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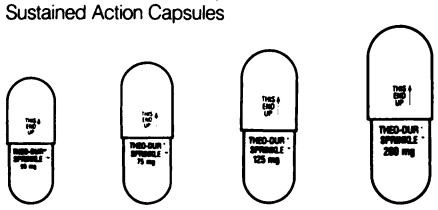

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Excessive theophylline doses may be associated with toxicity; serum theophylline levels should be monitored to insure maximum benefit with minimum risk. Incidence of toxicity increases at serum levels greater than 20 mcg/ml. High blood levels of theophylline resulting from conventional doses are correlated with clinical manifestation of toxicity in: patients with lowered body plasma clearances, patients with liver dysfunction or chronic obstructive lung disease, and patients who are older than 55 years of age, particularly males. There are often no early signs of less serious theophylline toxicity such as nausea and restlessness, which may occur in up to 50% of patients prior to onset of convulsions. Ventricular arrhythmias or seizures may be the first signs of toxicity. Many patients who have higher theophylline levels exhibit tachycardia. Theophylline products may worsen pre-existing arrhythmias.

PRECAUTIONS:
THEO-DUR SPRINKLE CAPSULES SHOULD NOT BE CHEWED OR CRUSHED. Theophylline should not be administered concurrently with other xanthine medications. Use with caution in patients with severe cardiac disease, severe hypoxemia, hypertension, hyperthyroidism, acute myocardial injury, cor pulmonale, congestive heart failure, liver disease, in the elderly (especially males) and in neonates. In particular, great caution should be used in giving theophylline to patients with congestive heart failure. Frequently, such patients have markedly prolonged theophylline serum levels with theophylline persisting in serum for long periods following discontinuation of the drug. Use theophylline cautiously in patients with history of peptic ulcer. Theophylline may occasionally act as a local irritant to the G.I. tract although gastrointestinal symptoms are more commonly centrally mediated and associated with serum drug concentrations over 20 mcg/ml.

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

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Pediatric Use:
Safety and effectiveness of THEO-DUR SPRINKLE in children under 6 years of age have not been established.

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1. Weinberger M, Ginchansky E: *J Pediatr* 1977;91:820-824.

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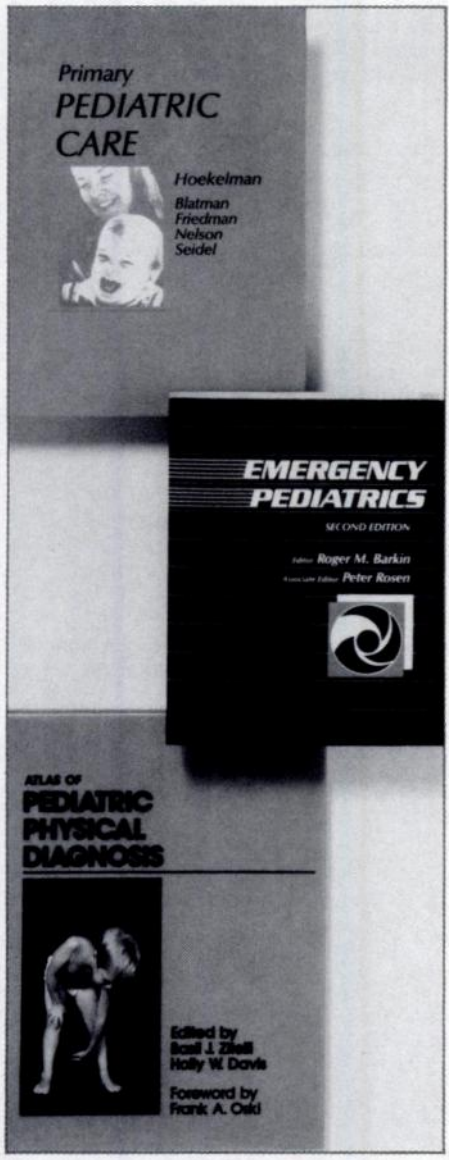

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October 31–November 5

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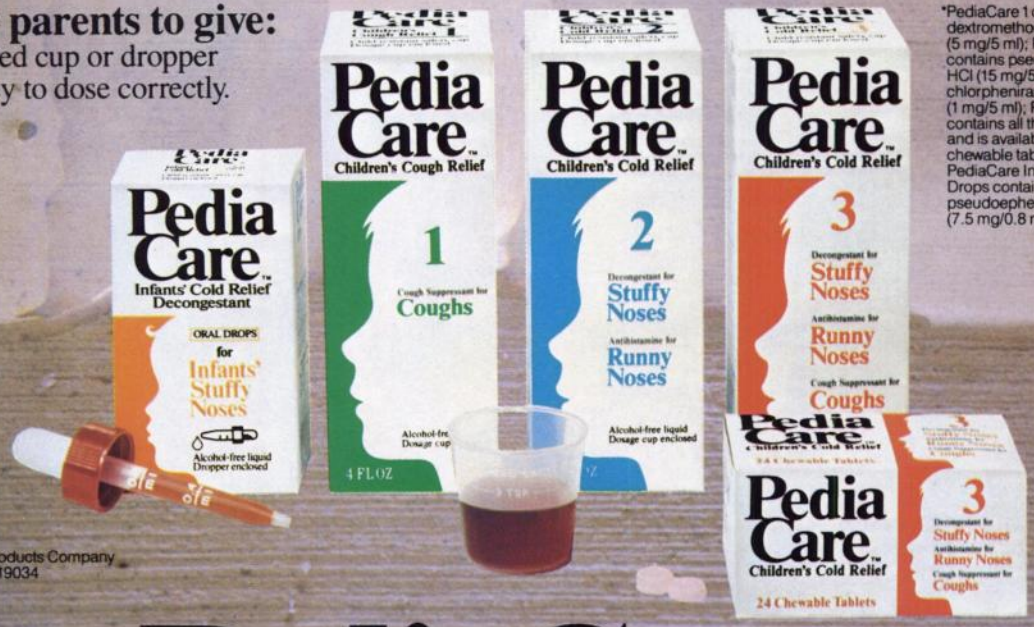

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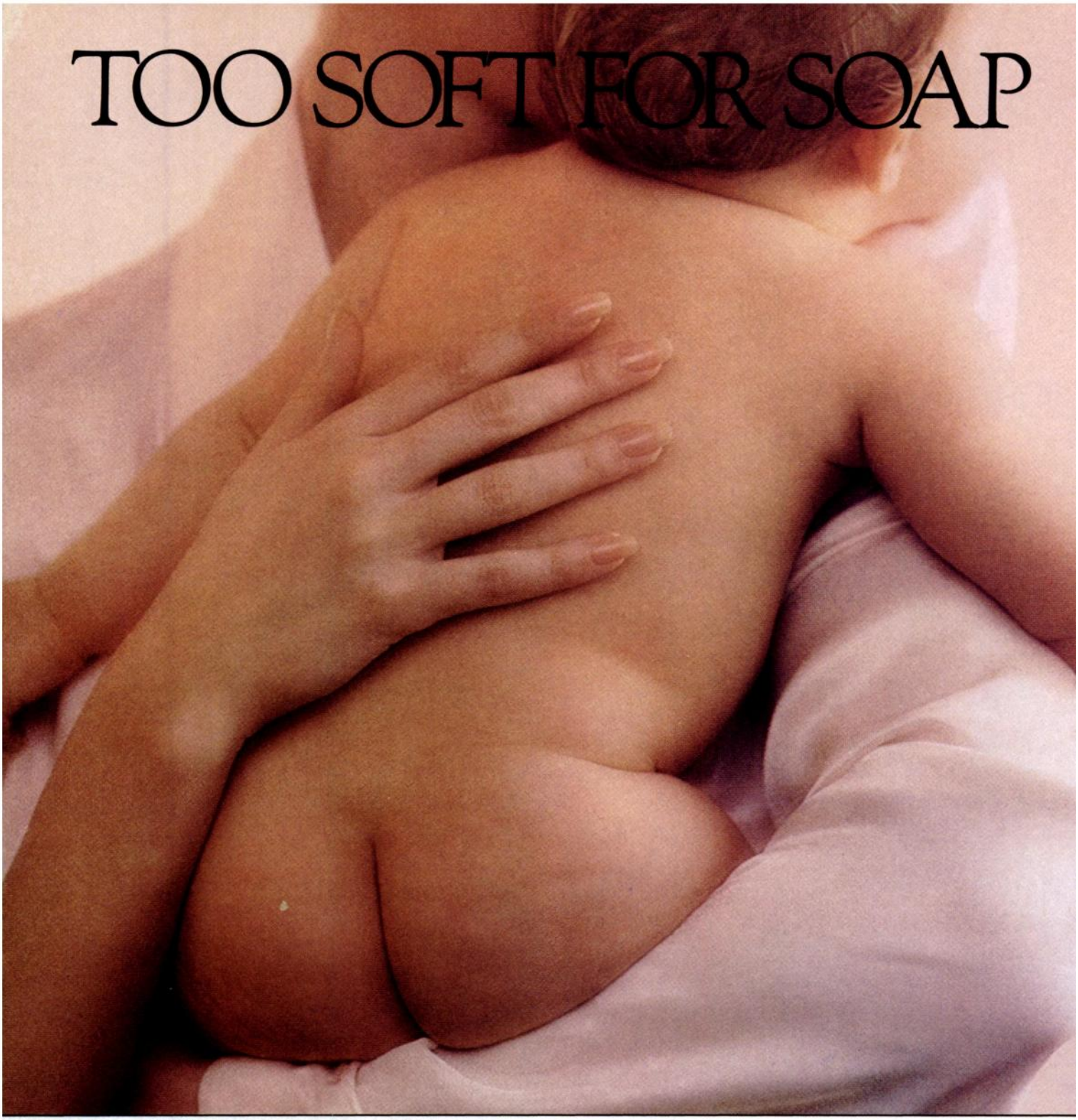

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1987

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Kauai, Hawaii
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April 3-5

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AMERICAN ACADEMY OF PEDIATRICS

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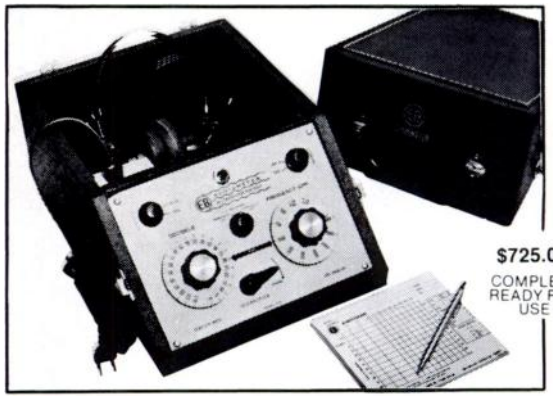

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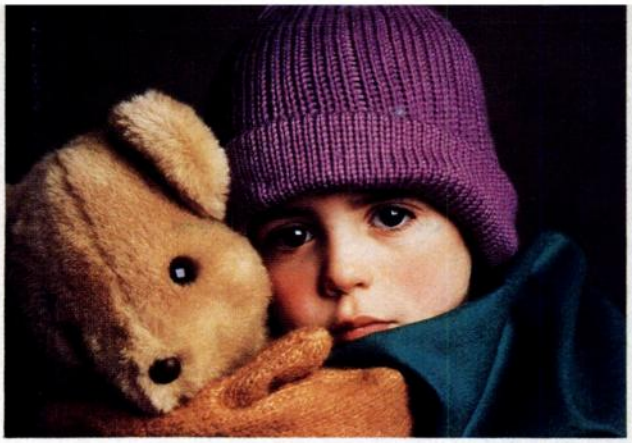

