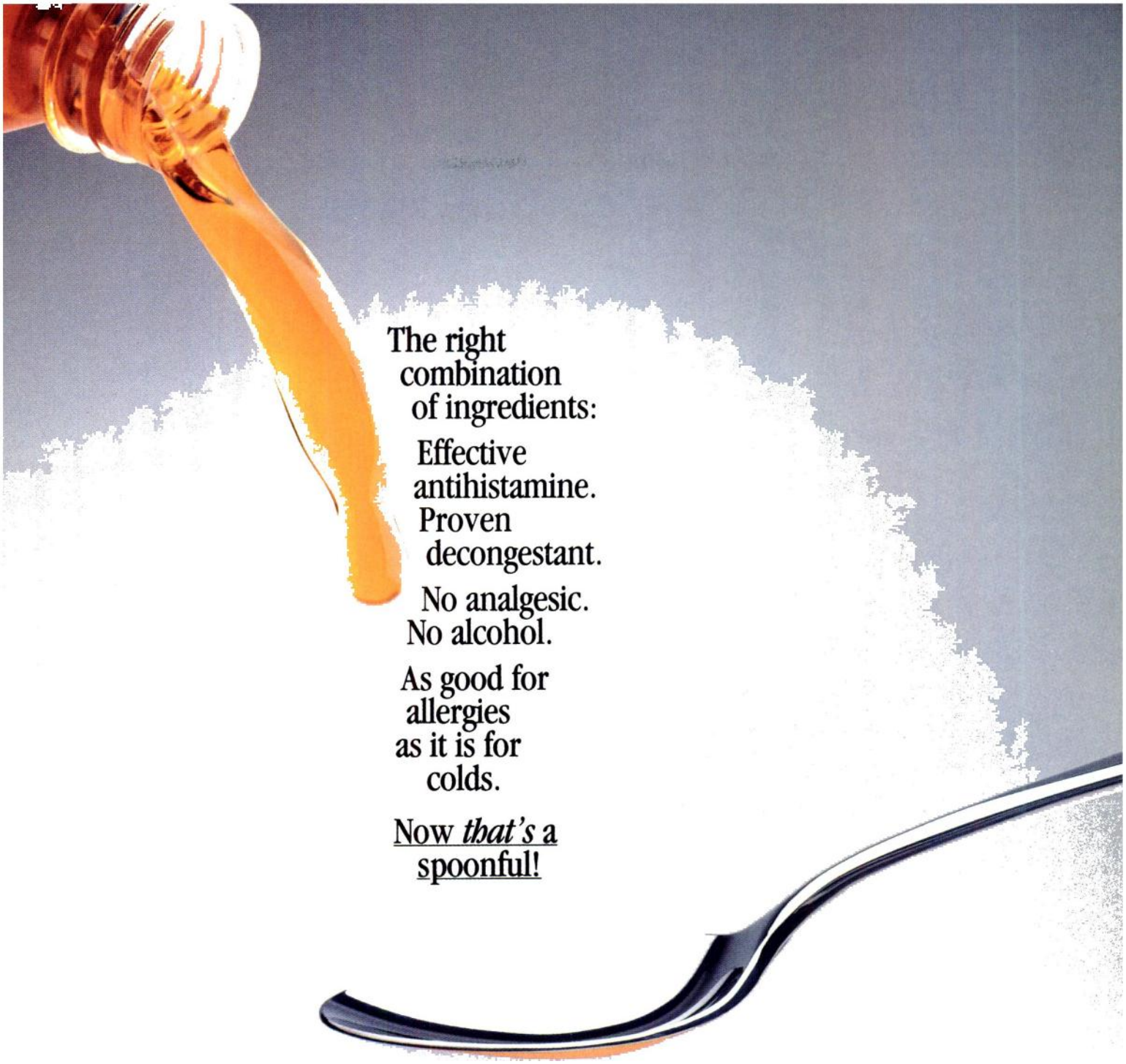
Reporting of Adverse Events

Reporting by parents and patients of all adverse events occurring within 4 weeks of antigen administration should be encouraged.

The following illnesses have been reported as temporally associated with the vaccine; neurological complications including cochlear lesion, brachial plexus neuropathies, paralysis of the radial nerve, paralysis of the recurrent nerve, accommodation paresis, and EEG disturbances with encephalopathy. In the differential diagnosis of polyradiculoneuropathies following administration of a vaccine containing tetanus toxoid, tetanus toxoid should be considered as a possible etiology.

Product information as of July, 1986

Mfd. by: CONNAUGHT LABORATORIES, INC.
Swiftwater, Pennsylvania 18370, U.S.A.
MKT0246 12/88
Printed in U.S.A. 0585



The right combination of ingredients:

Effective antihistamine. Proven decongestant.

No analgesic. No alcohol.

As good for allergies as it is for colds.

Now *that's* a spoonful!

#1 PEDIATRICIAN RECOMMENDED FOR COUGHS AND COLDS

Triaminic®
SYRUP

The "orange medicine" for colds and allergies

SANDOZ PHARMACEUTICALS CORPORATION
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NUMBER ONE PEDIATRICIAN RECOMMENDED BRAND FOR COUGHS AND COLDS.

For rapid, safe, symptomatic relief of cutaneous candidiasis

Mycostatin®
Topical Powder
(nystatin topical powder USP)

MYCOSTATIN® Topical Powder (Nystatin Topical Powder) provides, in every gram, 100,000 units of Nystatin USP dispersed in talc USP.

Supplied in convenient, unbreakable plastic squeeze bottles.

Please see brief summary of prescribing information on adjacent page.

For a happy ending

- Clinical and mycologic cure in most cases of localized candidiasis
- Virtually nontoxic and nonsensitizing (contains no preservatives)
- Well tolerated by children of all ages—including debilitated infants—even on prolonged administration
- Ideal for moist lesions—an ideal alternative to MYCOSTATIN® Cream (Nystatin Cream) or MYCOSTATIN® Ointment (Nystatin Ointment USP)

SQUIBB®

698-502

Issued: July 1988

MYCOSTATIN® CREAM
Nystatin Cream

MYCOSTATIN® TOPICAL POWDER
Nystatin Topical Powder

MYCOSTATIN® OINTMENT
Nystatin Ointment USP

DESCRIPTION: Mycostatin Cream contains the antifungal antibiotic Nystatin USP at a concentration of 100,000 units per gram in an aqueous, perfumed vanishing cream base containing aluminum hydroxide concentrated wet gel, titanium dioxide, propylene glycol, cetearyl alcohol (and) ceteareth-20, white petrolatum, sorbitol solution, glyceryl monostearate, polyethylene glycol monostearate, sorbic acid and simethicone.

Mycostatin Topical Powder provides, in each gram, 100,000 units Nystatin USP dispersed in Talc USP.

Mycostatin Ointment provides 100,000 units Nystatin USP per gram in Plastibase® (Plasticized Hydrocarbon Gel), a polyethylene and mineral oil gel base.

INDICATIONS AND USAGE: Mycostatin topical preparations are indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida* (Monilia) *albicans* and other Candida species.

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

PRECAUTIONS: Should a reaction of hypersensitivity occur the drug should be immediately withdrawn and appropriate measures taken.

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.

For full prescribing information, consult package insert.

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.

Mycostatin Topical Powder (Nystatin Topical Powder) is supplied in plastic squeeze bottles providing, in each gram, 100,000 units Nystatin USP.

Mycostatin Ointment (Nystatin Ointment USP) is supplied in tubes providing 100,000 units Nystatin USP per gram.

(J3-327A)

698-502 Issued: July 1988

Accreditation: Albert Einstein College of Medicine/ Montefiore Medical Center

GROWTH AND DEVELOPMENT IN CRANIOFACIAL ANOMALIES

Controversies in Surgical Correction and Management

Waldorf Astoria Hotel-New York City
March 29-31, 1990

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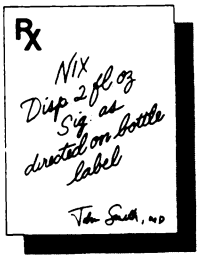

PEDICULICIDAL/OVICIDAL ACTIVITIES: *In vitro* data indicate that permethrin has pediculicidal and ovicidal activity against *Pediculus humanus* var. *capitis*. The high cure rate (97-99%) of Nix in patients with head lice demonstrated at 14 days following a single application is attributable to a combination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

References:

1. Brandenburg K, Deinard AS, DiNapoli J, et al: 1% permethrin cream rinse vs 1% lindane shampoo in treating pediculosis capitis. *Am J Dis Child* 1986; 140:894-896.
2. Bowerman JG, Gomez MP, Austin RD, et al: Comparative study of permethrin 1% creme rinse and lindane shampoo for the treatment of head lice. *Pediatr Infect Dis J* 1987; 6:252-255.
3. DiNapoli JB, Austin RD, Englender SJ, et al: Eradication of head lice with a single treatment. *Am J Public Health* 1988; 78:978-980.
4. Carson DS, Tribble PW, Weart CW: Pyrethrins combined with piperonyl butoxide (RID) vs 1% permethrin (NIX) in the treatment of head lice. *Am J Dis Child* 1988; 142:768-769.
5. Davies JE, Dedhia HV, Morgade C, et al: Lindane poisonings. *Arch Dermatol* 1983; 119:142-144.

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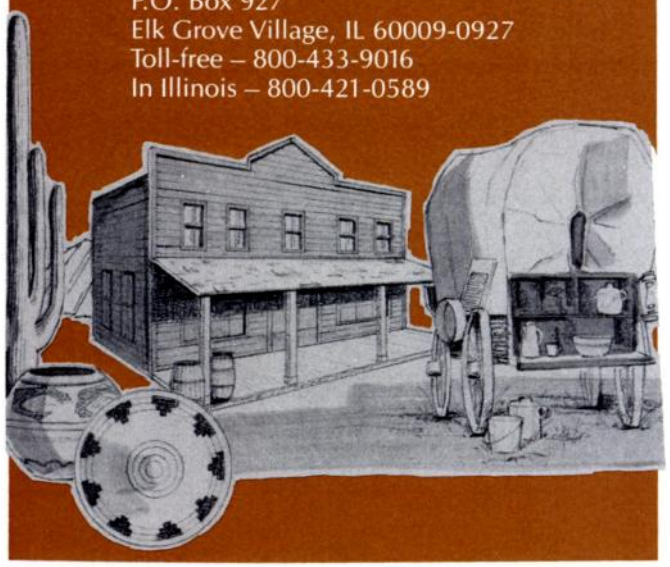

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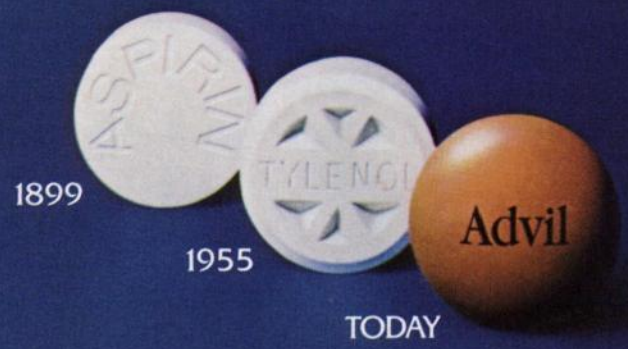

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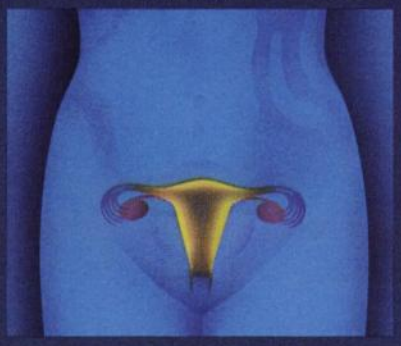

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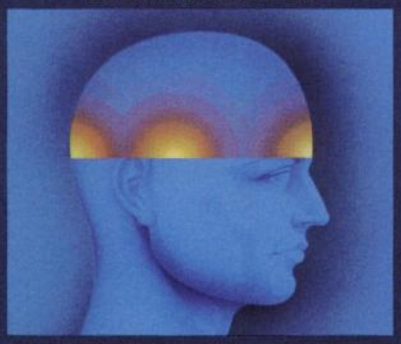
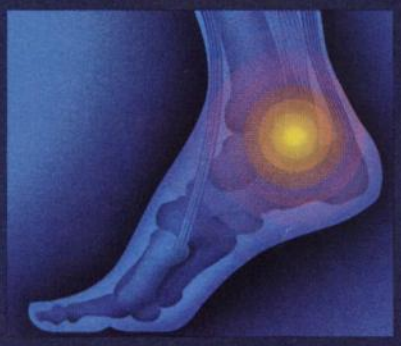


HEADACHE



MUSCLE ACHES

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 (FEV_1), 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 FEV_1 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 $beta_1$-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 contractibility. 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 LD_{50} 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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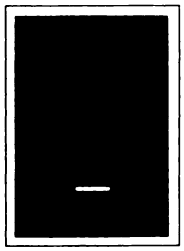
This multimedia educational program is endorsed by the American Academy of Pediatrics and is intended to serve as a resource for you, your adolescent patients, and their parents.

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.



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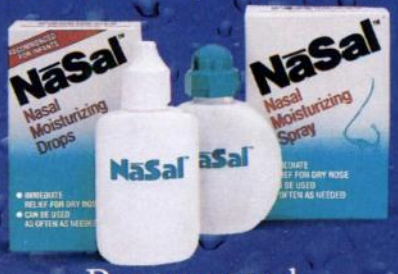

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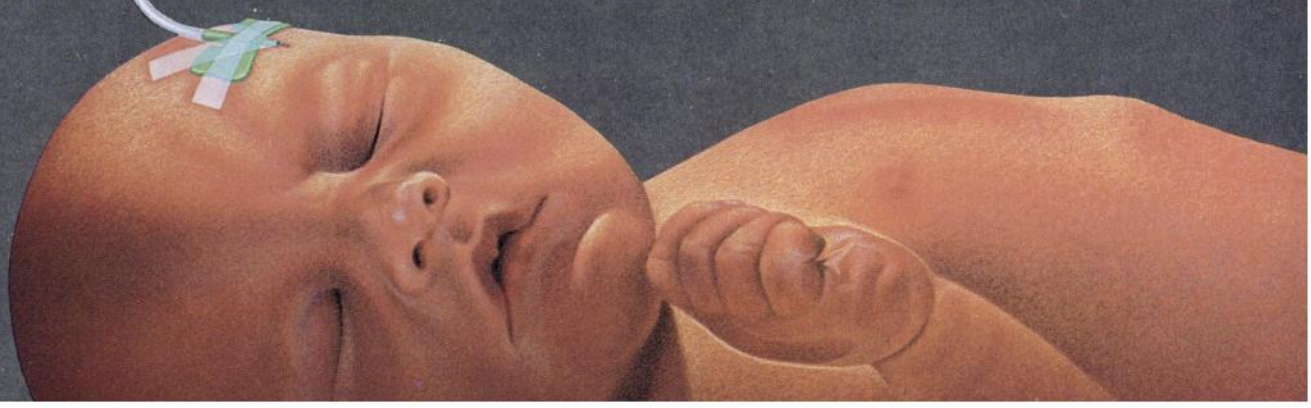

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Highly effective first-line therapy for a broad range of indications in neonates, infants and older children

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The economy cost-containment requires

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Claforan®

(cefotaxime sodium)*

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

The bottom line.