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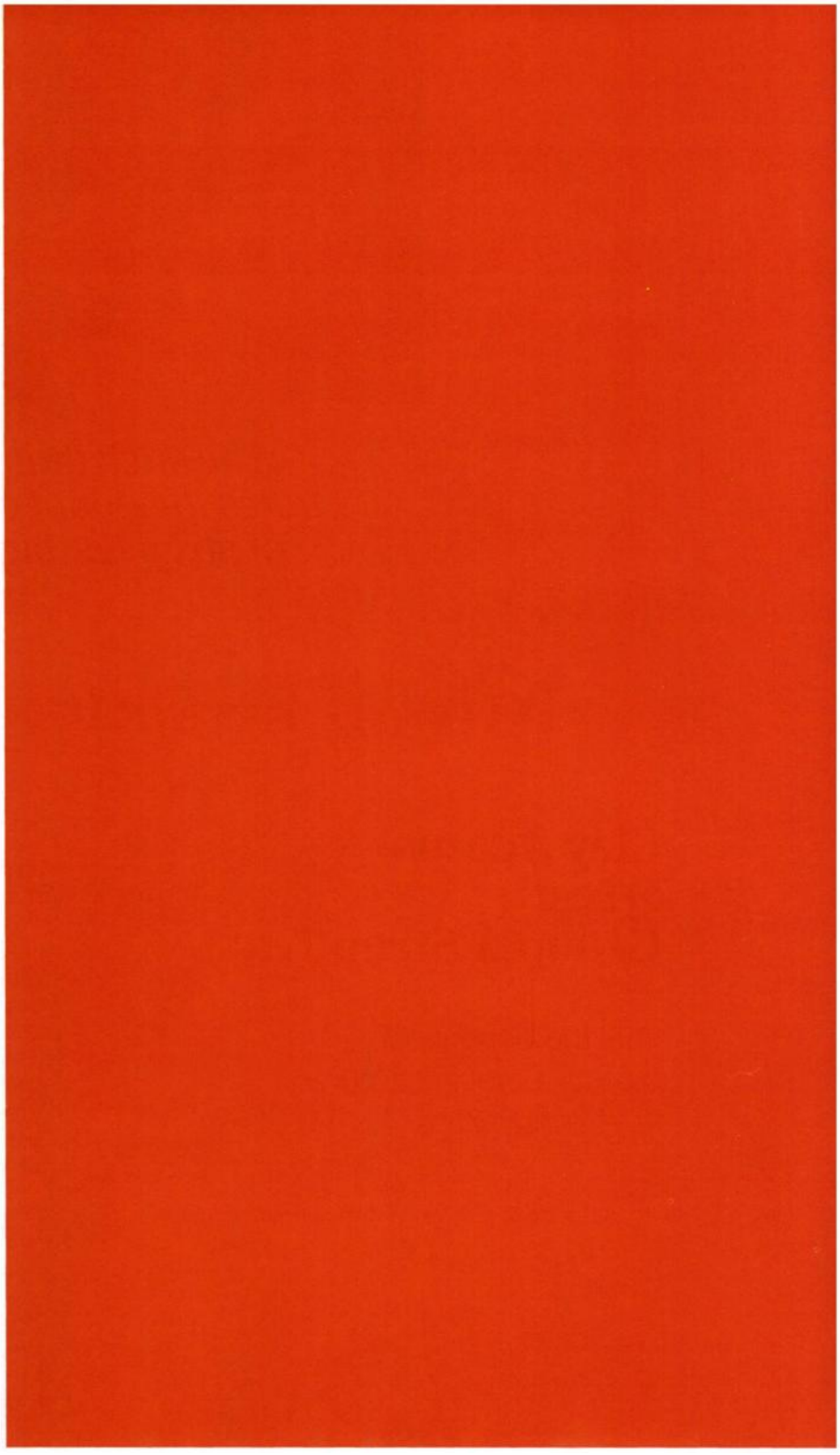

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BOOKS RECEIVED

Ethics of Dealing With Persons With Severe Handicaps: Toward a Research Agenda. P. R. Dokecki, R. M. Zaner. Baltimore, Paul H. Brookes Publishing Co, 1986, $21.95, 294 pp.

Social Survival for Children: A Trainer's Resource Book. Peter W. Dowrick. New York, Brunner/Mazel, Inc, 1986, 275 pp.

Pediatric Psychology. M. C. Roberts. New York, Pergamon Press, Inc, 1986, $19.50 (hardcover), $10.95 (softcover), 123 pp.

Anesthesia for Obstetrics, ed 2. S. M. Shnider and G. Levinson, Baltimore, Williams & Wilkins, 1987, $65.95, 566 pp.

The Politics of Baby Foods: Successful Challenges to an International Marketing Strategy. A. Chetley. New York, St Martin's Press, 1986, 189 pp.

A Family Affair: Helping Families Cope with Mental Illness. Committee on Psychiatry & the Community Group for the Advancement of Psychiatry. New York, Brunner/Mazel, 1986, $12.50 (paper), $17.95 (cloth), 110 pp.

Brought to Bed: Child-Bearing in America 1750–1950. J. W. Leavitt. New York, Oxford University Press, 1986, $21.95, 284 pp.

Newborns at Risk: Medical Care and Psychoeducational Intervention. G. L. Ensher, and D. A. Clark. Rockville, MD, 1986, $33.50, 319 pp.

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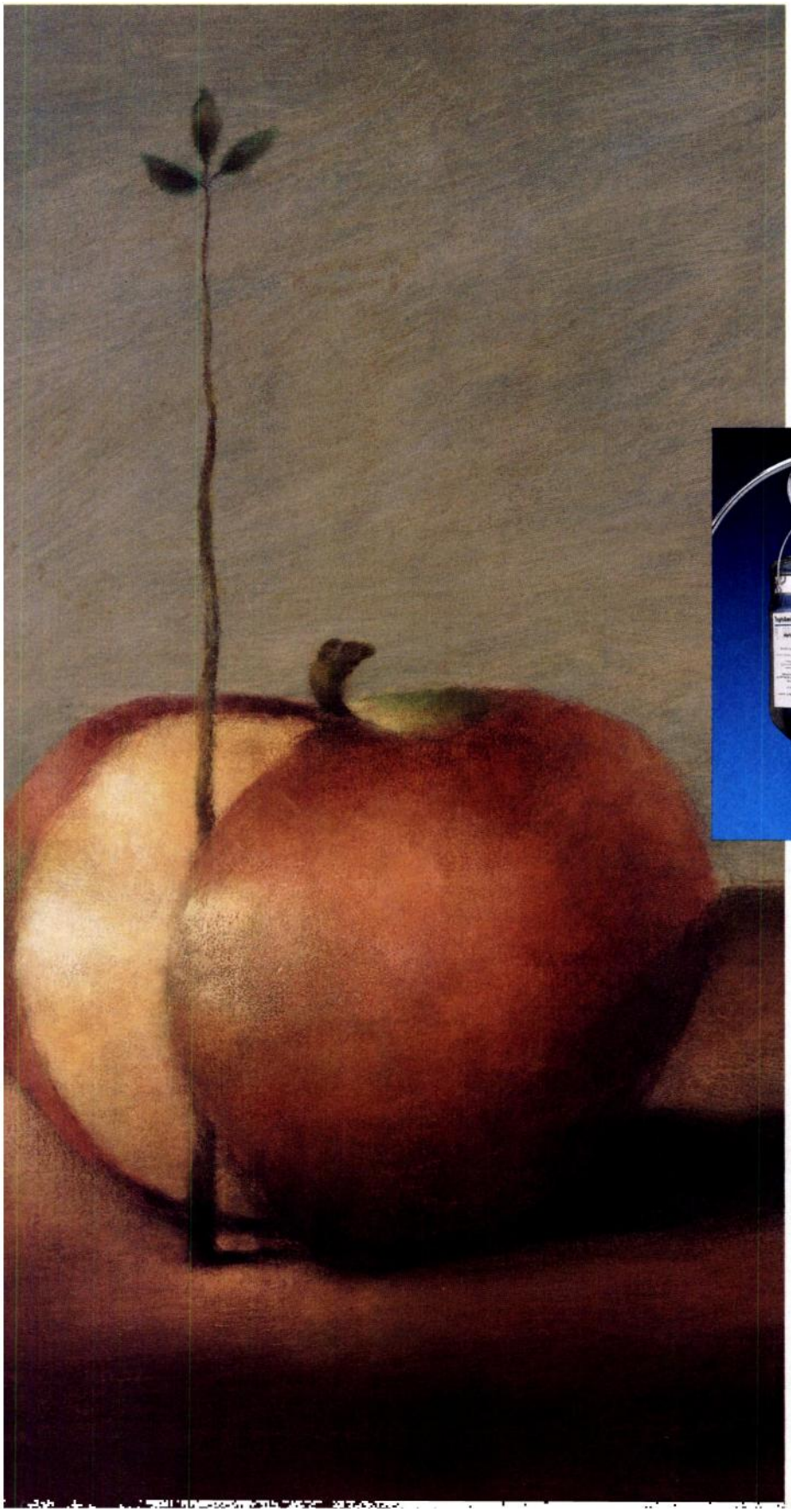

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WARNING: Parenteral nutrition should be used only by those familiar with its administration and complications.

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Isoleucine USP	0.49	g
Leucine USP	0.84	g
Lysine (added as Lysine Acetate USP)	0.49	g
Methionine USP	0.20	g
Phenylalanine USP	0.29	g
Threonine USP	0.25	g
Tryptophan USP	0.12	g
Valine USP	0.47	g
Cysteine HCl•H₂O USP[1]	<0.02	g
Histidine USP[1]	0.29	g
Tyrosine (As 0.04 g Tyrosine USP and 0.12 g N-Acetyl-L-Tyrosine)[1]	0.14	g
Nonessential amino acids		
Alanine USP	0.32	g
Arginine USP	0.73	g
Proline USP	0.41	g
Serine USP	0.23	g
Glycine USP	0.22	g
L-Aspartic Acid	0.19	g
L-Glutamic Acid	0.30	g
Taurine[2,3]	0.015	g
Sodium Metabisulfite NF (as an antioxidant)	0.050	g
Water for Injection USP		qs

pH adjusted with Glacial Acetic Acid USP
pH Approx. 5.5
Calculated Osmolarity Approx. 525 mOsm/liter
Concentration of Electrolytes (mEq/liter): Sodium 5, Acetate approx. 56 (provided as acetic acid and lysine acetate), Chloride <3

[1]Holt L.E., Snyderman S.E. The amino acid requirements of infants. **JAMA 175(2)**:124-127, 1961
[2]Rigo J., Senterre J. Is taurine essential for the neonates? **Biol Neonate 32**:73-76, 1977
[3]Gaull G., Sturman J.A., Raiha N.C.R. Development of mammalian sulfur metabolism: Absence of cystothionase in human fetal tissues. **Pediatr Res 6**:538-547, 1972

Indications and Usage TrophAmine is indicated for the nutritional support of infants (including those of low birth weight) and young children requiring TPN via either central or peripheral infusion routes. Parenteral nutrition with 6% TrophAmine is indicated to prevent nitrogen and weight loss or treat negative nitrogen balance in infants and young children where (1) the alimentary tract, by the oral, gastrostomy, or jejunostomy route, cannot or should not be used, or adequate protein intake is not feasible by these routes; (2) gastrointestinal absorption of protein is impaired; or (3) protein requirements are substantially increased as with extensive burns. Dosage, route of administration, and concomitant infusion of non-protein calories are dependent on various factors, such as nutritional and metabolic status of the patient, anticipated duration of parenteral nutritional support, and vein tolerance. **Central Venous Nutrition** Central venous infusion should be considered when amino acid solutions are to be admixed with hypertonic dextrose to promote protein synthesis in hypercatabolic or severely depleted infants, or those requiring long-term parenteral nutrition. **Peripheral Parenteral Nutrition** For moderately catabolic or depleted patients in whom the central venous route is not indicated, diluted amino acid solutions mixed with 5-10% dextrose solutions may be infused by peripheral vein, supplemented, if desired, with fat emulsion. **Contraindications** TrophAmine is contraindicated in patients with untreated anuria, hepatic coma, inborn errors of amino acid metabolism, including those involving branched chain amino acid metabolism such as maple syrup urine disease and isovaleric acidemia, or hypersensitivity to one or more amino acids present in the solution. **Warnings** Safe, effective use of parenteral nutrition requires a knowledge of nutrition as well as clinical expertise in recognition and treatment of the complications which can occur. **Frequent evaluation and laboratory determinations are necessary for proper monitoring of parenteral nutrition.** Studies should include blood sugar, serum proteins, kidney and liver function tests, electrolytes, hemogram, carbon dioxide content, serum osmolalities, blood cultures, and blood ammonia levels. Administration of amino acids in the presence of impaired renal function or gastrointestinal bleeding may augment an already elevated blood urea nitrogen. Patients with azotemia from any cause should not be infused with amino acids without regard to total nitrogen intake. Administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the solutions. Administration of amino acid solutions to a patient with hepatic insufficiency may result in plasma amino acid imbalances, hyperammonemia, prerenal azotemia, stupor and coma. Hyperammonemia is of **special significance in infants** as its occurrence in the syndrome caused by genetic metabolic defects is sometimes associated, although not necessarily in a causal relationship, with mental retardation. This reaction appears to be dose related and is more likely to develop during prolonged therapy. It is essential that blood ammonia be measured frequently in infants. The mechanisms of this reaction are not clearly defined but may involve genetic defects and immature or subclinically impaired liver function. Conservative doses of amino acids should be given, dictated by the nutritional status of the patient. Should symptoms of hyperammonemia develop, amino acid administration should be discontinued and the patient's clinical status reevaluated. This product contains sodium metabisulfite, a sulfite that may cause allergic-type reactions (*e.g.*, hives, itching, flushing, anaphylaxis) in certain susceptible persons. Although the overall prevalence of sulfite sensitivity in the general population is probably low, it is seen more frequently in asthmatic or in atopic nonasthmatic persons. **Precautions General** Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require the use of additional electrolyte supplements. Strongly hypertonic nutrient solutions should be administered via an intravenous catheter placed in a central vein, preferably the superior vena cava. Care should be taken to avoid circulatory overload, particularly in patients with cardiac insufficiency. Special care must be taken when giving hypertonic dextrose to a diabetic or pre-diabetic patient. To prevent severe hyperglycemia in such patients, insulin may be required. Administration of glucose at a rate exceeding the patient's utilization rate may lead to hyperglycemia, coma, and death. Administration of amino acids without carbohydrates may result in the accumulation of ketone bodies in the blood. Correction of this ketonemia may be achieved by the administration of carbohydrate. Fat emulsion coadministration should be considered when prolonged (more than 5 days) parenteral nutrition is required in order to prevent essential fatty acid deficiency (E.F.A.D.). Serum lipids should be monitored for evidence of E.F.A.D. in patients maintained on fat free TPN. Peripheral administration of TrophAmine® (6% Amino Acid Injection) requires appropriate dilution and provision of adequate calories. Care should be taken to assure proper placement of the needle within the lumen of the vein. The venipuncture site should be inspected frequently for signs of infiltration. If venous thrombosis or phlebitis occurs, discontinue infusions or change infusion site and initiate appropriate treatment. Extraordinary electrolyte losses such as may occur during protracted nasogastric suction, vomiting, diarrhea, or gastrointestinal fistula drainage may necessitate additional electrolyte supplementation. Metabolic acidosis can be prevented or readily controlled by adding a portion of the cations in the electrolyte mixture as acetate salts and in the case of hyperchloremic acidosis, by keeping the total chloride content of the infusate to a minimum. TrophAmine contains less than 3 mEq chlorides; contains no added phosphate. Patients, especially those with hypophosphatemia, may require the addition of phosphate. To prevent hypocalcemia, calcium supplementation should always accompany phosphate administration. To assure adequate intake, serum levels should be monitored frequently. To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration. Use only if solution is clear, the seal unbroken, and vacuum is present. **Carcinogenesis, Mutagenesis, Impairment of Fertility** No *in vitro* or *in vivo* carcinogenesis, mutagenesis, or fertility studies have been conducted with TrophAmine® (6% Amino Acid Injection). **Usage in Pregnancy** Pregnancy Category C. Animal reproduction studies have not been conducted with TrophAmine (6% Amino Acid Injection). It is also not know whether TrophAmine (6% Amino Acid Injection) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **Special Precautions for Central Venous Administration. Administration by central venous catheter should be used only by those familiar with this technique and its complications.** Central venous nutrition may be associated with complications which can be prevented or minimized by careful attention to all aspects of the procedure, including solution preparation, administration, and patient monitoring. **It is essential that a carefully prepared protocol, based on current medical practices, be followed, preferably by an experienced team.** Although a detailed discussion of the complications is beyond the scope of this insert, the following summary lists those based on current literature. **Technical.** The placement of a central venous catheter should be regarded as a surgical procedure. One should be fully acquainted with various techniques of catheter insertion as well as recognition and treatment of complications. For details of techniques and placement sites, consult the medical literature. X-ray is the best means of verifying catheter placement. Complications known to occur from the placement of central venous catheters are pneumothorax, hemothorax, hydrothorax, artery puncture and transection, injury to the brachial plexus, malposition of the catheter, formation of arteriovenous fistula, phlebitis, thrombosis, and air and catheter embolus. **Septic.** The constant risk of sepsis is present during central venous nutrition. Since contaminated solutions and infusion catheters are potential sources of infection, it is imperative that the preparation of parenteral nutrition solutions and the placement and care of catheters be accomplished under controlled aseptic conditions. Solutions should ideally be prepared in the hospital pharmacy in a laminar flow hood. The key factor in their preparation is careful aseptic technique to avoid inadvertent touch contamination during mixing of solutions and subsequent admixtures. Parenteral nutrition solutions should be used promptly after mixing. Any storage should be under refrigeration for as brief a time as possible. Administration time for a single bottle and set should never exceed 24 hours. Consult the medical literature for a discussion of the management of sepsis during central venous nutrition. In brief, typical management includes replacing the solution being administered with a fresh container and set, and the remaining contents are cultured for bacterial or fungal contamination. If sepsis persists and another source of infection is not identified, the catheter is removed, the proximal tip cultured, and a new catheter reinserted when the fever has subsided. Nonspecific, prophylactic antibiotic treatment is not recommended. Clinical experience indicates that the catheter is likely to be the prime source of infection as opposed to aseptically prepared and properly stores solutions. **Metabolic.** The following metabolic complications have been reported: metabolic acidosis, hypophosphatemia, alkalosis, hyperglycemia and glycosuria, osmotic diuresis and dehydration, rebound hypoglycemia, elevated liver enzymes, hypo- and hypervitaminosis, electrolyte imbalances, and hyperammonemia in children. Frequent clinical evaluation and laboratory determinations are necessary, especially during the first few days of venous nutrition to prevent or minimize these complications. **Adverse Reactions** See **"Warnings"** and **"Special Precautions for Central Venous Nutrition"** Reactions reported in clinical studies as a result of infusion of the parenteral fluid were water weight gain, edema, increase in BUN, and mild acidosis. Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia. Local reaction at the infusion site, consisting of a warm sensation, erythema, phlebitis and thrombosis, have been reported with peripheral amino acid infusions, especially if other substances are also administered through the same site. If electrolyte supplementation is required during peripheral infusion, it is recommended that additives be administered throughout the day in order to avoid possible venous irritation. Irritating additive medications may require injection at another site and should not be added directly to the amino acid infusate. Symptoms may result from an excess or deficit of one or more of the ions present in the solution; therefore, frequent monitoring of electrolyte levels is essential. Phosphorus deficiency may lead to impaired tissue oxygenation and acute hemolytic anemia. Relative to calcium, excessive phosphorus intake can precipitate hypocalcemia with cramps, tetany and muscular hyperexcitability. If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary. **Overdosage** In the event of a fluid or solute overload during parenteral therapy, reevaluate the patient's condition, and institute appropriate corrective treatment.

References

1. Jarvenpaa A-L, et al. Preterm infants fed human milk attain intrauterine weight gain. *Acta Paediatr Scand* 72:239, 1983. 2. Ziegler EE, et al. Nutritional requirements of the premature infant. *Textbook of Pediatric Nutrition*, pp. 29-39, 1981.

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INDICATIONS AND USAGE: For the treatment of acute otitis media in children due to susceptible strains of *Streptococcus pneumoniae* or *Haemophilus influenzae* when in the judgment of the physician Septra offers some advantage over the use of other antimicrobial agents. To date, there are limited data on the safety of repeated use of Septra in children under two years of age. Septra is not indicated for prophylactic or prolonged administration in otitis media at any age.

CONTRAINDICATIONS: Hypersensitivity to trimethoprim or sulfonamides. Patients with documented megaloblastic anemia due to folate deficiency. Pregnancy at term and during the nursing period, because sulfonamides pass the placenta and are excreted in the milk and may cause kernicterus. Infants less than two months of age.

WARNINGS: FATALITIES ASSOCIATED WITH THE ADMINISTRATION OF SULFONAMIDES, ALTHOUGH RARE, HAVE OCCURRED DUE TO SEVERE REACTIONS, INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS.

SEPTRA SHOULD BE DISCONTINUED AT THE FIRST APPEARANCE OF SKIN RASH OR ANY SIGN OF ADVERSE REACTION. Clinical signs, such as rash, sore throat, fever, pallor, purpura or jaundice may be early indications of serious reactions. In rare instances a skin rash may be followed by more severe reactions, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatic necrosis or serious blood disorder. Complete blood counts should be done frequently in patients receiving sulfonamides.

SEPTRA SHOULD NOT BE USED IN THE TREATMENT OF STREPTOCOCCAL PHARYNGITIS. Clinical studies have documented that patients with group A β-hemolytic streptococcal tonsillopharyngitis have a greater incidence of bacteriologic failure when treated with Septra than do those patients treated with penicillin, as evidenced by failure to eradicate this organism from the tonsillopharyngeal area.