Please see following page for brief summary of prescribing information.

STERILE & INJECTION

Claforan®

(cefotaxime sodium)*

Brief Summary
INDICATIONS AND USAGE

Treatment
Claforan is indicated for the treatment of patients with serious infections caused by susceptible strains of the designated microorganisms in the diseases listed below.
(1) **Lower respiratory tract infections,** including pneumonia, caused by *Streptococcus pneumoniae* (formerly *Diplococcus pneumoniae*), *Streptococcus pyogenes*† (Group A streptococci) and other streptococci (excluding enterococci, e.g., *Streptococcus faecalis*), *Staphylococcus aureus* (penicillinase and 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*).
(2) **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.
(3) **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*†).
(4) **Bacteremia/Septicemia** caused by *Escherichia coli*, *Klebsiella* species, *Serratia marcescens*, *Staphylococcus aureus*, and *Streptococcus* species (including *S. pneumoniae*).
(5) **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).
(6) **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†.
(7) **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*†.
(8) **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 ½ to 1½ hours before surgery. (See **DOSAGE AND ADMINISTRATION** section.)

For patients undergoing gastrointestinal surgery, preoperative bowel preparation by mechanical cleansing as well as with a 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 impairment, severity of infection, and susceptibility of the causative organism.

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

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

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

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

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

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

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

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

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

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

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

Local (4.3%)—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):
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.

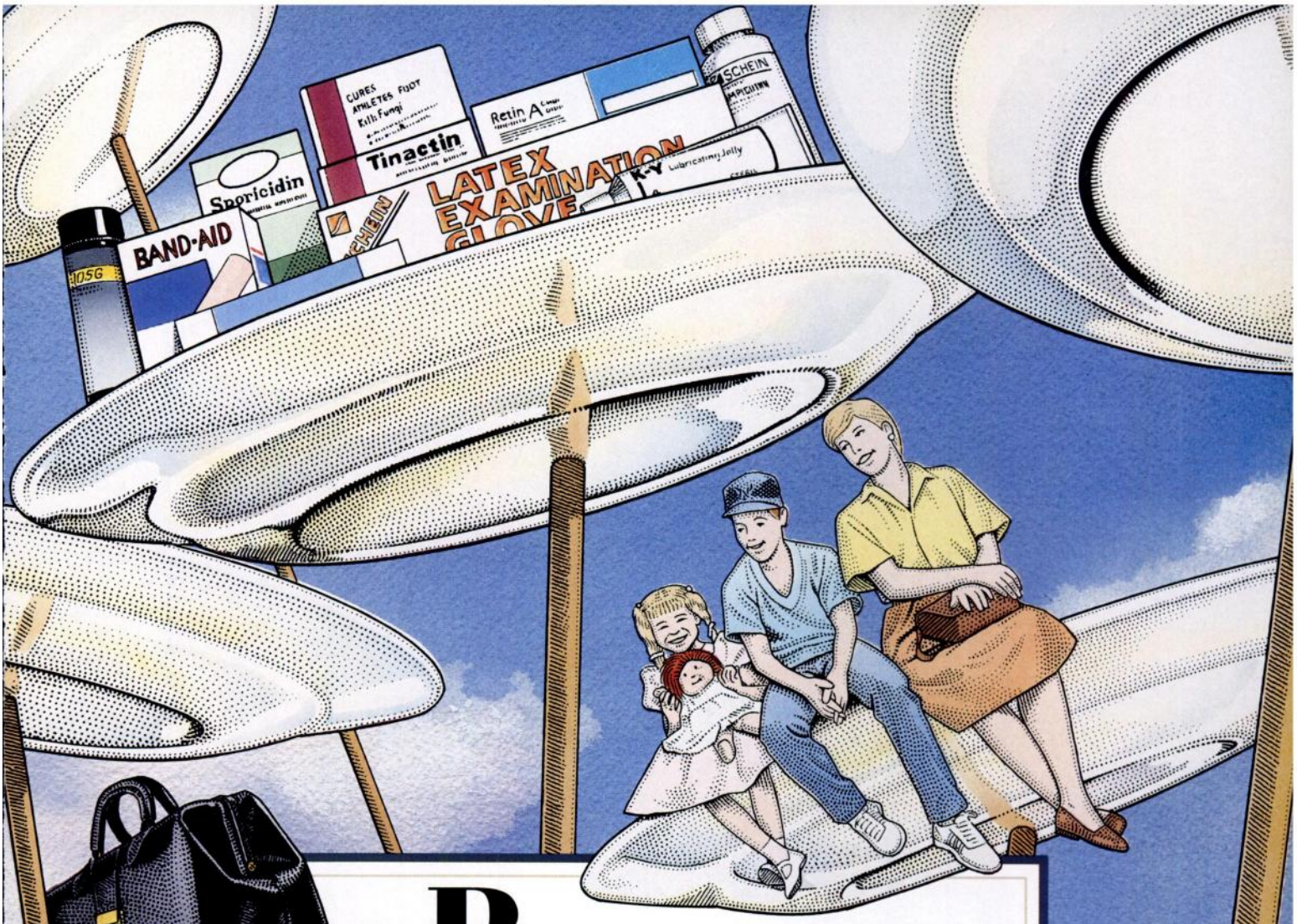
*US Patent 4,152,432 CLAFORAN® REG TM ROUSSEL-UCLAF

71789T
Revised 10/87

Hoechst-Roussel Pharmaceuticals Inc.
Somerville, New Jersey 08876

Hoechst

Q74338-589



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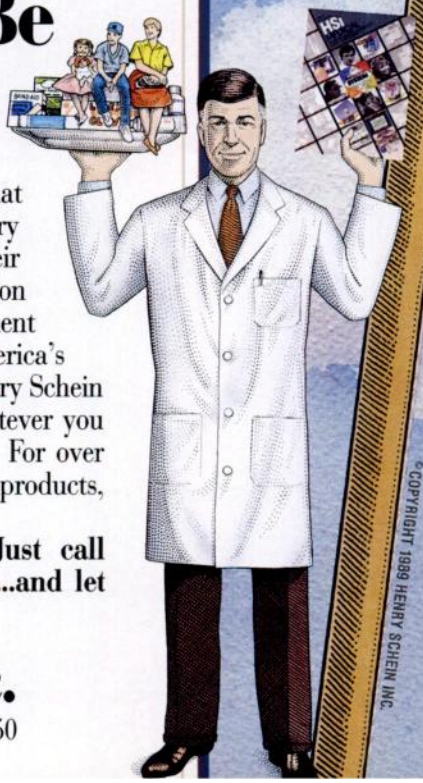

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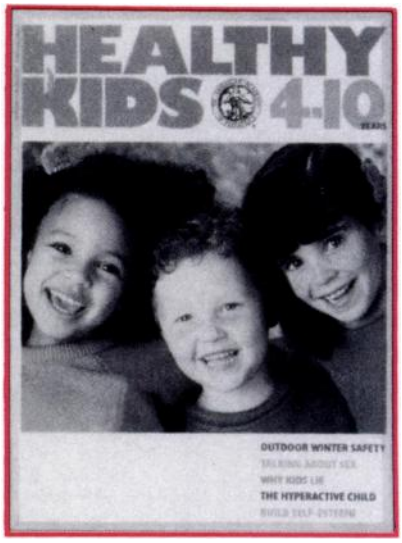
Look for more details in the mail soon, or look for the major HEALTHY KIDS: 4-10 YEARS announcement in next month's Pediatrics.



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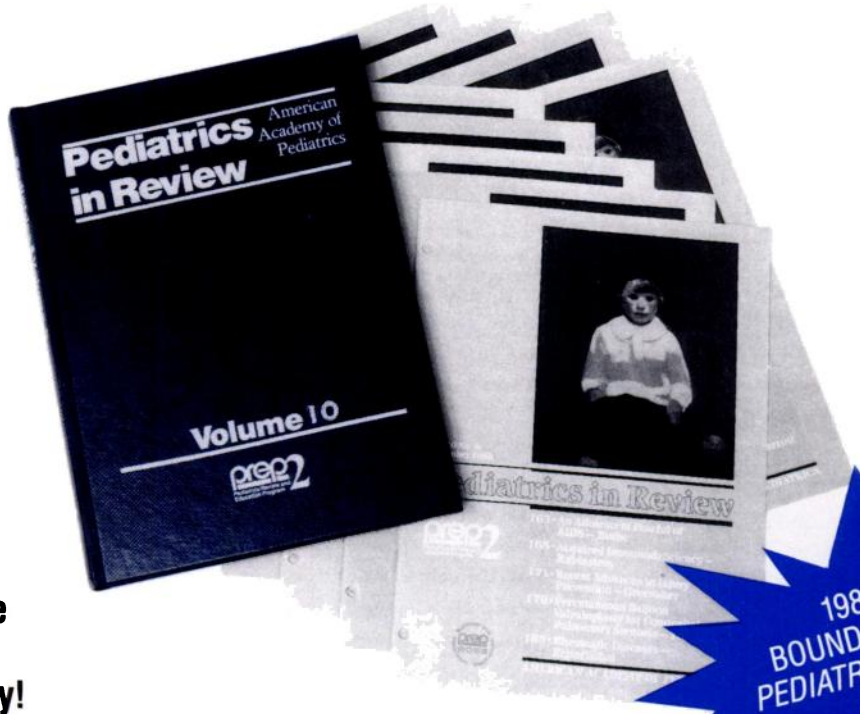

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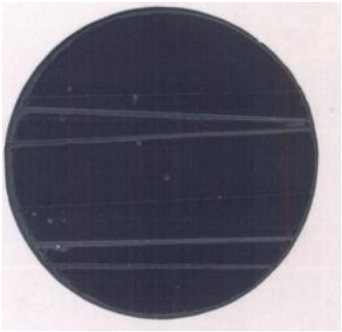

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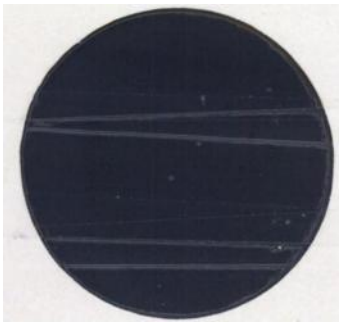

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At Gerber®, we believe that mother's milk is the ideal first food for babies, and we support a mother's decision to breast-feed as long as possible during a baby's first year.

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READY TO USE
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32 Fl. oz. (1 qt.)

With a nutrient balance that has been successfully fed to millions of babies.

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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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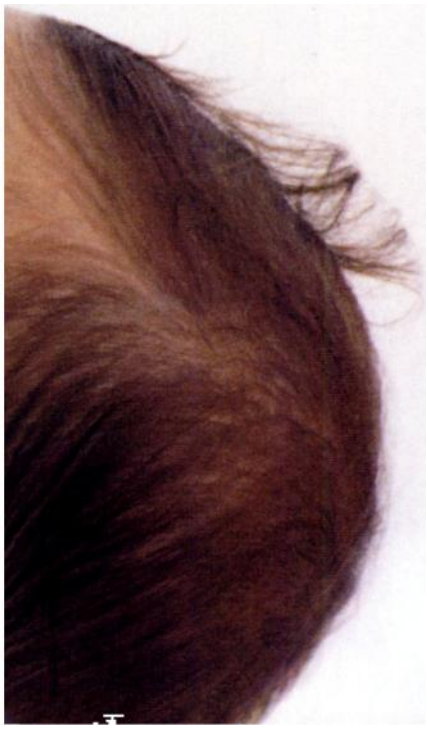
Breast milk is the best for babies... but no formula comes closer than Gerber™ Baby Formula.

Gerber™ Baby Formula closely resembles average breast milk in micronutrient composition. It also is formulated to provide the levels of nutrients specified by the Infant Formula Act.

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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Compare Gerber™ Baby Formula to mother's... and others.

Gerber™ Baby Formula is comparable to breast milk in essential nutrients.

Caloric Distribution		Gerber™ Baby Formula	Breast Milk
Protein	% kcal	9	6
Fat	% kcal	48	56
CHO	% kcal	43	38

Gerber™ Baby Formula Nutrient Sources

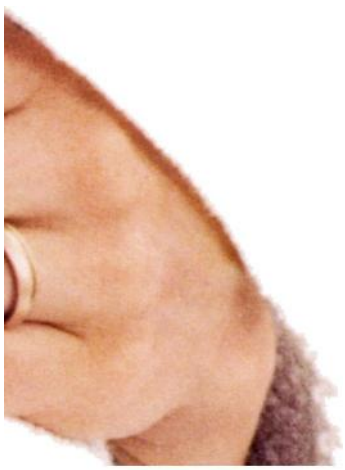
Protein – Nonfat milk 82:18 casein/whey
Fat – Soy oil predominant (corn oil in powder form)
CHO – Lactose

The nutrient content of Gerber™ Baby Formula is equivalent to that of leading formulas.

Caloric Distribution		Gerber™ Baby Formula	Others (Similac® and Enfamil®)*
Protein	g/qt	14.2	14.2-14.4
Fat	g/qt	35	34-36
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.
Enfamil is a registered trademark of Mead Johnson & Company.



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Available in 125 mg per 5 mL oral suspension and 250- or 500-mg tablets

COMPLIANCE IN A SPOON

Please see next page for a brief summary of Prescribing Information.

American Academy of Pediatrics
1989 Annual Meeting

Section on Otolaryngology/ Bronchoesophagology

October 22, 1989
7:50 am - 5:15 pm
Ballroom C
Hyatt Regency Chicago

Topics for discussion:

"Tonsils and Adenoids: Basics, Dilemmas, and Controversies for the Practicing Pediatrician"

- Immunological and Microbiological Correlates of Tonsils and Adenoids
- Anaerobes: Unrecognized Villains of Tonsillitis
- The Mouth Breathing Child: Should the Pediatrician be Concerned?
- Snoring and Airway Obstruction: When to Worry
- Choosing Antibiotics for Acute and Chronic Tonsillitis
- Risks and Benefits of Tonsillectomy and Adenoidectomy: Whom to Refer

"Sinusitis in Children: Are We Missing The Diagnosis?"

- Radiology: What Study to Order
- Role of Allergies in Sinusitis
- Bacteriology and Medical Treatment of Sinusitis
- Traditional Surgical Treatment of Sinusitis: When to Refer
- Endoscopic Sinus Surgery, The New Frontier

Faculty:
Carol Roberts Gerson, MD, FAAP, Moderator
Ellen Friedman, MD, FAAP
Linda Brodsky, MD, FAAP
Itzhak Brook, MD
Henry Fields, Jr., DDS
Robert Brouillette, MD, FAAP
Robert Tanz, MD, FAAP
Charles Bluestone, MD, FAAP
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Sharon Byrd, MD
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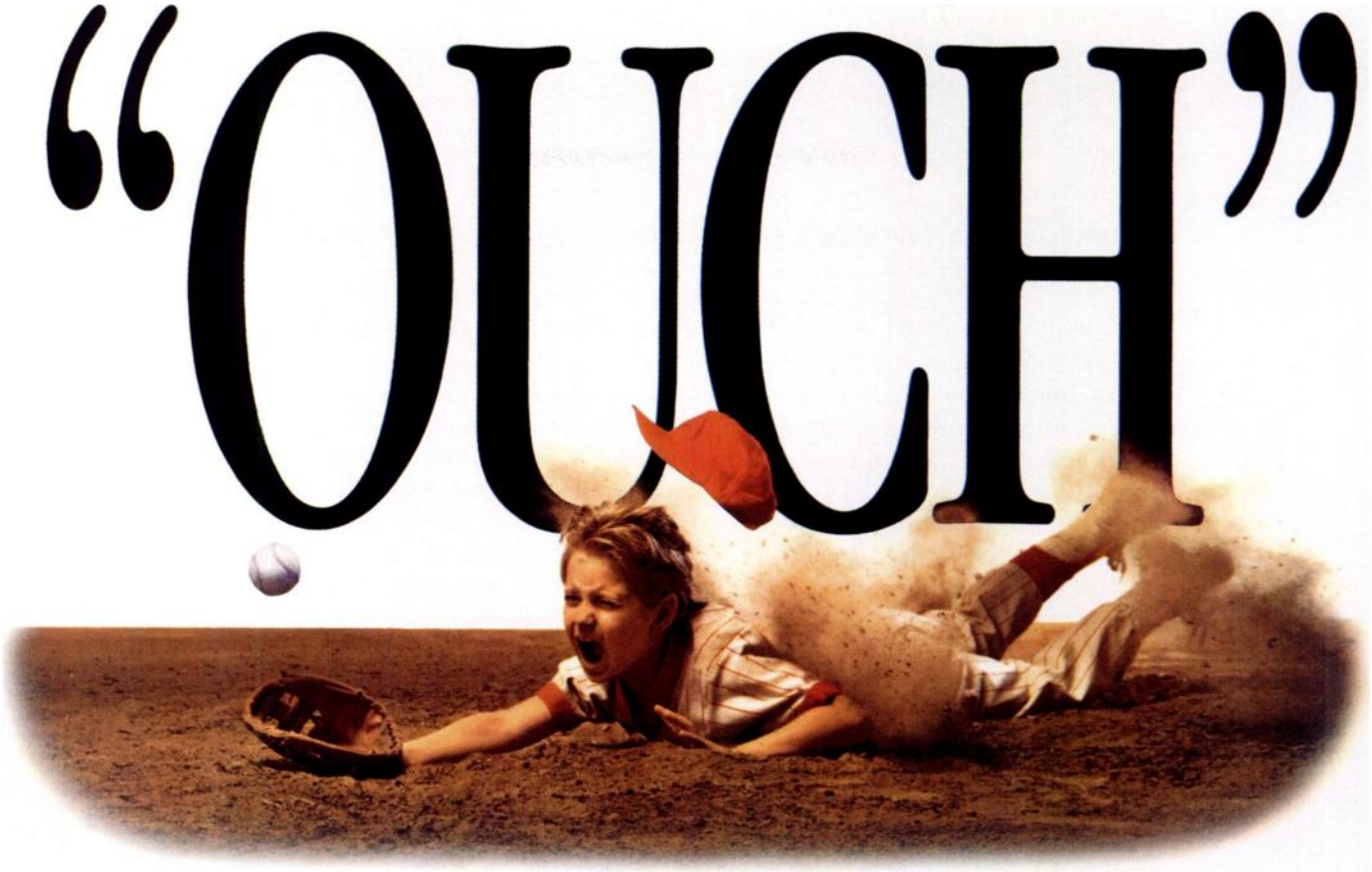

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So next time a junior patient says "Ouch!", recommend local therapy for the inflammation, and make your first choice Junior Strength TYLENOL® acetaminophen for the pain.

References: 1. Cooper SA: *Arch Intern Med* 1981;141:282–285. 2. Aspirin or paracetamol? *Lancet* 1981;II:287–289. 3. Senior RJ: *J Adolesc Health Care* 1986;7(suppl to No. 6):24S–30S.

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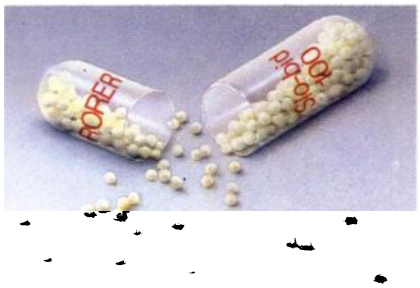
Growing up on a steady theophylline is an open-and-shut case



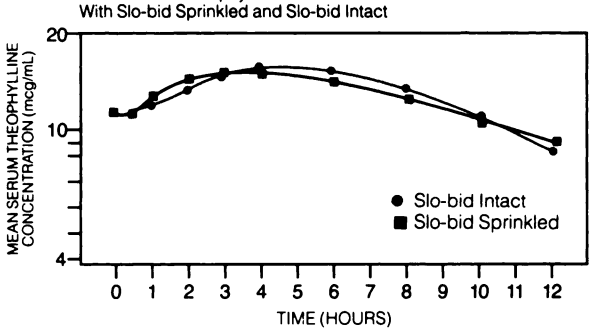
Sprinkled

Intact

Changing your patients from sprinkled to solid theophylline administration shouldn't mean changing their serum levels as well. With Slo-bid, you won't change a thing when your younger asthma patients are ready to switch to intact administration.

Slo-bid maintains steady theophylline levels when switching from sprinkled to solid administration[1]

Mean Serum Theophylline Concentration in 14 Children Dosed With Slo-bid Sprinkled and Slo-bid Intact



Switching from Slo-bid sprinkled to Slo-bid intact causes virtually no change in serum levels. Since the release system doesn't change, theophylline performance with both forms is identical. There's no need to restabilize your patients when they switch to taking capsules. In addition, capsules are the dosage form more patients prefer to take.[2]

Keep your patients' theophylline levels steady. Start and stay with Slo-bid. It's the perfect theophylline system for asthma patients to grow up with.

References: 1. Saccar CL, Gawchik S, Spitzer I, et al: Steady-state evaluation of sustained-release theophylline administered in applesauce 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.

In Asthma and Bronchitis

Slo-bid™

(theophylline, anhydrous)

Nothing beats our system

From the makers of **Azmacort™** (triamcinolone acetonide)

Please see next page for brief summary of prescribing information.

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Slo-bid™

(theophylline, anhydrous)

50 mg, 75 mg, 100 mg, 125 mg, 200 mg, and 300 mg

Gyrocaps®

Timed-Release Capsules

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 55 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 dysrhythmia and/or worsen preexisting arrhythmias and any significant change in rate and/or rhythm warrants monitoring and further investigation.

Studies in laboratory animals (minipigs, 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:	
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
Phenytoin	Decreased theophylline and phenytoin 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:

RORER PHARMACEUTICALS
a division of
RORER PHARMACEUTICAL CORPORATION
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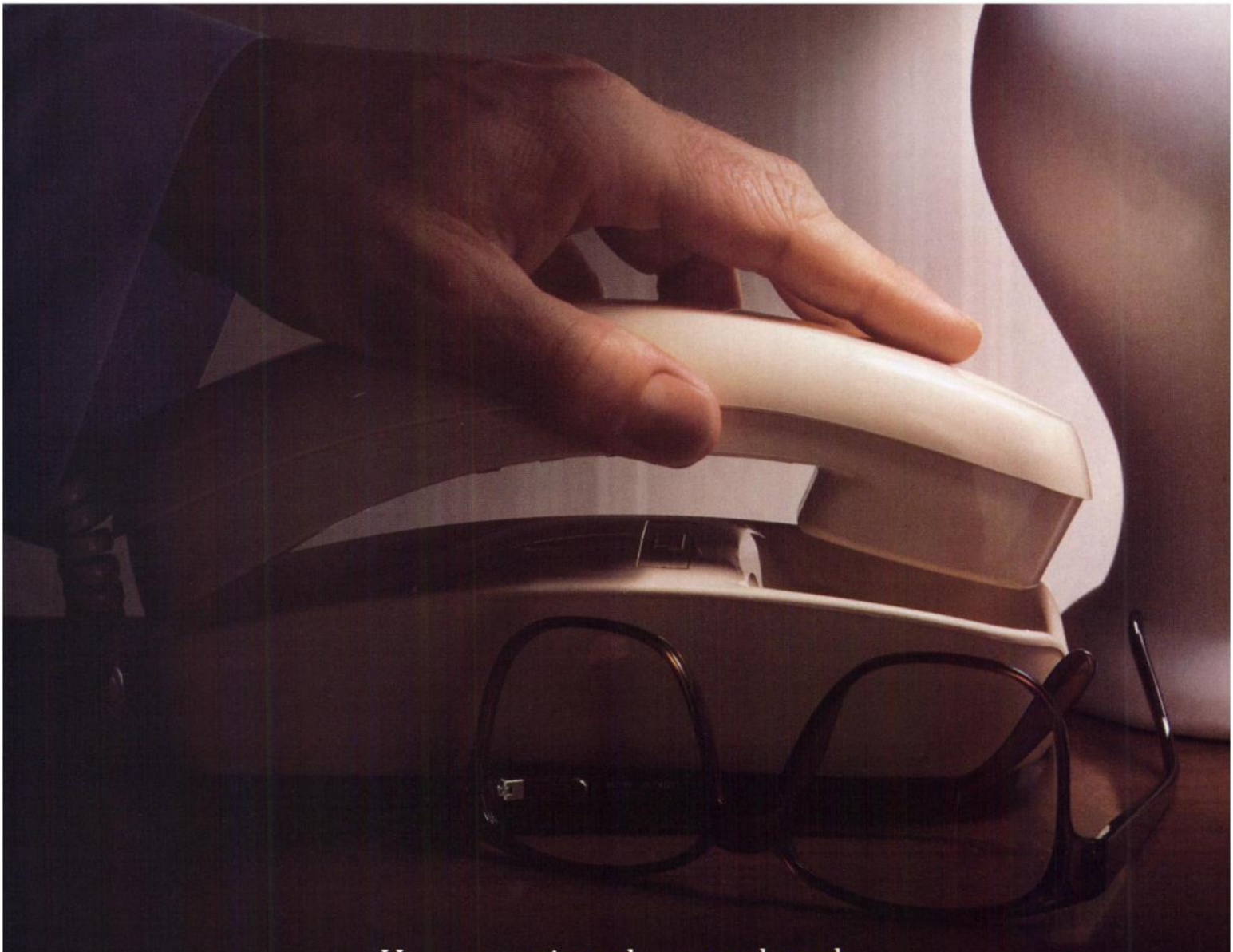

How many times have you heard...

"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.

For occasional use only. Use with caution in children under two years of age. For further information write: C.B. Fleet Co., Inc., Lynchburg, Va. 24506

In rhinorrhea and congestion†...

RYNATAN®-S® B.I.D.

PEDIATRIC SUSPENSION

Each teaspoonful (5 mL) contains: phenylephrine tannate, 5 mg; chlorpheniramine tannate, 2 mg; pyrilamine tannate, 12.5 mg.

Convenient Oral Dosing for Effective Relief

RYNATAN-S provides:

- More accurate and complete dispensing
- Better control to help reduce spills and mess
- More precise titration to help meet specific patient needs
- Flexibility of oral syringe or teaspoon administration

Most important, RYNATAN®-S delivers all the advantages you've come to expect from the RYNATAN Family. With RYNATAN-S, effective relief was never so easy.

* Patent pending. RYNATAN®-S is the combination of RYNATAN® Pediatric Suspension (4 fl oz) and a 10 mL calibrated oral syringe.

† When used for symptomatic relief of coryza and nasal congestion in allergic rhinitis or the common cold.

Please see following page for full prescribing information.

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

RYNATAN®-S* B.I.D.

PEDIATRIC SUSPENSION

Each teaspoonful (5 mL) contains: phenylephrine tannate, 5 mg; chlorpheniramine tannate, 2 mg; pyrilamine tannate, 12.5 mg.

Description
RYNATAN® is an antihistaminic/decongestant combination available for oral administration as *Tablets* and as *Pediatric Suspension*. Each tablet contains:

Phenylephrine Tannate	25 mg
Chlorpheniramine Tannate	8 mg
Pyrilamine Tannate	25 mg

Other ingredients: corn starch, dibasic calcium phosphate, magnesium stearate, methylcellulose, polygalacturonic acid, talc.

Each 5 mL (teaspoonful) of the Pediatric Suspension contains:

Phenylephrine Tannate	5 mg
Chlorpheniramine Tannate	2 mg
Pyrilamine Tannate	12.5 mg

Other ingredients: benzoic acid, FD&C Red No. 3, flavors (natural and artificial), glycerin, kaolin, magnesium aluminum silicate, methylparaben, pectin, purified water, saccharin sodium, sucrose.