PRECAUTIONS: General: Septra should be given with caution to patients with impaired renal or hepatic function, to those with possible folate deficiency and to those with severe allergy or bronchial asthma. In glucose-6-phosphate dehydrogenase-deficient individuals, hemolysis may occur. This reaction is frequently dose-related.

Laboratory Tests: Complete blood counts should be done frequently in patients receiving Septra; if a significant reduction in the count of any formed blood element is noted, Septra should be discontinued. Urinalysis, with careful microscopic examination and renal function tests should be performed during therapy, particularly for those patients with impaired renal function.

Drug Interactions: In elderly patients concurrently receiving certain diuretics, primarily thiazides, an increased incidence of thrombocytopenia with purpura has been reported.

It has been reported that Septra may prolong the prothrombin time in patients who are receiving the anticoagulant warfarin. This interaction should be kept in mind when Septra is given to patients already on anticoagulant therapy, and the coagulation time should be reassessed.

Septra may inhibit the hepatic metabolism of phenytoin. Septra, given at a common clinical dosage, increased the phenytoin half-life by 39% and decreased the phenytoin metabolic clearance rate by 27%. When administering these drugs concurrently, one should be alert for possible excessive phenytoin effect. Sulfonamides can also displace methotrexate from plasma protein binding sites, thus increasing free methotrexate concentrations.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals to evaluate carcinogenic potential and bacterial mutagenic studies have not been conducted with Septra.

Pregnancy: *Teratogenic Effects:* Pregnancy Category C. In rats, oral doses of 533 mg/kg sulfamethoxazole or 200 mg/kg trimethoprim produced teratological effects manifested mainly as cleft palates. Because trimethoprim and sulfamethoxazole may interfere with folic acid metabolism, Septra should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

ADVERSE REACTIONS: The most common adverse effects are gastrointestinal disturbances (nausea, vomiting, anorexia) and allergic skin reactions (such as rash and urticaria). **FATALITIES ASSOCIATED WITH THE ADMINISTRATION OF SULFONAMIDES, ALTHOUGH RARE, HAVE OCCURRED DUE TO SEVERE REACTIONS, INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS (SEE WARNINGS SECTION).**

Hematologic: Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, neutropenia, hemolytic anemia, megaloblastic anemia, hypoprothrombinemia, methemoglobinemia, eosinophilia.

Allergic Reactions: Stevens-Johnson syndrome, toxic epidermal necrolysis, anaphylaxis, allergic myocarditis, erythema multiforme, exfoliative dermatitis, angioedema, drug fever, chills, Henoch-Schoenlein purpura, serum sickness-like syndrome, generalized allergic reactions, generalized skin eruptions, photosensitivity, conjunctivae and scleral injection, pruritus, urticaria and rash. In addition, periarteritis nodosa and systemic lupus erythematosus have been reported.

Gastrointestinal: Hepatitis including cholestatic jaundice and hepatic necrosis, elevation of serum transaminase and bilirubin, pseudomembranous enterocolitis, pancreatitis, stomatitis, glossitis, nausea, emesis, abdominal pain, diarrhea, anorexia.

Genitourinary: Renal failure, interstitial nephritis, BUN and serum creatinine elevation, toxic nephrosis with oliguria and anuria, and crystalluria.

Neurologic: Aseptic meningitis, convulsions, peripheral neuritis, ataxia, vertigo, tinnitus, headache.

Psychiatric: Hallucinations, depression, apathy, nervousness.

Endocrine: The sulfonamides bear certain chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents. Cross-sensitivity may exist with these agents. Diuresis and hypoglycemia have occurred rarely in patients receiving sulfonamides.

Musculoskeletal: Arthralgia and myalgia.

Miscellaneous: Weakness, fatigue, insomnia.

OVERDOSAGE: Chronic: Use of Septra at high doses and/or for extended periods of time may cause bone marrow depression manifested as thrombocytopenia, leukopenia, and/or megaloblastic anemia. If signs of bone marrow depression occur, the patient should be given leucovorin 5 to 15 mg daily until normal hematopoiesis is restored.

DOSAGE AND ADMINISTRATION: Not recommended for use in infants less than two months of age. The recommended dose for children weighing less than 40 kg with acute otitis media is 8 mg/kg trimethoprim and 40 mg/kg sulfamethoxazole per 24 hours given in two divided doses every 12 hours for 10 days. A child weighing 40 kg or more should receive 4 teaspoonfuls (20 ml) or 2 tablets (or1 DS tablet) every 12 hours for 10 days. For patients with renal impairment, use recommended dosage regimen when creatinine clearance is above 30 ml/min. If creatinine clearance is between 15 and 30 ml/min, use one-half the usual regimen. SEPTRA is not recommended if creatinine clearance is below 15 ml/min.

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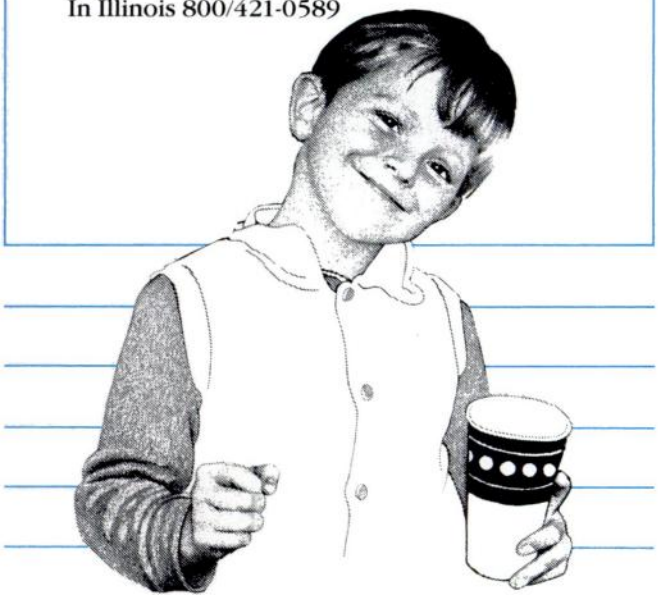

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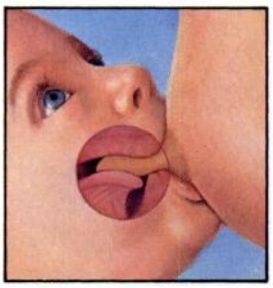

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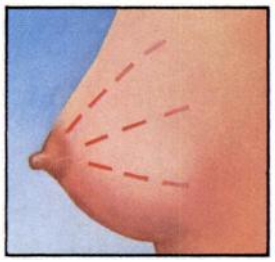

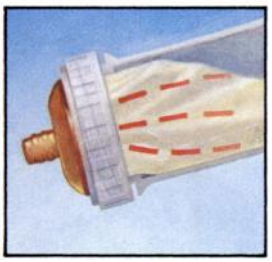

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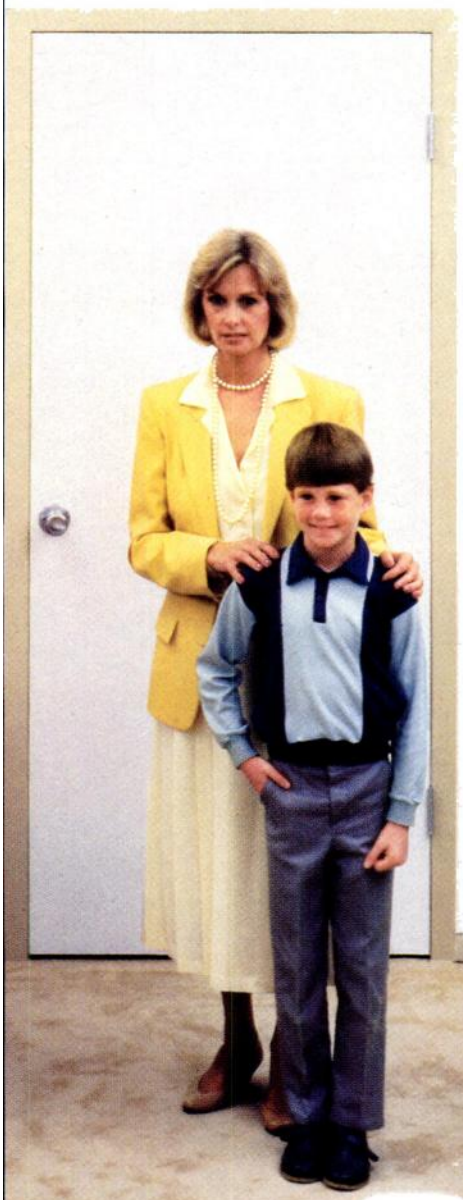

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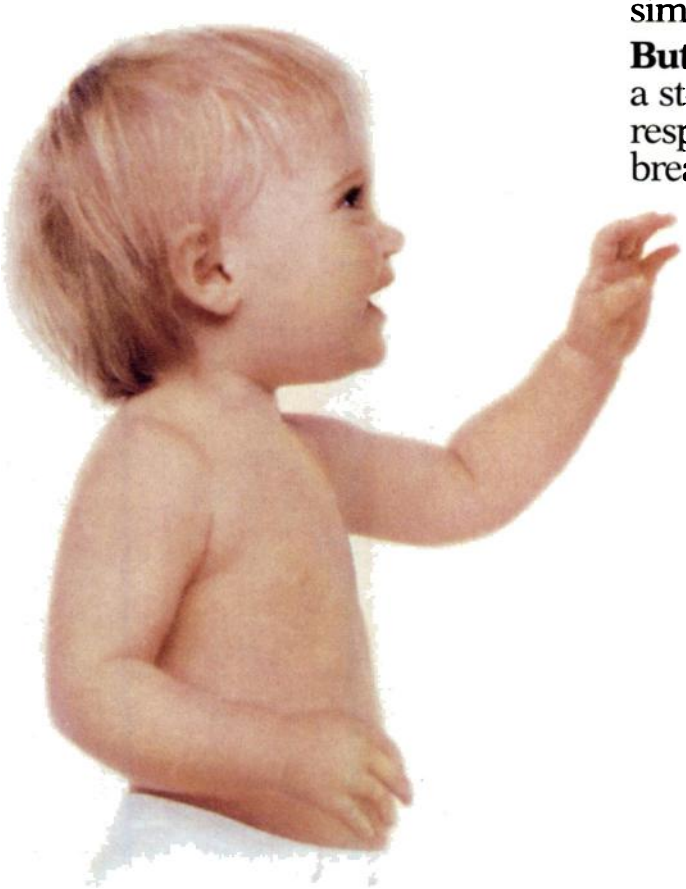

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Trichophyton sulphureum	Trichophyton gallinae
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Note: Prior to therapy, the type of fungi responsible for the infection should be identified. The use of the drug is not justified in minor or trivial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

It is *not* effective in:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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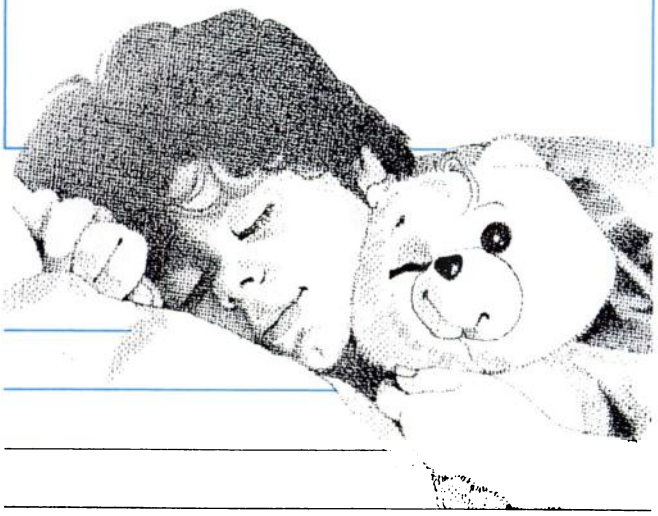

When I was a child there was no Orimune®

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.

Lederle Biologicals Protecting Families Through Immunization™

When I was a child there was no Orimune®

Proven in Millions of US Patients

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. Approximately 500 million doses have been administered since 1963.

Proven Safety Record*

Lederle takes every precaution during production and testing to ensure the safety of ORIMUNE. This dedication is evident by our 25-year safety record.

Uninterrupted Supply

Lederle has consistently met the nation's needs for oral polio vaccine for about 25 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.

*See adverse reactions section of brief summary

Orimune®
Poliovirus Vaccine Live, Oral Trivalent

ORIMUNE®
Poliovirus Vaccine, Live, Oral Trivalent

INDICATIONS
For prevention of poliomyelitis caused by Poliovirus Types 1, 2, and 3. For complete references and Indications and Usage statement, see package insert.

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. 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. IPV is preferred for immunizing all persons in this setting.

PRECAUTIONS
Other viruses (including poliovirus and other enterovirus) 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.

It would seem prudent not to administer TOPV shortly after Immune Serum Globulin (ISG) unless such a procedure is unavoidable, for example, with unexpected travel to or contact with epidemic areas or endemic areas. If TOPV is given with or shortly after ISG, the dose probably should be repeated after three months, if immunization is still indicated. However, ISG may not interfere with immunization with TOPV.

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

Use in Pregnancy: Although there is no convincing evidence documenting adverse effects of either TOPV 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, TOPV 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 stool 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. The risk of vaccine-associated paralysis is extremely small for vaccinees, susceptible family members, and other close personal contacts. However, 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. The Centers for Disease Control report that during the years 1969 through 1980 approximately 290 million doses of TOPV were distributed in the United States. In the same 12 years, 25 "vaccine-associated" and 55 "contact vaccine-associated" paralytic cases were reported. Twelve other "vaccine-associated" cases have been reported in persons (recipients or contacts) with immune deficiency conditions. These statistics do not provide a satisfactory basis for estimating these risks on a per person basis.

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 minimized by giving these adults three doses of IPV a month apart before the children receive ORIMUNE. 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 Immunization Practices Advisory Committee of the US Public Health Service 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 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 Immunization Practices Advisory Committee has concluded that "Oral polio vaccine remains the vaccine of choice for primary immunization of Children."

Rev. 6/86

Lederle Biologicals
™ Protecting Families Through Immunization™

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PRESCRIBE LURIDE®

...when children need supplemental fluoride.

Adjustable dose Luride gives you the flexibility to prescribe optimal daily dosage (based on age and fluoride content of water).

Luride drops and tablets meet all your criteria for prescribing optimal daily dosage. And Luride gives you the flexibility to prescribe the most desirable systemic fluoride dosage depending on your patients' needs. Available in increments of approximately 0.125 (⅛) mg. F.

Plus, with Luride, you don't have the problem that may occur with fluoride-vitamin combinations. That is, recommending optimum fluoride levels may alter desired vitamin intake, while maintaining optimum vitamin levels may result in too little or too much fluoride.

For your patients' welfare, prescribe Luride drops for infants, Luride Lozi-Tabs® tablets for older children.

Accepted COUNCIL ON DENTAL THERAPEUTICS AMERICAN DENTAL ASSOCIATION

This advertisement has been reviewed for compliance with the advertising standards of the American Dental Association.

For complete product information call Hoyt, toll free: 1-800-225-3756

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LURIDE® DROPS let you adjust dosage to 0.125 (⅛) mg. F.

One study showed that fluoride supplements such as Luride drops and tablets, used daily, prevented caries as effectively as fluoridated water.[1] Luride Drops and Lozi-Tabs have been shown to reduce caries up to 80% when used on a daily basis in non-fluoridated areas.[2] (Luride DMFS = 1.57, Control = 7.93)

Luride drops are sugar-free and saccharin-free, unlike many fluoride-vitamin combinations. And you can adjust dosage to the nearest 0.125 mg. F—to a single ⅛ mg. drop.

LURIDE® LOZI-TABS® TABLETS: 3 fluoride strengths, 7 child-pleasing flavors.

For children old enough to chew a tablet or let it dissolve in the mouth, Luride tablets are the logical choice. A variety of delicious fruit flavors (including our unique 4-flavor assorted package) encourages the habit of consistent, continuous use. Three strengths available—1.0 mg. F, 0.5 mg. F, and 0.25 mg. F.

LURIDE® BRAND OF SODIUM FLUORIDE DENTAL CARIES PREVENTIVE.
DESCRIPTION and HOW SUPPLIED:
All LURIDE systemic fluoride products are free of sugar and saccharin.

Product	Strength (F ION)	Package Size	Flavor
DROPS	Approx. 0.125 mg. per drop	30 ml.	peach
0.25 F TABLETS	0.25 mg. per tablet (quarter-strength)	120	vanilla
0.5 F TABLETS	0.5 mg. per tablet (half-strength)	120 1200*	grape grape
1.0 F TABLETS	1.0 mg. per tablet (full-strength)	120 1000* 5000*	cherry & assorted (cherry, orange, lemon, lime) cherry, assorted cherry
SF 1.0 F TABLETS	1.0 mg. per tablet (full-strength)	120	Special Formula, no artificial flavor or color.

*For dispensing only in quantities containing 120 mg. F. or less.
CAUTION: Federal (U.S.A.) law prohibits dispensing without prescription.

ADMINISTRATION AND DOSAGE FLEXIBILITY:
Adjustable dose LURIDE gives you the flexibility to prescribe optimal DAILY dosage (based on age and fluoride content of water).

F-Content of Drinking Water	Daily Dosage (Fluoride Ion)* Birth to Age 2	Age 2-3	Age 3-13
less than 0.3 ppm	0.25 mg. tab or 2 drops	0.5 mg. tab or 4 drops	1.0 mg. tab or 8 drops
0.3 to 0.7 ppm	one-half above dosage		
over 0.7 ppm	Fluoride dietary supplements contraindicated		

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

PRECAUTIONS: Recommended dosage should not be exceeded since prolonged overdosage may result in dental fluorosis.

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

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

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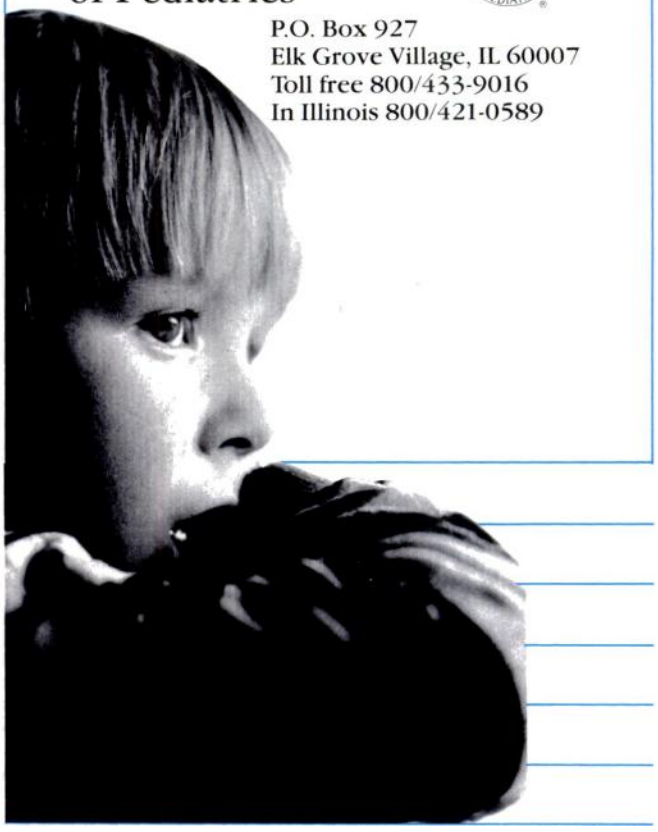
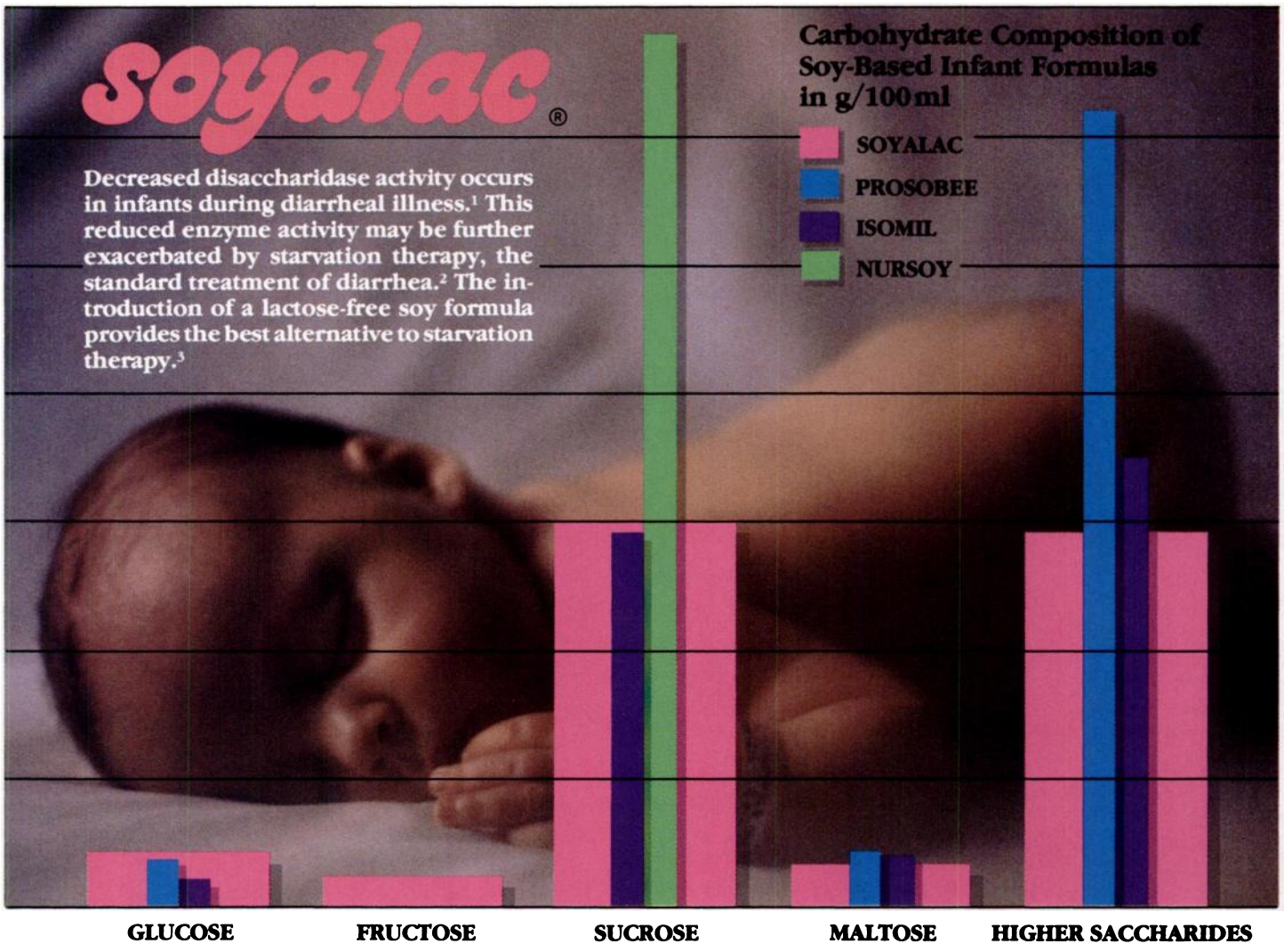


The alternative to starvation therapy in the treatment of infantile diarrhea



SOYALAC, a lactose-free formula, contains a mixed carbohydrate source. The combination of corn syrup solids, sucrose, and naturally occurring soy bean carbohydrates in SOYALAC provides the intestinal enzymes with adequately differentiated substrates.