Clinical Pharmacology
RYNATAN combines the sympathomimetic decongestant effect of phenylephrine with the antihistaminic actions of chlorpheniramine and pyrilamine.

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

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

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

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

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

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

Carcinogenesis, mutagenesis, impairment of fertility: No long-term animal studies have been performed with RYNATAN.

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

Nursing mothers: RYNATAN should not be administered to a nursing woman.

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

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

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

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

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

RYNATAN® Pediatric Suspension: pink with strawberry-currant flavor, in 4 fl. oz. bottles (NDC 0037-0715-67, labeled RYNATAN®-S*) and in pint bottles (NDC 0037-0715-68).

Storage: RYNATAN® Tablets—Store at room temperature; avoid excessive heat—above 40°C (104°F).

RYNATAN® Pediatric Suspension—Store at controlled room temperature—between 15°C–30°C (59°F–86°F); protect from freezing.

***Patent pending.**
RYNATAN®-S is the combination of RYNATAN® Pediatric Suspension (4 fl. oz.) and a 10 mL, calibrated, oral syringe.

WALLACE LABORATORIES
Division of
CARTER-WALLACE, INC.
Cranbury, New Jersey 08512

Printed in U.S.A. Rev. 6/88

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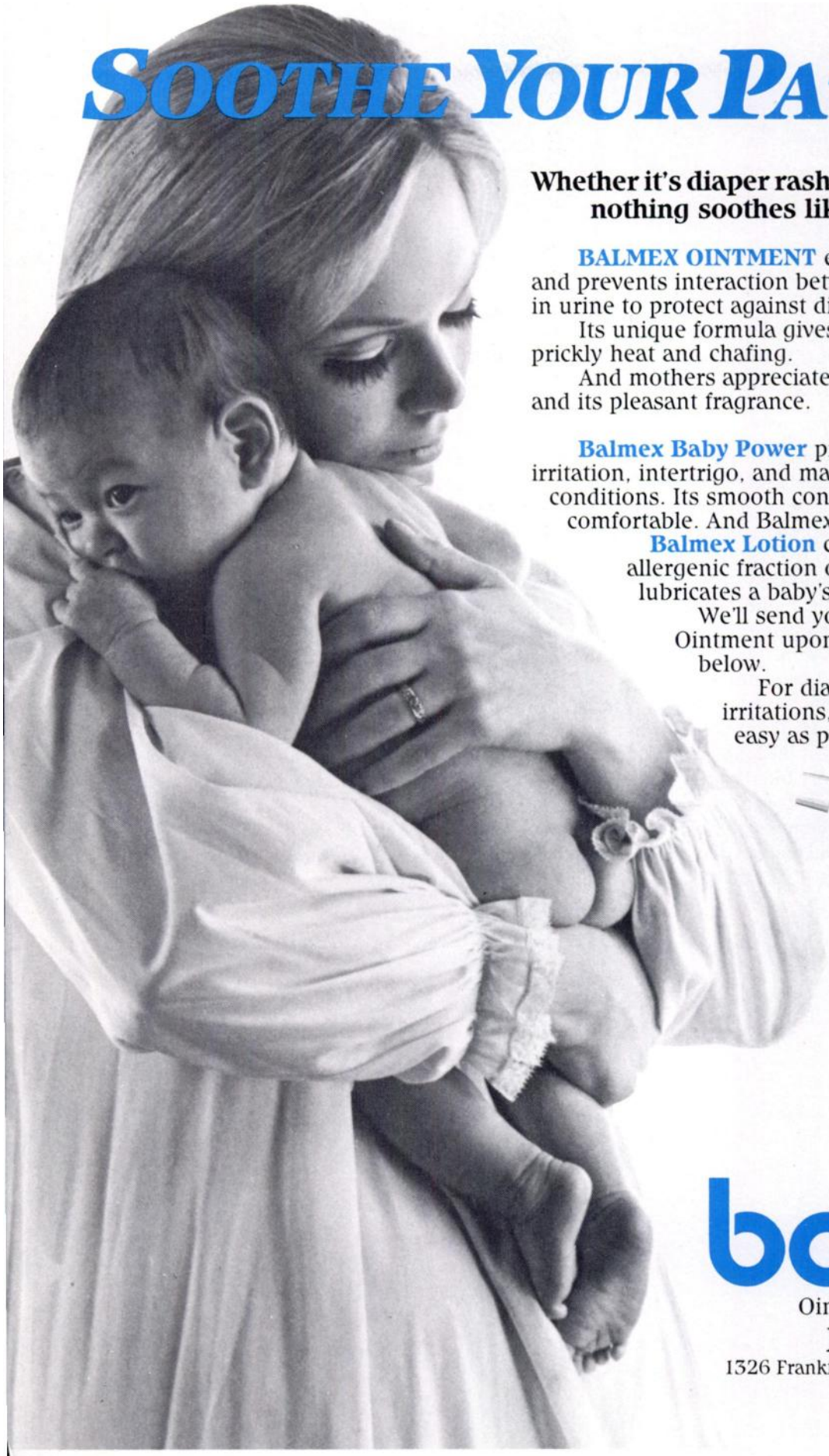
Cranbury, New Jersey 08512



SOOTHE YOUR PATIENTS.

Whether it's diaper rash or simple skin disorders, nothing soothes like Balmex Ointment.

BALMEX OINTMENT effectively promotes healing and prevents interaction between ammoniagenes and urea in urine to protect against diaper rash.

Its unique formula gives babies quick relief from prickly heat and chafing.

And mothers appreciate the smoothness of Balmex and its pleasant fragrance.

Balmex Baby Power protects against diaper irritation, intertrigo, and many other dermatological conditions. Its smooth consistency keeps babies dry and comfortable. And Balmex Baby Powder is talc-free.

Balmex Lotion contains a special hypo-allergenic fraction of lanolin oil. It gently lubricates a baby's skin.

We'll send you free samples of Balmex Ointment upon request to our address below.

For diaper rash and other skin irritations, soothing your patients is as easy as prescribing Balmex.

balmex®

Ointment for Diaper Rash.

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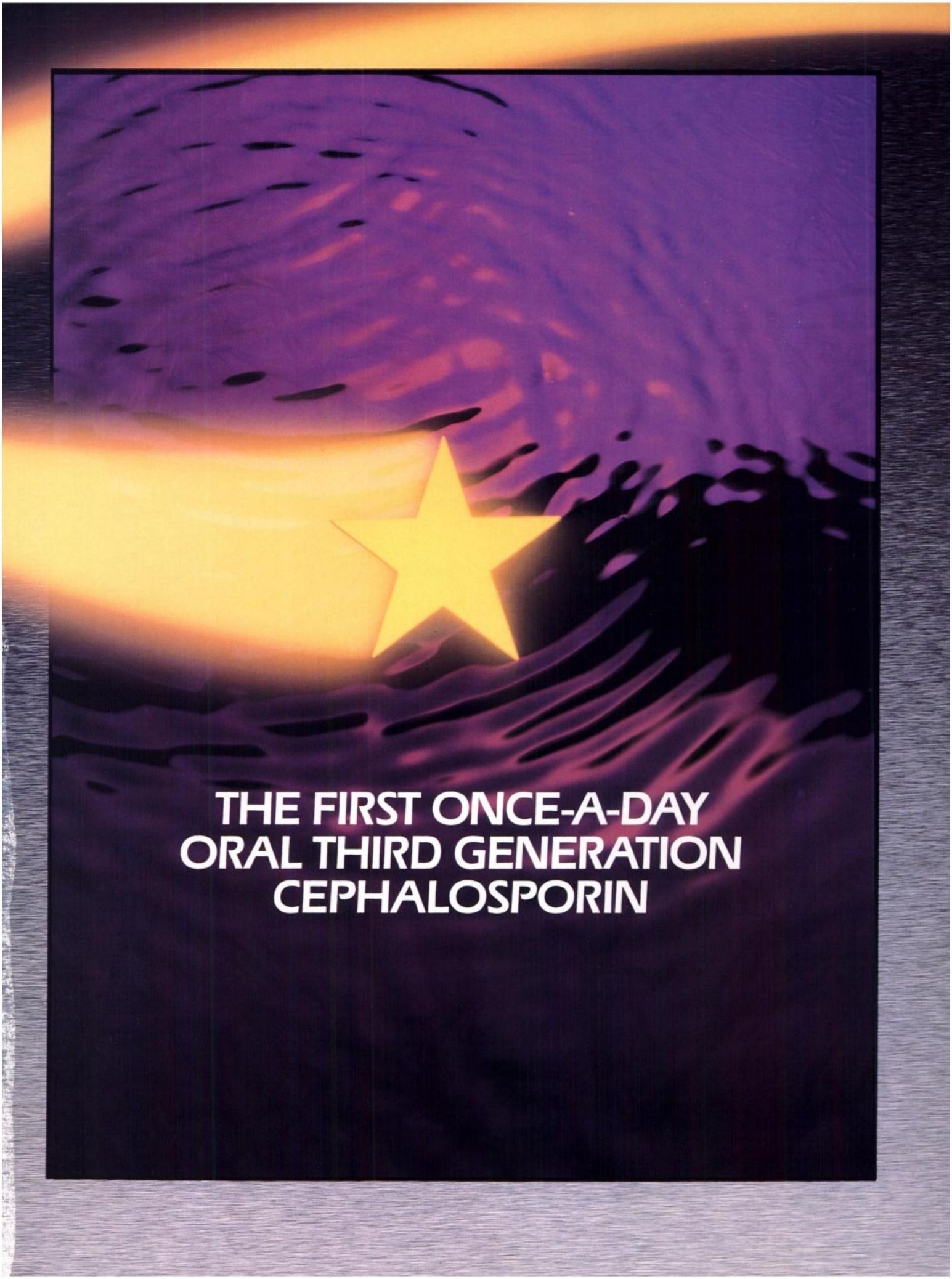
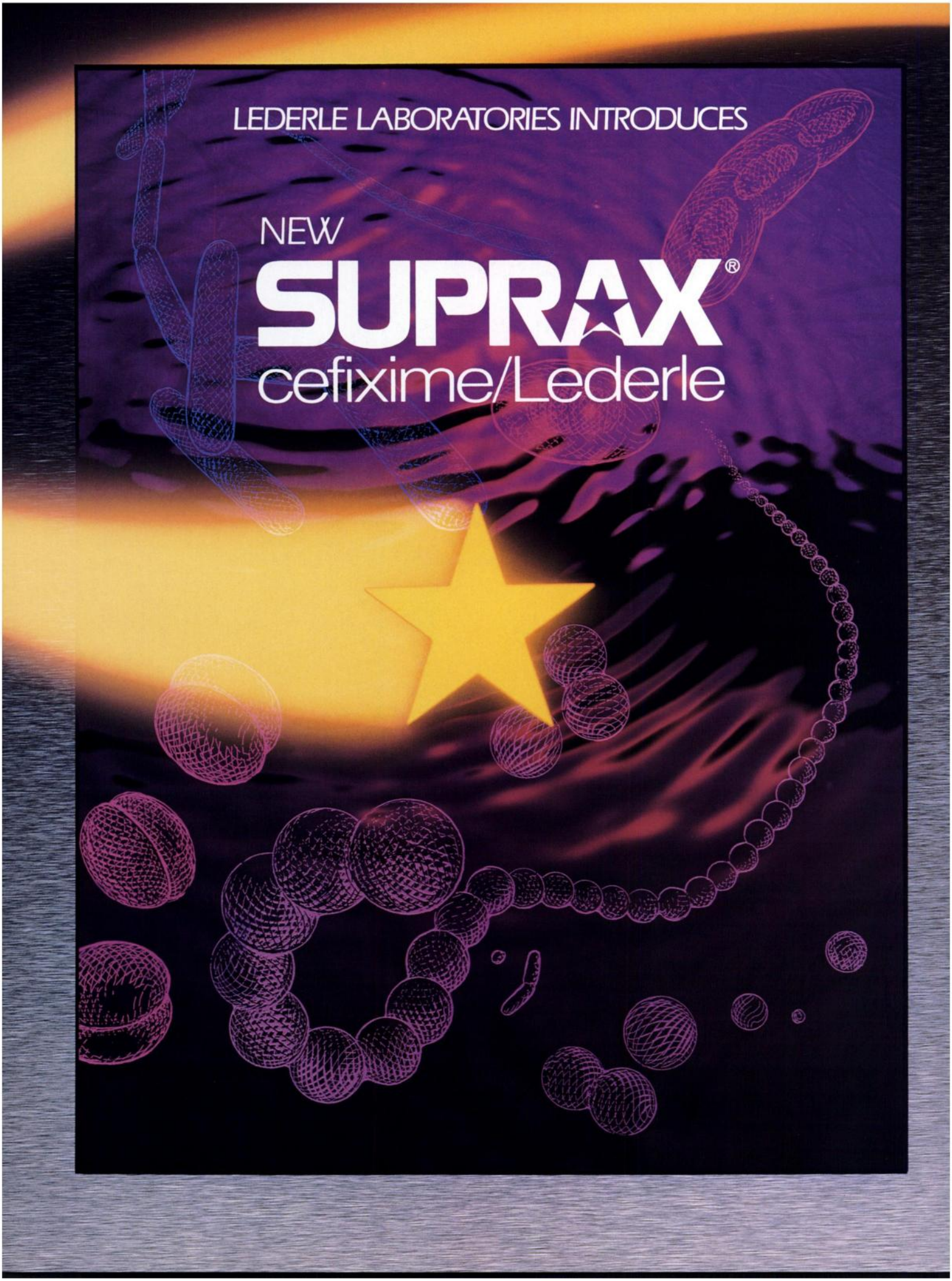
1326 Frankford Avenue/Philadelphia, PA 19125


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.