SOYALAC also assists in the control of diarrhea through a low osmolality (240mOsm/kg water). This low osmolality provides the necessary osmotic gradient to produce a net flux of water out of the intestinal lumen.[4]

REFERENCES

[1] Lebenthal, E. and Lee, P.C. (1980) Glucoamylase and Disaccharide Activities in Normal Subjects and in Patients with Mucosal Injury of the Small Intestine. J. Ped. 93:389-393.

[2] Knudsen, K.B., Bradley, E.M., Lecocq, F.R., Bellamy, H.M., and Welsh, J.D. (1968) Effect of Fasting and Refeeding on the Histology and Disaccharidase Activity of the Human Intestine. Gastroenterology 55 (1): 46-51.

[3] Santoskam, M., Foster, S., Reid, R., Bertrando, R., Yolken, R., Burns, B., and Sack, B. (1985) Role of Soy-based, Lactose-free Formula During Treatment of Acute Diarrhea. Pediatrics 76 (2): 292-298.

[4] Torres-Pinedo, R., Rivera, C.L., and Fernandez, S. (1966) Studies on Infant Diarrhea. II. Absorption of Glucose and Net Fluxes of Water and Sodium Chloride in a Segment of the Jejunum. J. Clin. Invest. 45: 1916-1922.

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A "DECLARATION OF INTENTION"

We consider that life is good but that the chances to lead a happy and productive life with others rests on being structurally normal. I request that my physician give me all examinations and tests that would permit me to know that my infant does not have significant risks of abnormality. In the case that a significant risk is noted, my physicians should provide me or refer me to someone who will perform a therapeutic interruption of pregnancy.

At the time of delivery, if by chance my infant is not normal, I ask formally that the doctors do not resuscitate him. If the baby is structurally normal but fails to breathe appropriately, I ask that the doctors do everything possible so that the baby will live, but that they continue the resuscitation only as long as they can be reasonably sure that his brain will stay intact and function normally.

I wish to assure all of you who will execute my wishes that I understand fully the implications and I hope that no one will contradict them.

_____

_____

Signature of Prospective Parents

Submitted by Student

Circulated to prospective parents in France by Association Pour La Prevention de l'Enfance Handicapee BP18, 94802, Villejuif Cedex France.

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Submitted by Student

From Hollie PG: Health care commercials. *The New York Times*, April 27, 1986.

Some mommies don't know about waterproof

SUNDOWN®
SUNBLOCK

Some parents don't know that SUNDOWN® Sunblock SPF 15 keeps their children "covered" for at least 80 minutes when they play in the water.[1]

SUNDOWN is waterproof to withstand splashing or sweating. And it effectively blocks ultraviolet radiation with a three-sunscreen formulation.* So SUNDOWN helps prevent sunburn, and may help prevent the development of more serious sun-related problems such as premature aging of the skin and skin cancer.[1,2]

So don't keep SUNDOWN—and your patients—under wraps. Recommend it for the children in your practice.

References: 1. FDA Advisory Review Panel on Sunscreen Products for Over-the-Counter Human Use: *Federal Register* 43(166): 38206-38269, 1978. **2.** Pathak MA, et al: in Petersdorf RG, et al (eds): *Harrison's Principles of Internal Medicine*, ed 10. New York, McGraw-Hill Book Co, 1983, pp 273-282.

*Octyl dimethyl PABA, oxybenzone and octyl methoxycinnamate.

†Refer to package labeling; contraindicated in patients sensitive to any ingredient contained in this product.

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Effective protection for every patient under the sun†

Johnson & Johnson

Too many cough-cold choices?

The choice is simple with RONDEC®-DM ℞

antihistamine/decongestant/antitussive

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

Just two forms:

for infants 1 to 18 months old

RONDEC®-DM Oral Drops ℞

each dropperful (1 mL) contains 2 mg carbinoxamine maleate, 25 mg pseudoephedrine HCl, 4 mg dextromethorphan HBr, less than 0.6% alcohol

for adults and children 18 months and older

RONDEC®-DM Syrup ℞

each teaspoonful (5 mL) contains 4 mg carbinoxamine maleate, 60 mg pseudoephedrine HCl, 15 mg dextromethorphan HBr, less than 0.6% alcohol

- Oral Drops for infants
- Syrup for children and adults
- Safe and effective for adults, children, and infants
- Great grape flavor for excellent patient compliance
- ℞: By your prescription only

B103/6808

ROSS LABORATORIES
COLUMBUS, OHIO 43216
Division of Abbott Laboratories, USA

DESCRIPTION

Antihistamine/Decongestant/Antitussive for oral use for adults and children

RONDEC®-DM Syrup ℞

each teaspoonful (5 ml) contains carbinoxamine maleate, 4 mg; pseudoephedrine hydrochloride, 60 mg; dextromethorphan hydrobromide, 15 mg; less than 0.6% alcohol.

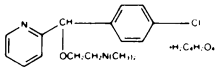
Inactive Ingredients: Alcohol less than 0.6%, DC Red No. 33, FDC Blue No. 1, glycerin, liquid glucose, menthol, sodium benzoate, sucrose, water, natural & artificial flavoring and other ingredients.

for infants

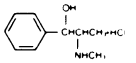
RONDEC®-DM Oral Drops ℞

each dropperful (1 ml) contains carbinoxamine maleate, 2 mg; pseudoephedrine hydrochloride, 25 mg; dextromethorphan hydrobromide, 4 mg; less than 0.6% alcohol.

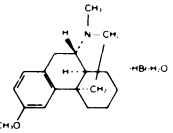
Inactive Ingredients: Alcohol less than 0.6%, DC Red No. 33, FDC Blue No. 1, glycerin, liquid glucose, menthol, sodium benzoate, sucrose, water, natural & artificial flavoring and other ingredients.



Carbinoxamine maleate (2-[p-Chloro-α-[2-(dimethylamino)ethoxy]benzyl]pyridine maleate) is one of the ethanolamine class of H_1 antihistamines.



Pseudoephedrine hydrochloride (Benzenemethanol, α-[1-(methylamino)ethyl]-,[S-(R*, R*)]-, hydrochloride) is the hydrochloride of pseudoephedrine, a naturally occurring dextrorotatory stereoisomer of ephedrine.



Dextromethorphan hydrobromide (Morphinan, 3-methoxy-17-methyl-, (9α, 13α, 14α)-,hydrobromide, monohydrate) is the hydrobromide of d-form racemethorphan.

CLINICAL PHARMACOLOGY

Antihistaminic, decongestant and antitussive actions.

Carbinoxamine maleate possesses H_1 antihistaminic activity and mild anticholinergic and sedative effects. Serum half-life for carbinoxamine is estimated to be 10 to 20 hours. Virtually no intact drug is excreted in the urine.

Pseudoephedrine hydrochloride is an oral sympathomimetic amine which acts as a decongestant to respiratory tract mucous membranes. While its vasoconstrictor action is similar to that of ephedrine, pseudoephedrine has less pressor effect in normotensive adults. Serum half-life for pseudoephedrine is 6 to 8 hours. Acidic urine is associated with faster elimination of the drug. About one half of the administered dose is excreted in the urine.

Dextromethorphan hydrobromide is a nonnarcotic antitussive with effectiveness equal to codeine. It acts in the medulla oblongata to elevate the cough threshold. Dextromethorphan does not produce analgesia or induce tolerance, and has no potential for addiction. At usual doses, it will not depress respiration or inhibit ciliary activity. Dextromethorphan is rapidly metabolized, with trace amounts of the parent compound in blood and urine. About one half of the administered dose is excreted in the urine as conjugated metabolites.

INDICATIONS AND USAGE

For relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.

CONTRAINDICATIONS

Patients with hypersensitivity or idiosyncrasy to any ingredients, patients taking monoamine oxidase (MAO) inhibitors, patients with narrow-angle glaucoma, urinary retention, peptic ulcer, severe hypertension or coronary artery disease, or patients undergoing an asthmatic attack.

WARNINGS

Use in Pregnancy: Safety for use during pregnancy has not been established.

Nursing Mothers: Use with caution in nursing mothers.

Special Risk Patients: Use with caution in patients with hypertension or ischemic heart disease, and persons over 60 years.

PRECAUTIONS

Before prescribing medication to suppress or modify cough, identify and provide therapy for the underlying cause of cough.

Use with caution in patients with hypertension, heart disease, asthma, hyperthyroidism, increased intraocular pressure, diabetes mellitus and prostatic hypertrophy.

Information for Patients: Avoid alcohol and other CNS depressants while taking these products. Patients sensitive to antihistamines may experience moderate to severe drowsiness. Patients sensitive to sympathomimetic amines may note mild CNS stimulation. While taking these products, exercise care in driving or operating appliances, machinery, etc.

Drug Interactions: Antihistamines may enhance the effects of tricyclic antidepressants, barbiturates, alcohol, and other CNS depressants. MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines. Sympathomimetic amines may reduce the antihypertensive effects of reserpine, veratrum alkaloids, methyldopa and mecamylamine. Effects of sympathomimetics are increased with MAO inhibitors and beta-adrenergic blockers. The cough suppressant action of dextromethorphan and narcotic antitussives are additive.

Pregnancy Category C.: Animal reproduction studies have not been conducted with Rondec-DM. It is also not known whether these products can cause fetal harm when administered to a pregnant woman or affect reproduction capacity. Give to pregnant women only if clearly needed.

ADVERSE REACTIONS

Antihistamines: Sedation, dizziness, diplopia, vomiting, diarrhea, dry mouth, headache, nervousness, nausea, anorexia, heartburn, weakness, polyuria and dysuria and, rarely, excitability in children.

Sympathomimetic Amines: Convulsions, CNS stimulation, cardiac arrhythmias, respiratory difficulty, increased heart rate or blood pressure, hallucinations, tremors, nervousness, insomnia, weakness, pallor and dysuria.

Dextromethorphan: Drowsiness and GI disturbance.