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NEW

SUPRAX®

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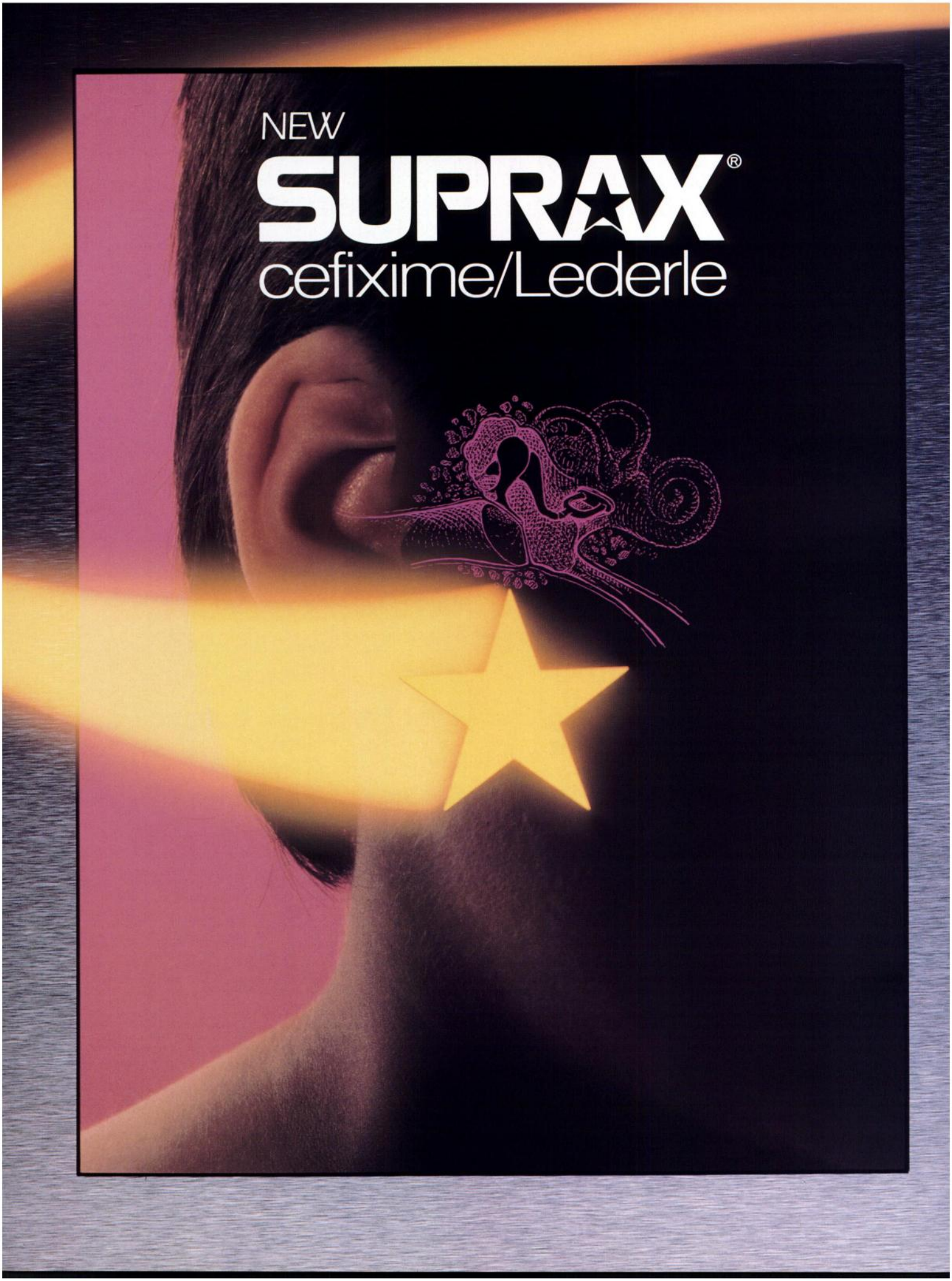

NEW
SUPRAX®
cefixime/Lederle

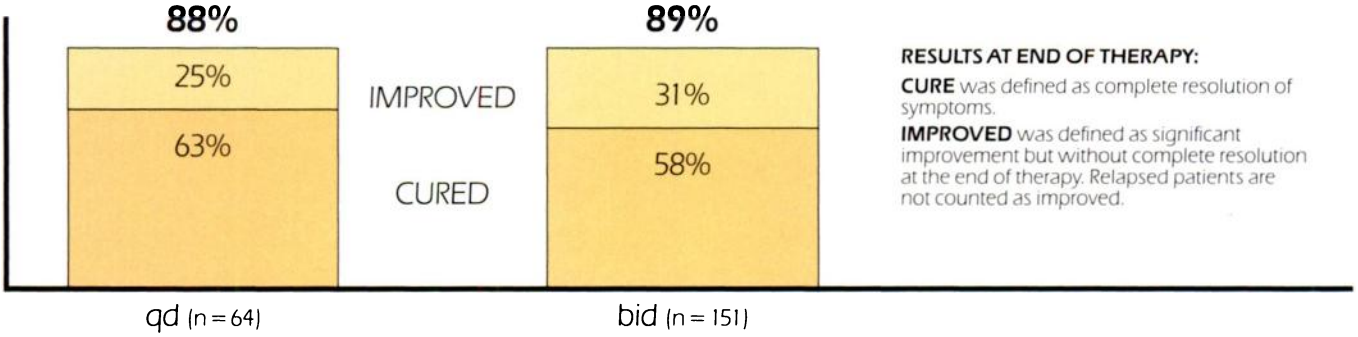
THE FIRST ORAL THIRD GENERATION CEPHALOSPORIN FOR OTITIS MEDIA*

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.

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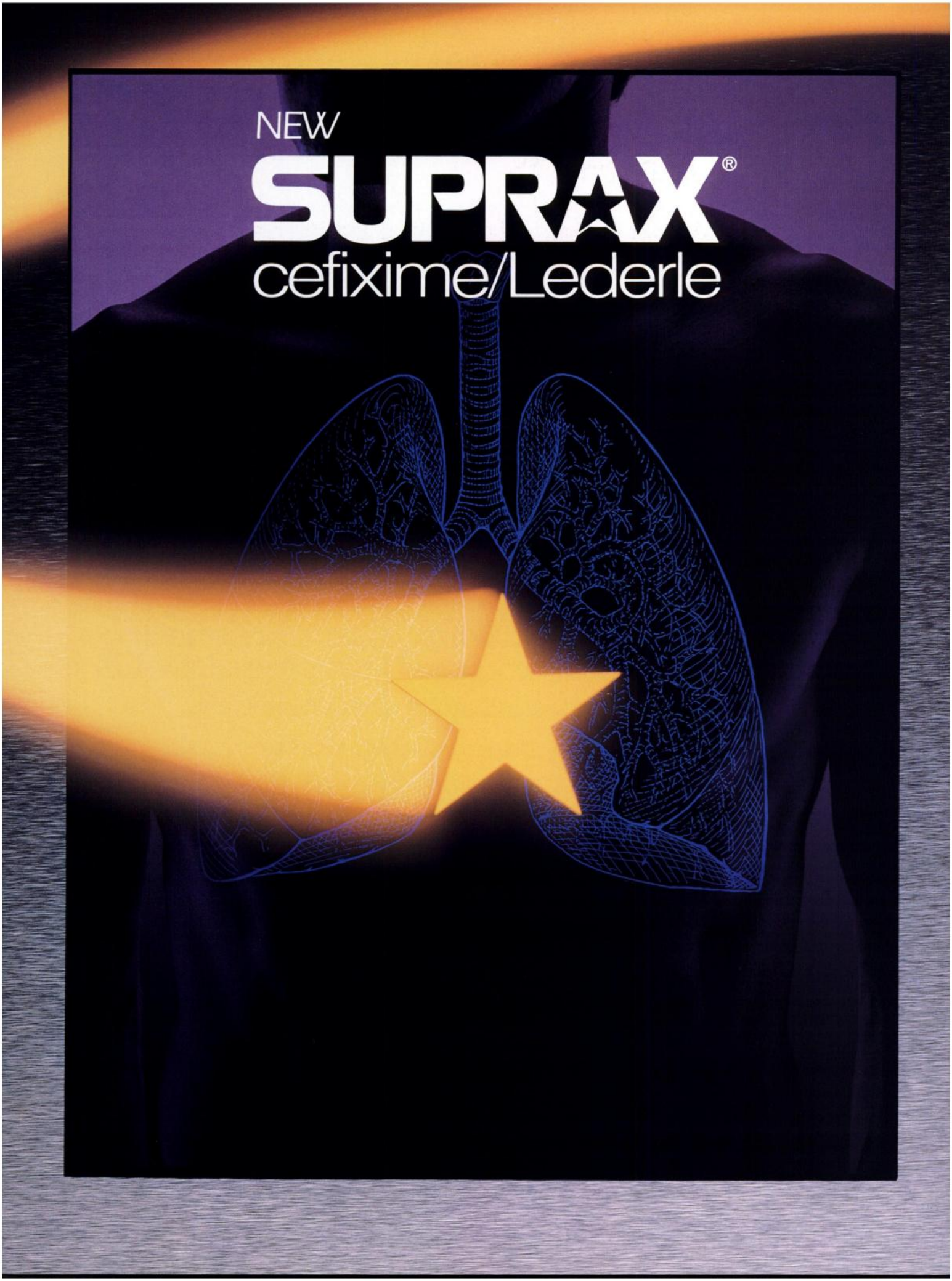
NEW
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NEW

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*

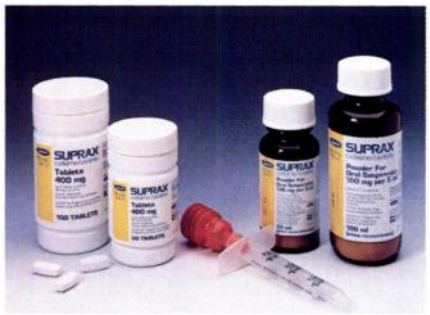
- The recommended adult dose is 400 mg given once daily. Or, if preferred, 400 mg in divided doses, bid.
- The recommended dose for children is 8 mg/kg daily, qd or bid. Children weighing more than 50 kg or older than 12 years should be treated with the recommended adult dose. The tablet should not be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

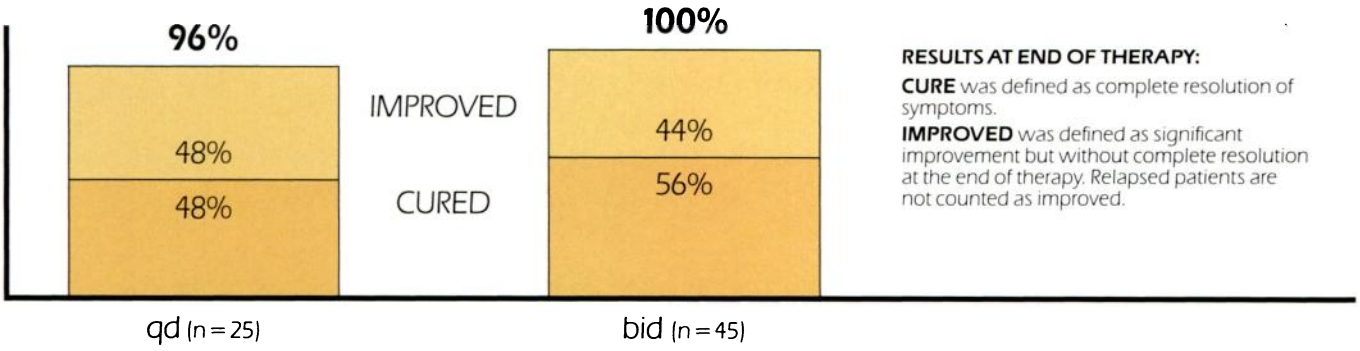
THIRD GENERATION SPECTRUM AND POTENCY FOR BRONCHITIS*

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 Bronchitis[4]

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

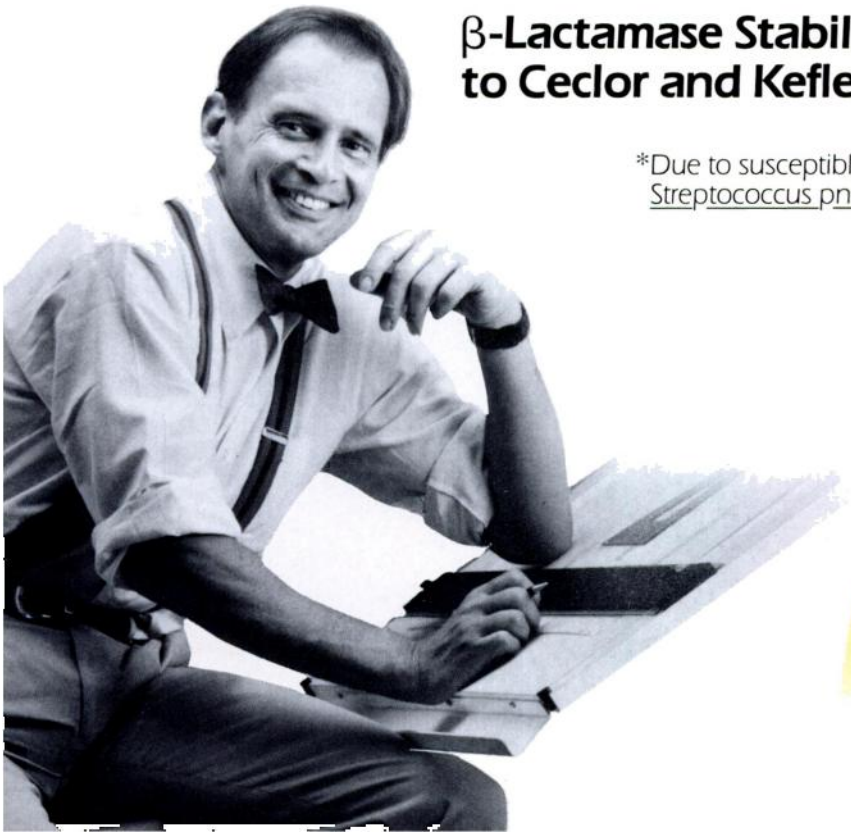


RESULTS AT END OF THERAPY:

CURE was defined as complete resolution of symptoms.

IMPROVED was defined as significant improvement but without complete resolution at the end of therapy. Relapsed patients are not counted as 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 Keflex[1-3]

*Due to susceptible organisms, Haemophilus influenzae and Streptococcus pneumoniae

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SUPRAX®

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Please see brief summary of Prescribing Information on last page.

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** section.

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
Streptococcus pneumoniae	48/70 (69%)	18/22 (82%)	82/100 (82%)
Haemophilus influenzae beta-lactamase negative	24/34 (71%)	13/17 (76%)	23/34 (68%)
Haemophilus influenzae beta-lactamase positive	17/22 (77%)	9/12 (75%)	1/1[b]
Moraxella (Branhamella) catarrhalis	26/31 (84%)	5/5	18/24 (75%)
Streptococcus pyogenes	5/5	3/3	6/7
All Isolates	120/162 (74%)	47/58 (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 discontinuance, 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.