OVERDOSAGE

No information is available as to specific results of an overdose of these products. The signs, symptoms and treatment described below are those of H_1 antihistamine, ephedrine and dextromethorphan overdose.

Symptoms: Should antihistamine effects predominate, central action constitutes the greatest danger. In the small child, predominant symptoms are excitation, hallucination, ataxia, incoordination, tremors, flushed face and fever. Convulsions, fixed and dilated pupils, coma, and death may occur in severe cases. In the adult, fever and flushing are uncommon; excitement leading to convulsions and postictal depression is often preceded by drowsiness and coma. Respiration is usually not seriously depressed; blood pressure is usually stable.

Should sympathomimetic symptoms predominate, central effects include restlessness, dizziness, tremor, hyperactive reflexes, talkativeness, irritability and insomnia. Cardiovascular and renal effects include difficulty in micturition, headache, flushing, palpitation, cardiac arrhythmias, hypertension with subsequent hypotension and circulatory collapse. Gastrointestinal effects include dry mouth, metallic taste, anorexia, nausea, vomiting, diarrhea and abdominal cramps.

Dextromethorphan may cause respiratory depression with a large overdose.

Treatment: a) Evacuate stomach as condition warrants. Activated charcoal may be useful. *b)* Maintain a nonstimulating environment. *c)* Monitor cardiovascular status. *d)* Do not give stimulants. *e)* Reduce fever with cool sponging. *f)* Treat respiratory depression with naloxone if dextromethorphan toxicity is suspected. *g)* Use sedatives or anticonvulsants to control CNS excitation and convulsions. *h)* Physostigmine may reverse anticholinergic symptoms. *i)* Ammonium chloride may acidify the urine to increase urinary excretion of pseudoephedrine. *j)* Further care is symptomatic and supportive.

DOSAGE AND ADMINISTRATION

DOSAGE:

AGE	DOSE*	FREQUENCY
Rondec-DM Syrup		
18 months-6 years	½ teaspoonful (2.5 ml)	q.i.d.
adults and children 6 years and over	1 teaspoonful (5 ml)	q.i.d.
Rondec-DM Oral Drops for oral use only		
1-3 months	¼ dropperful (¼ ml)	q.i.d.
3-6 months	½ dropperful (½ ml)	q.i.d.
6-9 months	¾ dropperful (¾ ml)	q.i.d.
9-18 months	1 dropperful (1 ml)	q.i.d.

*In mild cases or in particularly sensitive patients, less frequent or reduced doses may be adequate.

HOW SUPPLIED

Rondec-DM Syrup, grape-flavored, in 16-fl-oz (1-pint) bottles, **NDC** 0074-5640-16; and 4-fl-oz bottles, **NDC** 0074-5640-04. Dispense in USP tight, light-resistant, glass container. Avoid exposure to excessive heat. Rondec-DM Oral Drops, grape-flavored, in 30-ml bottles for dropper dosage. Calibrated, shatterproof dropper enclosed in each carton. Container meets safety closure requirements. **NDC** 0074-5639-30. Avoid exposure to excessive heat.

Revised: June, 1985

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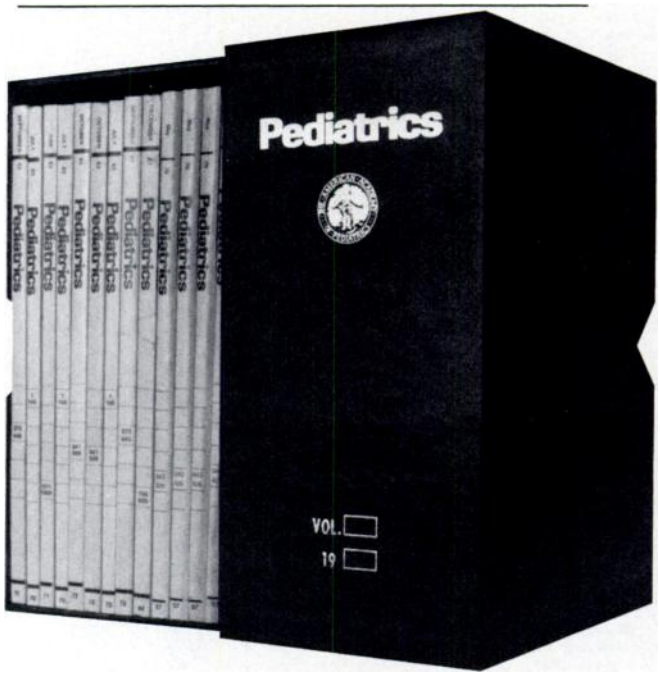

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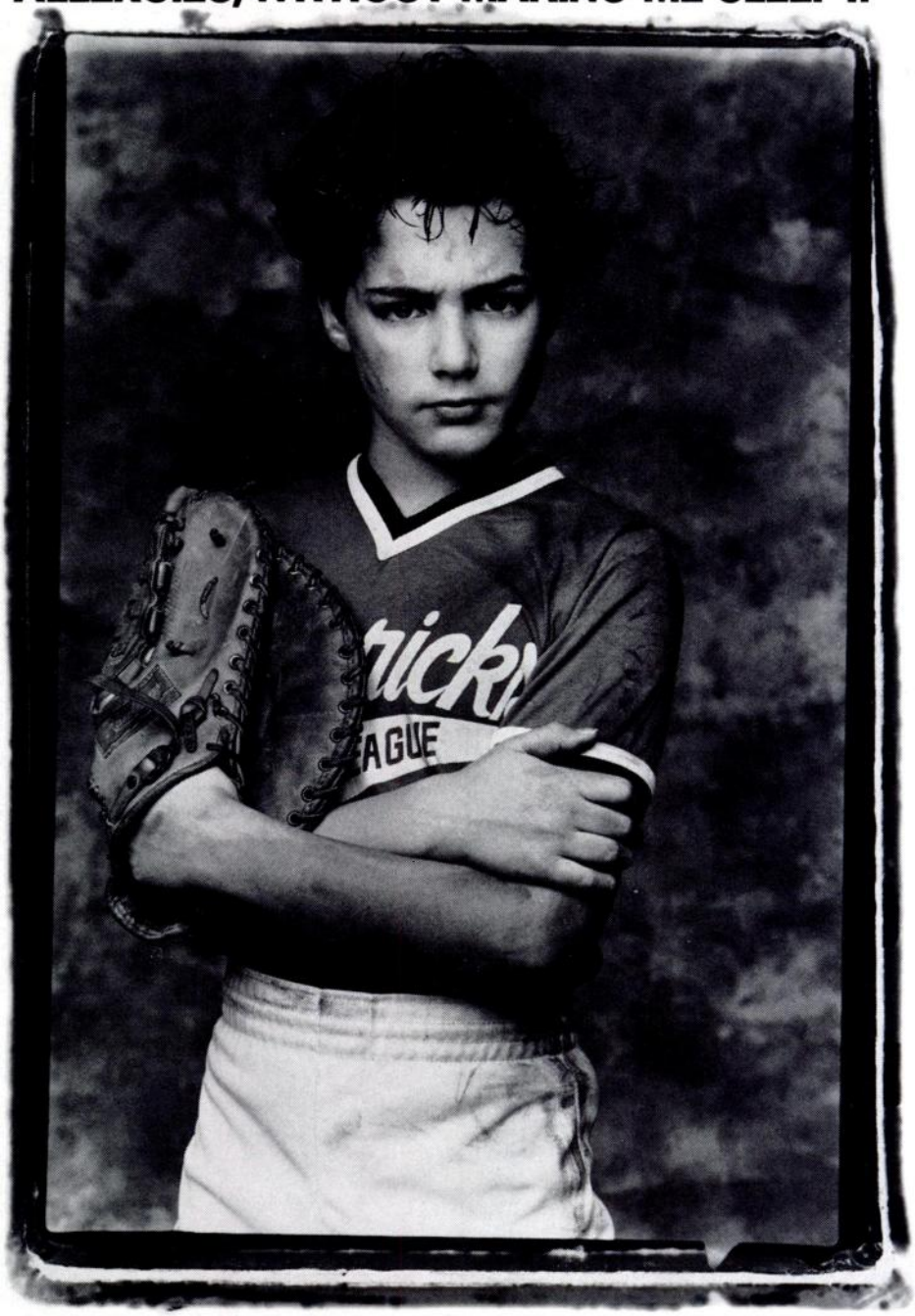
DESCRIPTION: Each milliliter of NASALCROM® (cromolyn sodium nasal solution, USP) contains 40 mg cromolyn sodium in purified water with benzalkonium chloride 0.01% and EDTA (edetate disodium) 0.01%.
INDICATIONS: NASALCROM is indicated for the prevention and treatment of the symptoms of allergic rhinitis.
CONTRAINDICATIONS: NASALCROM is contraindicated in those patients who have shown hypersensitivity to any of the ingredients.
PRECAUTIONS: General: Some patients may experience transient nasal stinging and/or sneezing immediately following instillation of NASALCROM. Except in rare occurrences, these experiences have not caused discontinuation of therapy.
In view of the biliary and renal routes of excretion for cromolyn sodium, consideration should be given to decreasing the dosage or discontinuing the administration of the drug in patients with impaired renal or hepatic function.
Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long term studies in mice (12 months intraperitoneal treatment followed by 6 months observation), hamsters (12 months intraperitoneal treatment followed by 12 months observation), and rats (18 months subcutaneous treatment) showed no neoplastic effect of cromolyn sodium.
No evidence of chromosomal damage or cytotoxicity was obtained in various mutagenesis studies.
No evidence of impaired fertility was shown in laboratory animal reproduction studies.
Pregnancy: Pregnancy Category B. Reproduction studies with cromolyn sodium administered parenterally to pregnant mice, rats, and rabbits in doses up to 338 times the human clinical doses produced no evidence of fetal malformations. Adverse fetal effects (increased resorptions and decreased fetal weight) were noted only at the very high parenteral doses that produced maternal toxicity. 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.
Drug Interaction During Pregnancy: Cromolyn sodium and isoproterenol were studied following subcutaneous injections in pregnant mice. Cromolyn sodium alone in doses of 60 to 540 mg/kg (38 to 338 times the human dose) did not cause significant increases in resorptions or major malformations. Isoproterenol alone at a dose of 2.7 mg/kg (90 times the human dose) increased both resorptions and malformations. The addition of cromolyn sodium (338 times the human dose) to isoproterenol (90 times the human dose) appears to have increased the incidence of both resorptions and malformations.
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 NASALCROM is administered to a nursing woman.
Pediatric Use: Safety and effectiveness in children below the age of 6 years have not been established.
ADVERSE REACTIONS: The most frequent adverse reactions occurring in the 430 patients included in the clinical trials with NASALCROM were sneezing (1 in 10 patients), nasal stinging (1 in 20), nasal burning (1 in 25), and nasal irritation (1 in 40). Headaches and bad taste were reported in about 1 in 50 patients. Epistaxis, postnasal drip, and rash were reported in less than one percent of the patients. One patient in the clinical trials developed anaphylaxis.
Adverse reactions which have occurred in the use of other cromolyn sodium formulations for inhalation include angioedema, joint pain and swelling, urticaria, cough, and wheezing. Other reactions reported rarely are serum sickness, periarteritic vasculitis, polymyositis, pericarditis, photodermatitis, exfoliative dermatitis, peripheral neuritis, and nephrosis.
NASALCROM® is a registered trademark of Fisons plc. Rev 3/85 FIS-035

FISONS
FISONS CORPORATION
BEDFORD, MA 01730

"I LIKE HOW FAST IT WORKS TO STOP MY ALLERGIES, WITHOUT MAKING ME SLEEPY."