**Clinitest® and Clinistix® are registered trademarks of Ames Division, Miles Laboratories, Inc. Tes-Tape® is a registered trademark of Eli Lilly and Company.

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Now, kids can have fewer coughs...

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BECAUSE NEW PEDIATRIC FORMULA 44® COATS ON THE WAY DOWN—FOR IMMEDIATE COUGH RELIEF.

Unlike thinner products, its viscous formula coats irritated cough receptors in the throat, to relieve coughs right from the start.

Then, for systemic relief, each PEDIATRIC FORMULA 44 syrup has the maximum allowable OTC level of effective medicine in a one-tablespoon dose:

Pediatric FORMULA 44	COUGH MEDICINE	COUGH & CONGESTION MEDICINE	COUGH & COLD MEDICINE
Dextromethorphan, 15 mg	X	X	X
Pseudoephedrine, 30 mg		X	X
Chlorpheniramine, 2 mg			X

There's a great cherry taste, too: preferred by children 5:1 over the leading OTC cough suppressant formula.

For children ages 6-11, the recommended dosage is one tablespoon every 6-8 hours; ages 2-5, ½ tablespoon; under age 2, dose at your discretion.

For further information about PEDIATRIC FORMULA 44, call toll-free, 1-800-358-8707.

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ALCOHOL-FREE

Fewer coughs from the very first swallow

With Children's NyQuil®, you can expect maximum cold relief...

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—2 mg of chlorpheniramine for runny nose
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- And a great cherry taste kids love.

So for maximum long-lasting, great-tasting nighttime relief...

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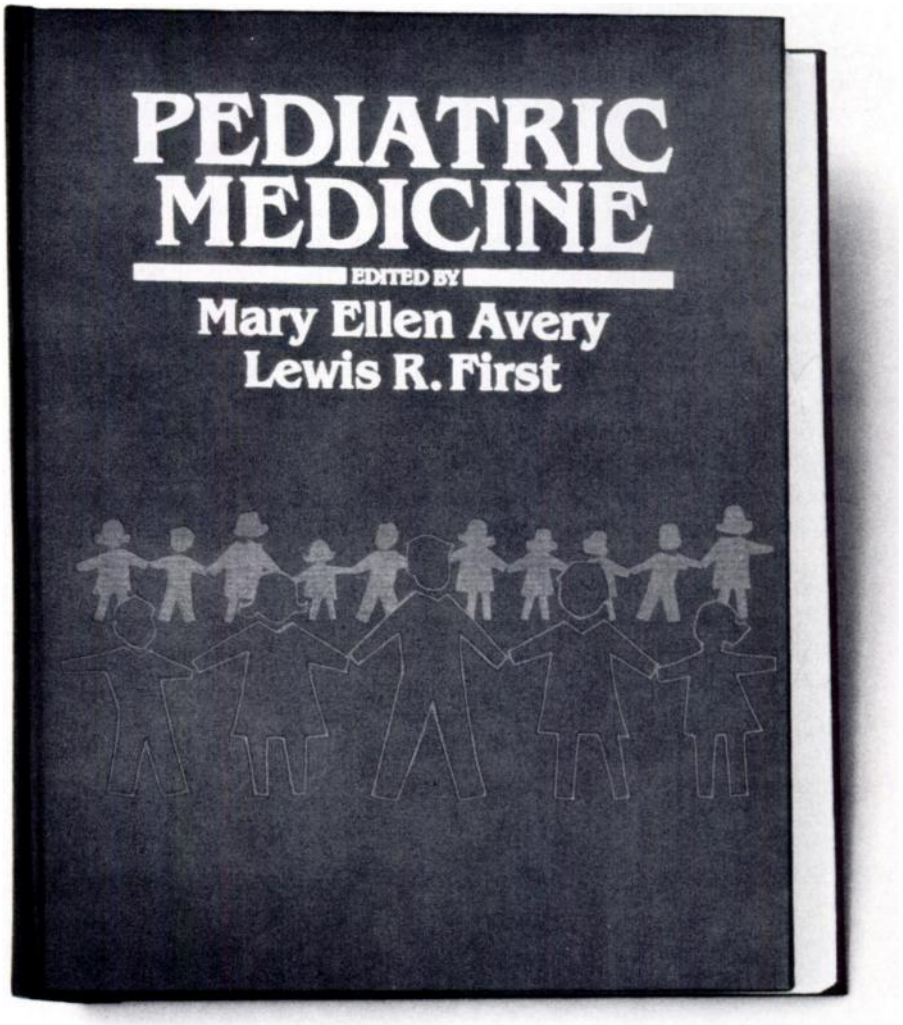

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Poliovirus Vaccine Live Oral Trivalent

Jackie DiLorenzo of Hastings-on-Hudson, New York, contracted polio in 1950, before a vaccine became available. She spent ten years in rehabilitation, during which time she underwent nine operations on her spine, legs and feet. Jackie currently lives in a house adapted for wheelchair living.

Ask your Lederle representative about the award-winning **Adolescent Wellness Program**

Lederle Biologicals Protecting Families Through Immunization®

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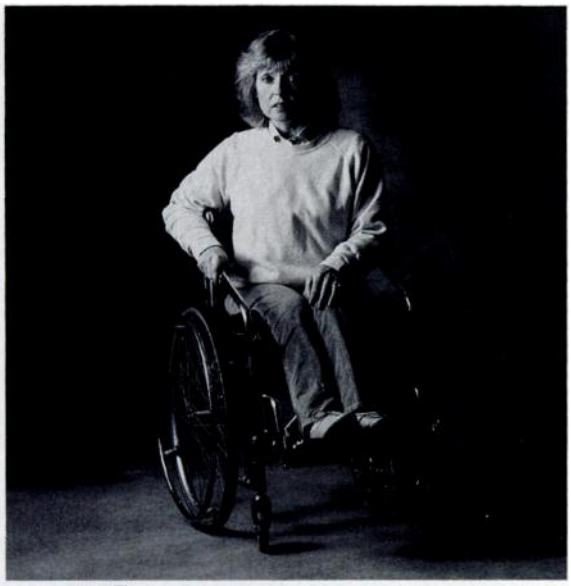

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ORIMUNE was the first live, oral, trivalent polio vaccine. No other oral polio vaccine has done more to help eradicate wild poliovirus in the US. Over 500 million doses have been distributed to date.

Proven Safety* Record

Lederle takes every precaution during production and testing to ensure the safety of ORIMUNE. This dedication is evident by our 27-year safety record.

Uninterrupted Supply

Lederle has consistently met the nation's needs for oral polio vaccine for about 27 years. In fact, when all other US manufacturers discontinued the production of oral polio vaccine, Lederle has remained committed to this essential product and to the health of America's children.

Available in Single-Doses

ORIMUNE is available in convenient, unit-dose DISPETTES® to help assure dosage accuracy and avoid the risk of contamination.

*Paralytic disease following ingestion of live poliovirus vaccine has been reported on rare occasions in individuals receiving the vaccine or in their close contacts.

Poliovirus Vaccine
Live Oral Trivalent
ORIMUNE®

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. It would also be prudent to withhold ORIMUNE from siblings of a child known to have an immunodeficiency syndrome or from children in a family which has a history of immunodeficiency until immune status of all members is determined. 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. 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: It would seem prudent not to administer trivalent oral poliovaccine (OPV) shortly after Immune Globulin (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 probably should 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.

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 1972 to 1983, approximately 278.8 million OPV doses were distributed in the United States. During this same period, 87 vaccine-associated cases in apparently immunologically normal individuals were reported. Thirty-two occurred among vaccine recipients (one case per 8.7 million OPV doses distributed), and 55 cases occurred among household and nonhousehold contacts of vaccinees (1 case per 5.1 million doses distributed). Sixteen other vaccine-associated cases have been reported in persons (recipients or contacts) with immune deficiency conditions.

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. 8/86

Orimune®
Poliovirus Vaccine Live Oral Trivalent

Lederle Biologicals
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1. Data on file, The Mennen Company.

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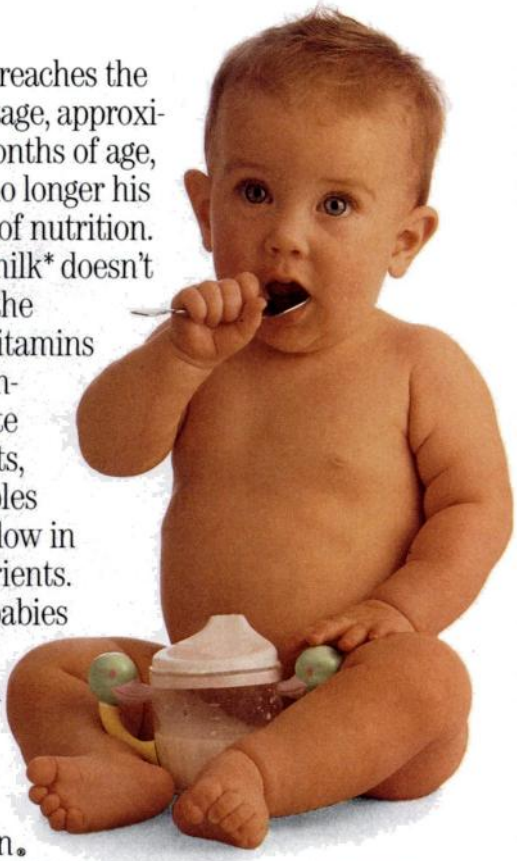
Iron Fortified Follow-Up Formula

For babies over six months of age eating solid foods



When baby reaches the solid food stage, approximately 6 months of age, formula is no longer his sole source of nutrition. Yet, whole milk* doesn't contain all the necessary vitamins and the high-carbohydrate cereals, fruits, and vegetables he eats are low in certain nutrients. And, older babies require less energy from fat[1] and more from protein.[2]

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The ratio of unsaturated to saturated fatty acids in GOOD NATURE is 2:1. GOOD NATURE is higher in monounsaturated fatty acids yet contains 28% less fat than starter formula to satisfy the changing needs of the older baby.

GOOD NATURE also has a carbohydrate blend of 63% corn syrup solids and 37% lactose to help assure tolerance. It contains 12 mg iron per quart to help ensure a sufficient supply at an age when inborn stores are depleted. GOOD NATURE costs less than starter formula and also tastes, smells, and looks like the real food baby is learning to enjoy.

When baby is ready for solid food, Mom may ask you about GOOD NATURE Follow-Up Formula. You can reassure her that GOOD NATURE is nutritionally sound and makes good sense for her baby.

For more information about GOOD NATURE Follow-Up Formula, please write to:
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GOOD NATURE Follow-Up Formula... now available to consumers in 32-fl-oz ready-to-feed fresh packs and 12-oz easy-to-mix powder canisters.

REFERENCES: 1. Kwiterovich PO Jr, Salz KM: Pediatric aspects of the diet-heart hypothesis, in Bond JT, Filer LJ, Leveille GA, et al (eds): *Infant and Child Feeding.* Academic Press, 1981, pp 283-315.
2. Food and Nutrition Board, NAS/MRC. *Recommended Dietary Allowances,* ed 9, 1980. *Pasteurized cow's milk.

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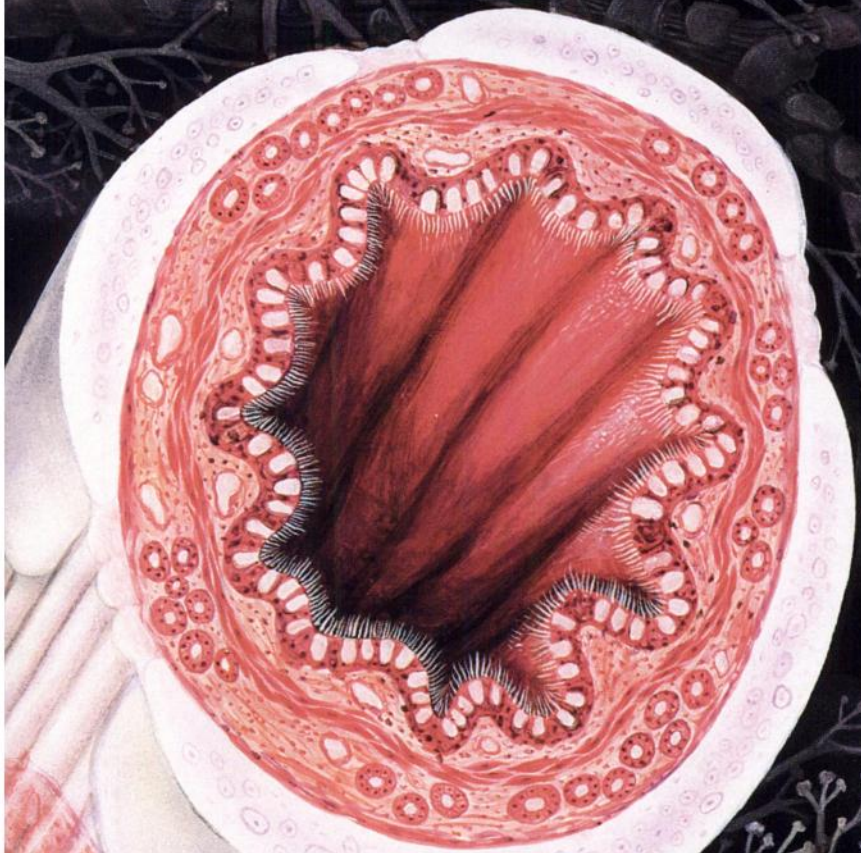
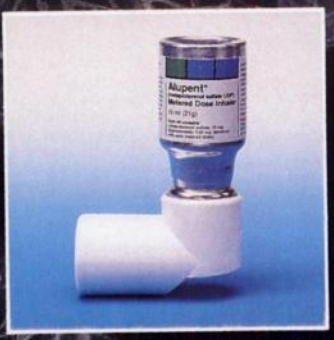
to relief...



Extended duration of action, unsurpassed bronchoselectivity*



Fast Action, Fast Relief in Asthma

Alupent®

(metaproterenol sulfate) Inhalation Aerosol

15 ml; 15 mg/ml (each metered dose delivers 0.65 mg metaproterenol sulfate)

*In controlled single-dose studies with Alupent Inhalation Aerosol, the duration of effect of two to three inhalations (20% or greater increase in FEV_1) has varied from one to five hours. In multiple-dose studies (up to q.i.d.), the duration of effect for a similar dose of Alupent has ranged from about one to two and a half hours.

Please see following page for brief summary of prescribing information

Fast Action, Fast Relief in Asthma

Alupent®

(metaproterenol sulfate)

Tablets 10 and 20 mg	Inhalation Aerosol 15 ml†	Syrup 10 mg/5 ml	Inhalation Solution 5% 10 ml and 30 ml	Inhalation Solution Unit-dose Vials 0.4% and 0.6%

†15 mg/ml (each metered dose delivers 0.65 mg metaproterenol sulfate)

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. Paradoxical bronchoconstriction with repeated excessive administration has been reported with sympathomimetic agents. Therefore, it is possible that this phenomenon could occur with Alupent. 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 Because Alupent® (metaproterenol sulfate USP) is a sympathomimetic drug, it should be used with great caution in patients with hypertension, coronary artery disease, congestive heart failure, hyperthyroidism or diabetes, or when there is sensitivity to sympathomimetic amines.
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.
Carcinogenesis Long-term studies in mice and rats to evaluate the oral carcinogenic potential of metaproterenol sulfate have not been completed. Studies of metaproterenol sulfate have not been conducted to determine mutagenic potential or effect on fertility.
Pregnancy *Teratogenic Effects: Pregnancy Category C.* Alupent has been shown to be teratogenic and embryocidal 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 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 reactions to Alupent® (metaproterenol sulfate USP) Inhalation Solution are nervousness and tachycardia which occur in about 1 in 7 patients, tremor which occurs in about 1 in 20 patients and nausea which occurs in about 1 in 50 patients. Less frequent adverse reactions are hypertension, palpitations, vomiting and bad taste which occur in approximately 1 in 300 patients.

HOW SUPPLIED ***Inhalation Aerosol:*** Each canister of Alupent® (metaproterenol sulfate USP) Inhalation Aerosol contains 225 mg of metaproterenol sulfate as a micronized powder in inert propellants. Alupent Inhalation Aerosol with mouthpiece (15 ml). Alupent Inhalation Aerosol refill (15 ml).
Store below 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.

AL-4268 AL-BPI-1/88

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- *Neonatal Emergencies:* neonatal resuscitation
- *Emergencies with Altered Levels of Consciousness:* diabetic ketoacidosis, meningitis, Reye syndrome, and status epilepticus

The experience of leading professionals

This reference guide was compiled by experts from the American Academy of Pediatrics/American College of Emergency Physicians, and the National Task Force on Advanced Pediatric Life Support. The manual also serves as the text for the official AAP/ACEP APLS Course. To find out about courses, call the National Course Coordinator at ACEP (214-550-0911).

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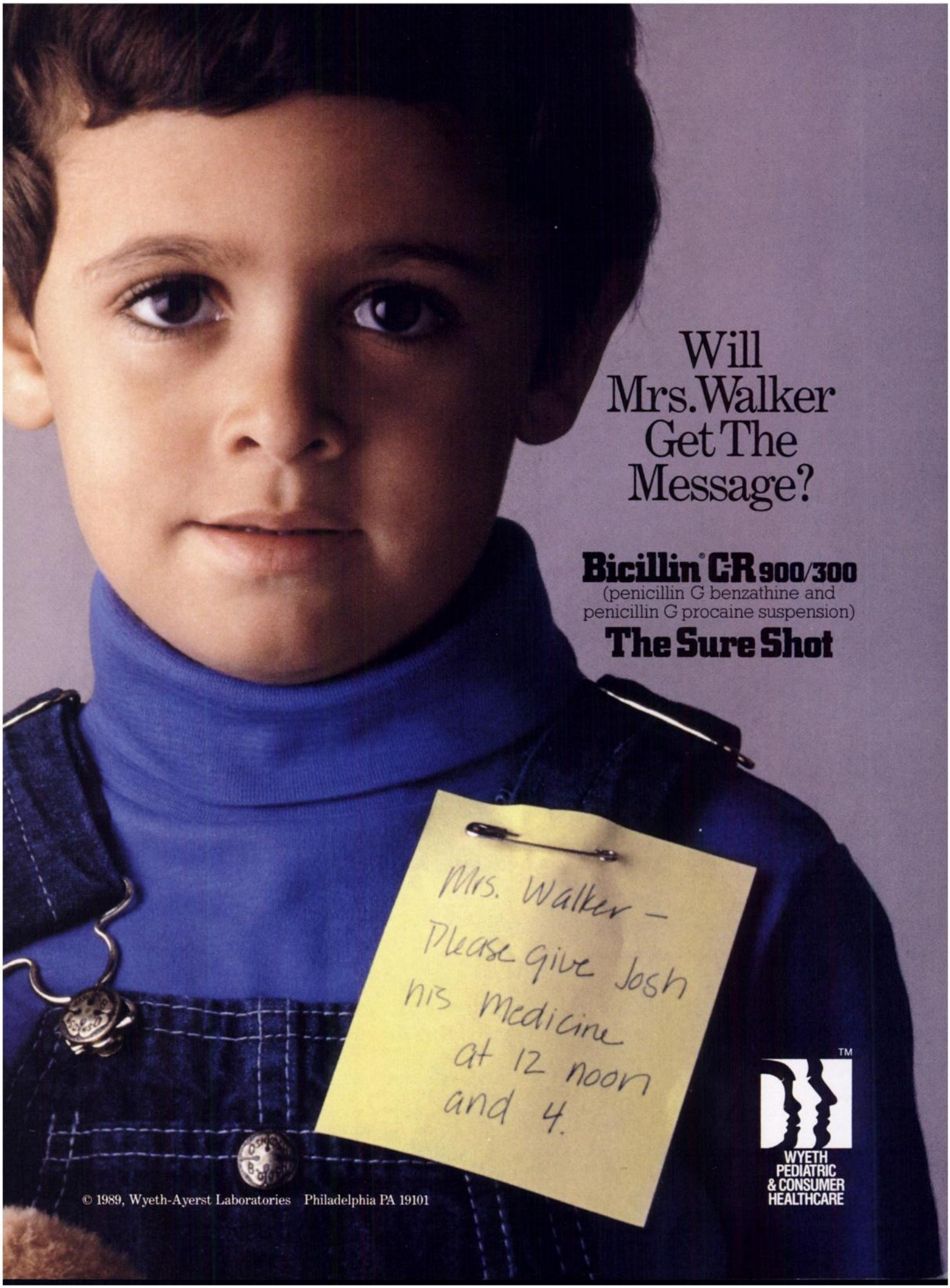
The *Advanced Pediatric Life Support* manual is indispensable for anyone who will administer pediatric emergency care. The manual is $55 for AAP/ACEP members ($75 nonmembers) plus a $3.75 handling charge per order. To charge your order (VISA/MasterCard), call 800-433-9016 (in IL, 800-421-0589). Or write the AAP Publications Dept., PO Box 927, Elk Grove Village, IL 60009-0927.

American Academy of Pediatrics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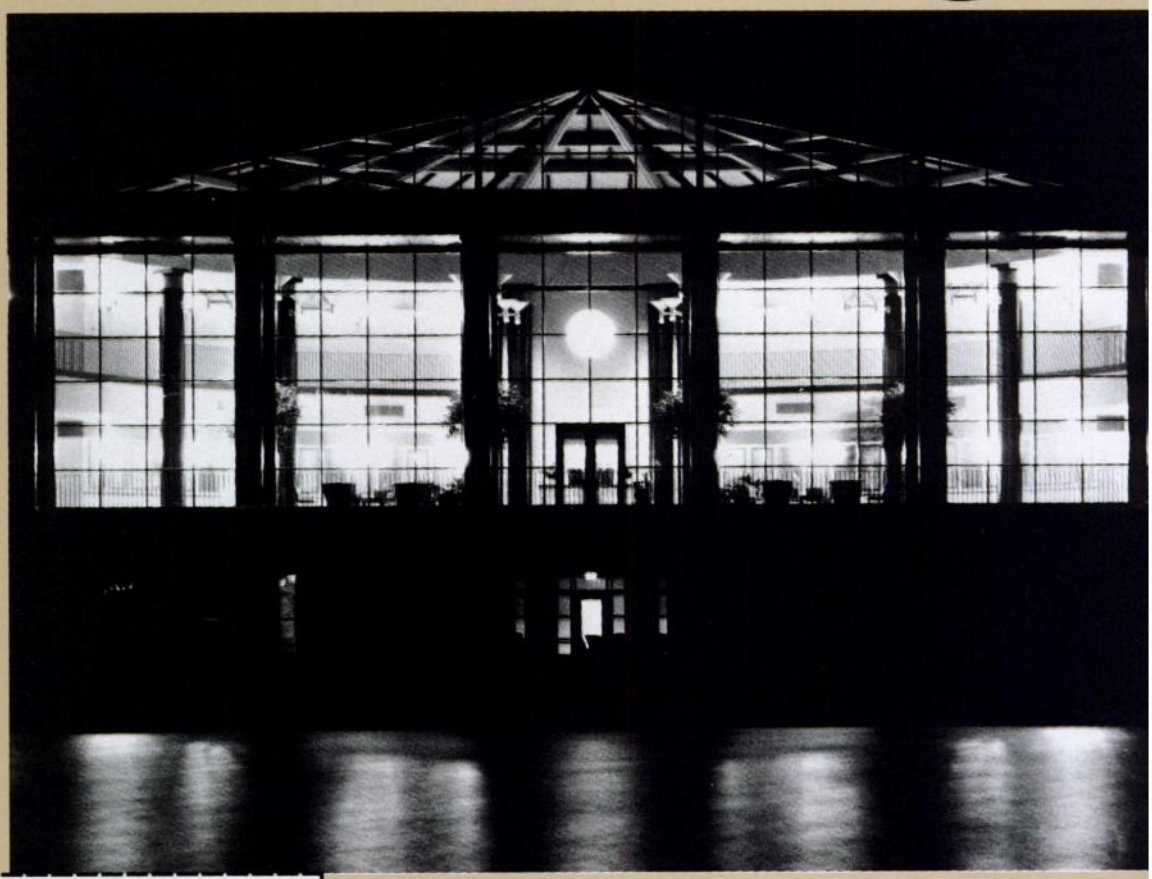

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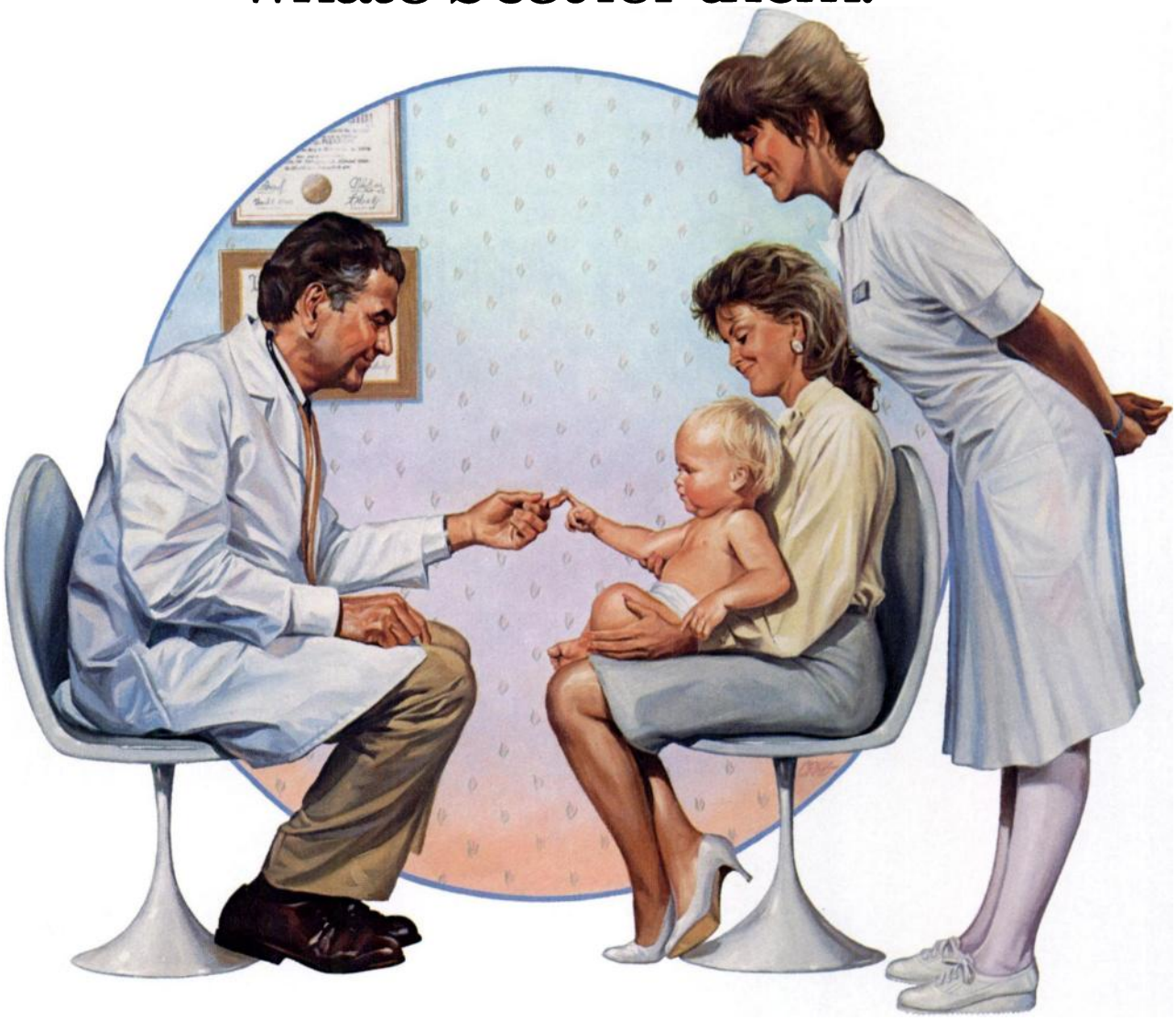

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Recent research indicates: Colds are "caught"...by hand.

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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Contaminated surfaces—or fomites—also help to transmit common cold infections. When a child touches a fomite (which could be a favorite toy), and then goes on to touch his eyes or nose...a cold may follow.

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Some experts recommend the use of a virucidal agent to help curb the spread of rhinovirus from fomites to fingers.[1,2] In laboratory studies with human volunteers, LYSOL Spray has been shown to virtually eliminate rhinovirus when applied to contaminated surfaces.[3]

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Throughout the year—and *especially* at the first sign of a cold—recommend frequent hand washing...avoidance of finger-to-eye and finger-to-nose contact...and widespread use of LYSOL Spray—to help eliminate rhinovirus on household surfaces, help make the common cold less common.

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References:

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4. Gwaltney JM Jr, Hendley JO: Transmission of experimental rhinovirus infection by contaminated surfaces. *Am J Epidemiol* 1982;116:828-833.

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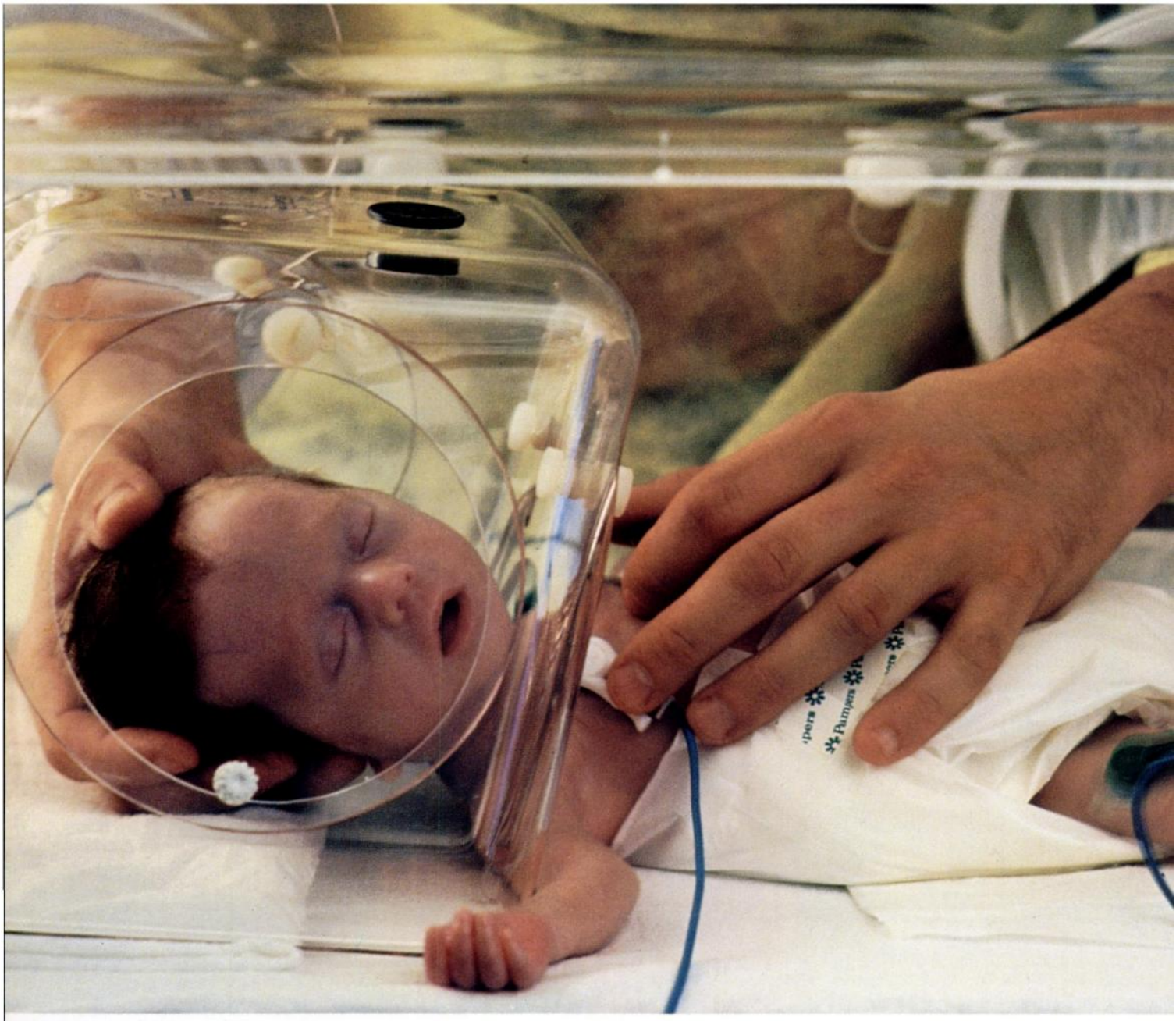

RSV can be life threatening

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 stay[3]—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:
1. Chanock RM, Kim HW, Brandt CD, et al: Respiratory syncytial virus, in Evans AS (ed): *Viral Infections of Humans: Epidemiology and Control*, ed 2. New York, Plenum Medical Book Company, 1984, pp 471-489.
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Virazole®
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lyophilized for aerosol administration

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For carefully selected hospitalized RSV patients

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Call the RSV Hotline, 1-800-572-7400, for free equipment and service

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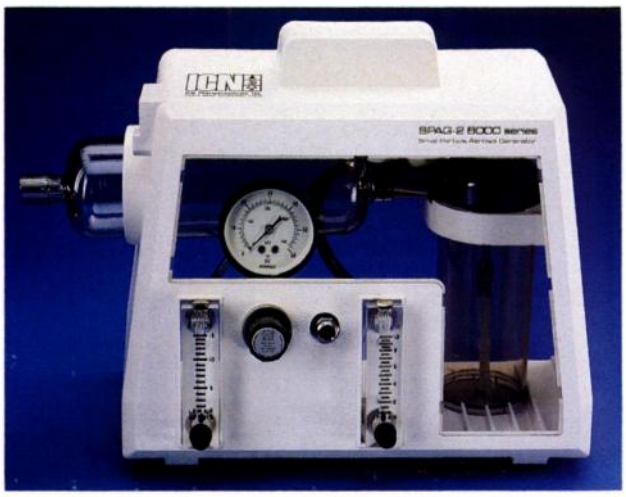

Small Particle Aerosol Generator (SPAG™-2)

SPI-72-R June 1989

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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.

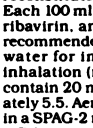
Deterioration of respiratory function has been associated with ribavirin use in infants, and in adults with chronic obstructive lung disease or asthma. Respiratory function should be carefully monitored during treatment. If initiation of ribavirin aerosol treatment appears to produce sudden deterioration 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 $C_8H_{12}N_4O_5$ 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 16μg/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 6.8μM.

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, plateauing 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[3,4] or ELISA[5] 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 antimetabolites 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 (Balb/C 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 ("rain out") 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 LD_{50} in mice is 2 gm orally. Hypoactivity and gastrointestinal symptoms occurred. In man, ribavirin is sequestered in red blood cells for weeks after dosing.

DOSAGE 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 or 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 widemouth 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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4. Hall CB, McBride JT, Walsh EE, Bell DM et al. Aerosolized ribavirin treatment of infants with respiratory syncytial viral infection. *N Engl J Med* 308:1443-7, 1983.
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January 1986
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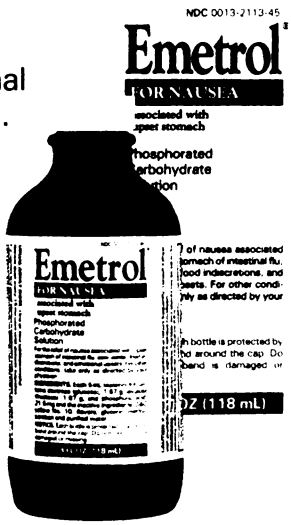

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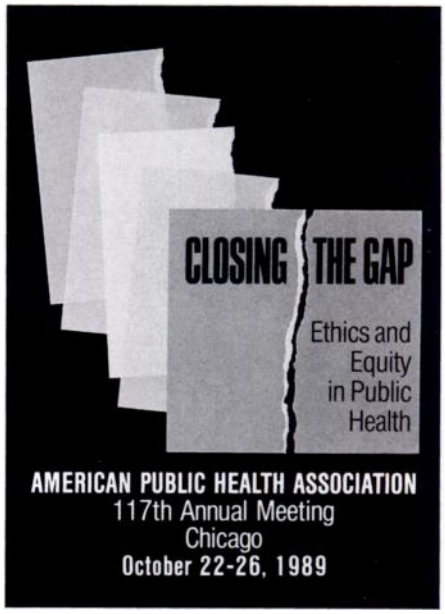

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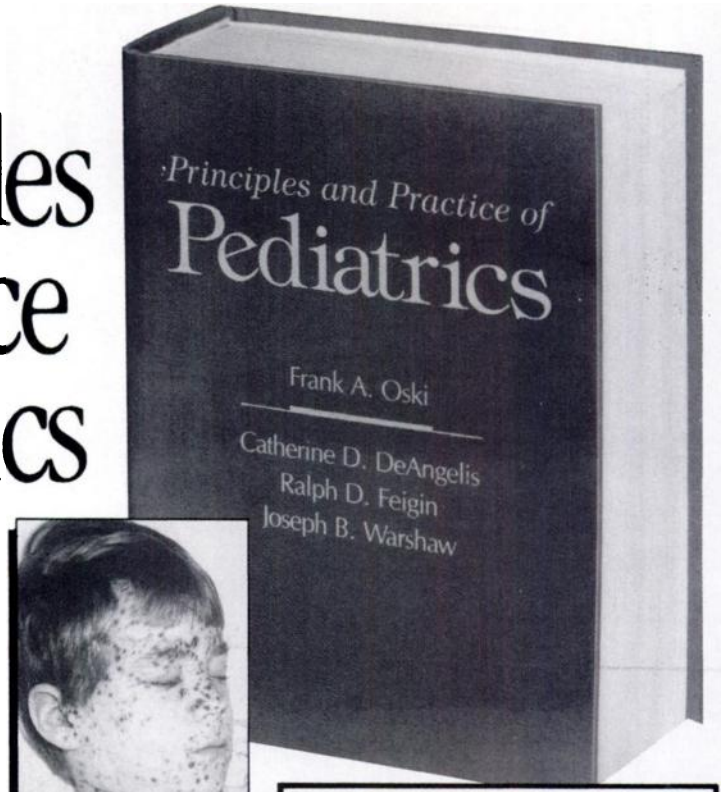

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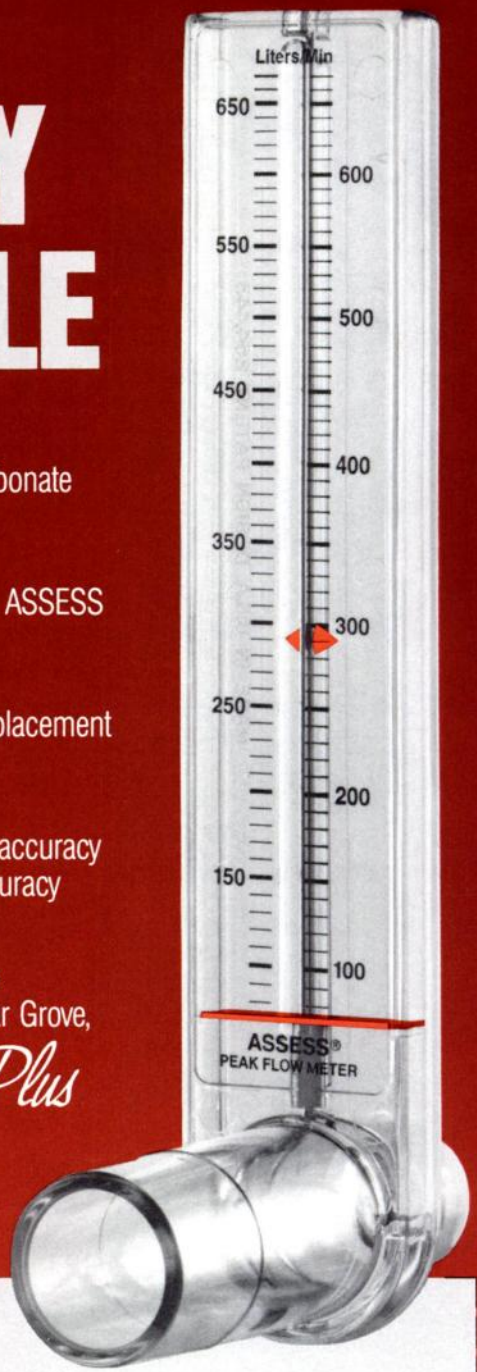

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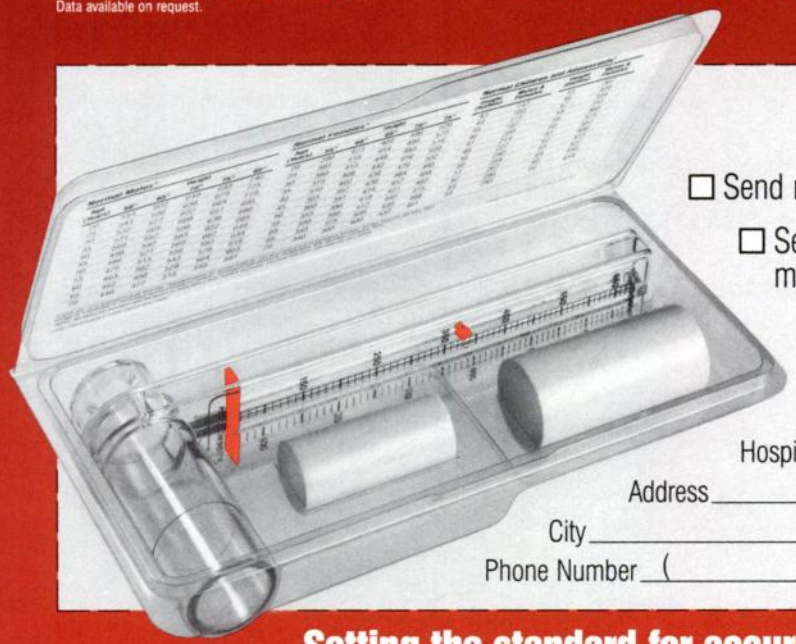

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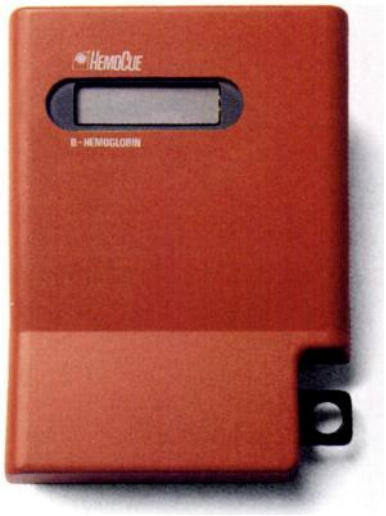

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