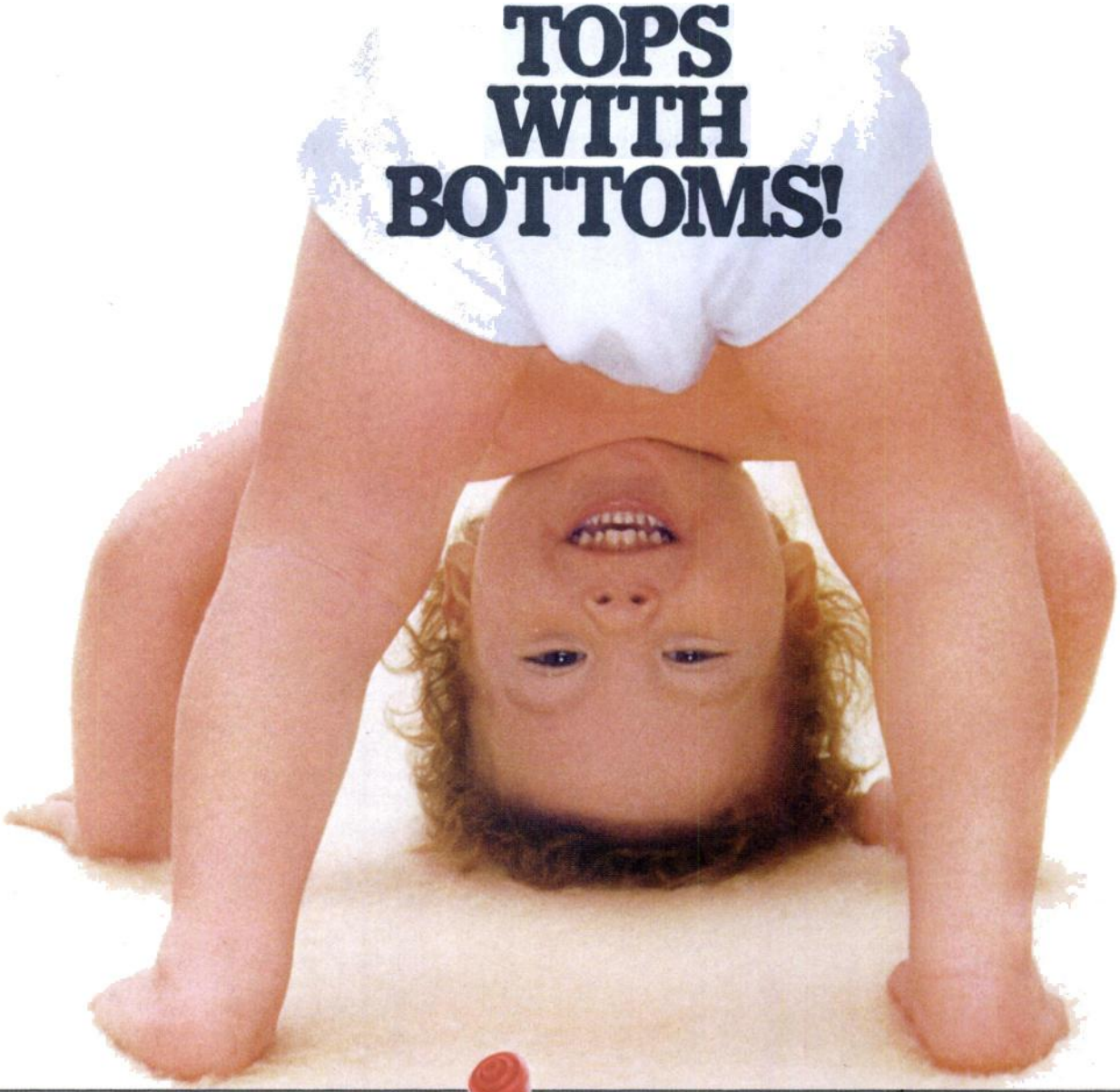
NASALCROM works rapidly—usually within the first few doses—to relieve the congestion, rhinorrhea, and sneezing of seasonal allergic rhinitis. However, for many patients, the side effects of traditional medications can be as troublesome as the allergic symptoms themselves. Unlike these medications, NASALCROM is extremely well-tolerated therapy, virtually uncomplicated by serious side effects, tolerance or contraindications.

NASAL SOLUTION
NASALCROM®
(cromolyn sodium / FISONS)

Stops allergic rhinitis rapidly, without traditional side effects

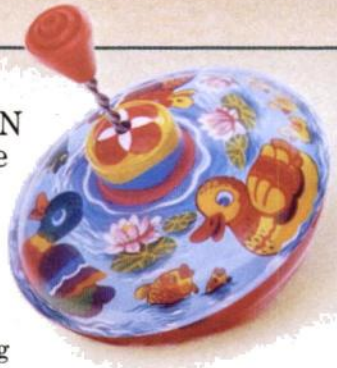
Schering

TOPS WITH BOTTOMS!



In diaper candidiasis, gentle LOTRIMIN Creamy Lotion spreads easily over wide areas — making it an ideal delivery system for babies. LOTRIMIN is highly effective in candidiasis[1]... and its safety record makes it tops to use, especially on infants.

Please see next page for brief summary of prescribing information.



LOTRIMIN®
(clotrimazole, USP)
CREAMY LOTION, 1%

DEPENDABLE IN DIAPER CANDIDIASIS...
IDEAL FOR BABY'S TENDER SKIN

Also available in Cream, USP 1% and Solution, USP 1%

LOTRIMIN®
(clotrimazole, USP)
CREAMY LOTION, 1%

DEPENDABLE IN DIAPER CANDIDIASIS...
IDEAL FOR BABY'S TENDER SKIN

FOR DERMATOLOGIC USE ONLY — NOT FOR OPHTHALMIC USE

INDICATIONS AND USAGE LOTRIMIN products are indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum,* and *Microsporum canis*; candidiasis due to *Candida albicans*; and tinea versicolor due to *Malassezia furfur.*

CONTRAINDICATIONS LOTRIMIN products are contraindicated in individuals who have shown hypersensitivity to any of their components.

WARNINGS LOTRIMIN products are not for ophthalmic use.

PRECAUTIONS General: If irritation or sensitivity develops with the use of clotrimazole, treatment should be discontinued and appropriate therapy instituted.

Information For Patients:
The patient should be advised to:
1. Use the medication for the full treatment time even though the symptoms may have improved. Notify the physician if there is no improvement after four weeks of treatment.
2. Inform the physician if the area of application shows signs of increased irritation (redness, itching, burning, blistering, swelling, oozing) indicative of possible sensitization.
3. Avoid the use of occlusive wrappings or dressings.
4. Avoid sources of infection or reinfection.

Laboratory Tests: If there is lack of response to clotrimazole, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens before instituting another course of antimycotic therapy.

Drug Interactions: Synergism or antagonism between clotrimazole and nystatin, or amphotericin B, or flucytosine against strains of *C. albicans* has not been reported.

Carcinogenesis, Mutagenesis, Impairment of Fertility: An 18-month oral dosing study with clotrimazole in rats has not revealed any carcinogenic effect.

In tests for mutagenesis, chromosomes of the spermatophores of Chinese hamsters which had been exposed to clotrimazole were examined for structural changes during the metaphase. Prior to testing, the hamsters had received five oral clotrimazole doses of 100 mg/kg body weight. The results of this study showed that clotrimazole had no mutagenic effect.

Usage in Pregnancy: Pregnancy Category B: The disposition of ^{14}C-clotrimazole has been studied in humans and animals. Clotrimazole is very poorly absorbed following dermal application or intravaginal administration to humans. (See **CLINICAL PHARMACOLOGY.**)

In clinical trials, use of vaginally applied clotrimazole in pregnant women in their second and third trimesters has not been associated with ill effects. There are, however, no adequate and well-controlled studies in pregnant women during the first trimester of pregnancy.

Studies in pregnant rats with intravaginal doses up to 100 mg/kg have revealed no evidence of harm to the fetus due to clotrimazole.

High oral doses of clotrimazole in rats and mice ranging from 50 to 120 mg/kg resulted in embryotoxicity (possibly secondary to maternal toxicity), impairment of mating, decreased litter size and number of viable young and decreased pup survival to weaning. However, clotrimazole was not teratogenic in mice, rabbits and rats at oral doses up to 200, 180 and 100 mg/kg, respectively. Oral absorption in the rat amounts to approximately 90% of the administered dose.

Because animal reproduction studies are not always predictive of human response, this drug should be used only if clearly indicated during the first trimester of pregnancy.

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 clotrimazole is used by a nursing woman.

Pediatric Use: Safety and effectiveness in children have been established for clotrimazole when used as indicated and in the recommended dosage.

ADVERSE REACTIONS The following adverse reactions have been reported in connection with the use of clotrimazole: erythema, stinging, blistering, peeling, edema, pruritus, urticaria, burning, and general irritation of the skin.

OVERDOSAGE Acute overdosage with topical application of clotrimazole is unlikely and would not be expected to lead to a life-threatening situation.

DOSAGE AND ADMINISTRATION Gently massage sufficient LOTRIMIN into the affected and surrounding skin areas twice a day, in the morning and evening.

Clinical improvement, with relief of pruritus, usually occurs within the first week of treatment with LOTRIMIN. If the patient shows no clinical improvement after four weeks of treatment with LOTRIMIN, the diagnosis should be reviewed.

HOW SUPPLIED LOTRIMIN Cream 1% is supplied in 15, 30, 45 and 90-g tubes (NDC 0085-0613-02, 05, 04, 03, respectively); boxes of one.

LOTRIMIN Lotion 1% is supplied in 30 ml bottles (NDC 0085-0707-02); boxes of one.

Shake well before using.

LOTRIMIN Solution 1% is supplied in 10 ml and 30 ml plastic bottles (NDC 0085-0182-02, 04, respectively); boxes of one.

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

REFERENCE: 1. Among patients using LOTRIMIN Cream. Spiekermann PH, Young MD: Clinical evaluation of clotrimazole: A broad-spectrum antifungal agent. *Arch Dermatol* 112:350-352, March 1976.

Schering Corporation
Kenilworth, New Jersey 07033

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Caring for the Young Athlete

As children and adolescents become more active in sports, you need a guide that has answers to common and special sports medicine problems.

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

The book discusses prevention and management of sports-related illness and injuries. Other chapters deal with nutrition, stress reduction, and the role of the athletic trainer.

This book is for every physician who has been or will be involved in sports medicine. As an advisor to parents. As a team physician. As the parent of a young athlete from elementary school through high school.

American Academy of Pediatrics

American Academy of Pediatrics (AAP)
Publications Department
P.O. Box 927, Elk Grove Village, IL 60007

Please send me _____ copies of *Sports Medicine: Health Care for Young Athletes* @ $20.00 each.
☐ Payment of $_____ enclosed.
☐ Bill me. Formal purchase order required.
☐ Bill me for UPS delivery within 2 weeks.

Name _____

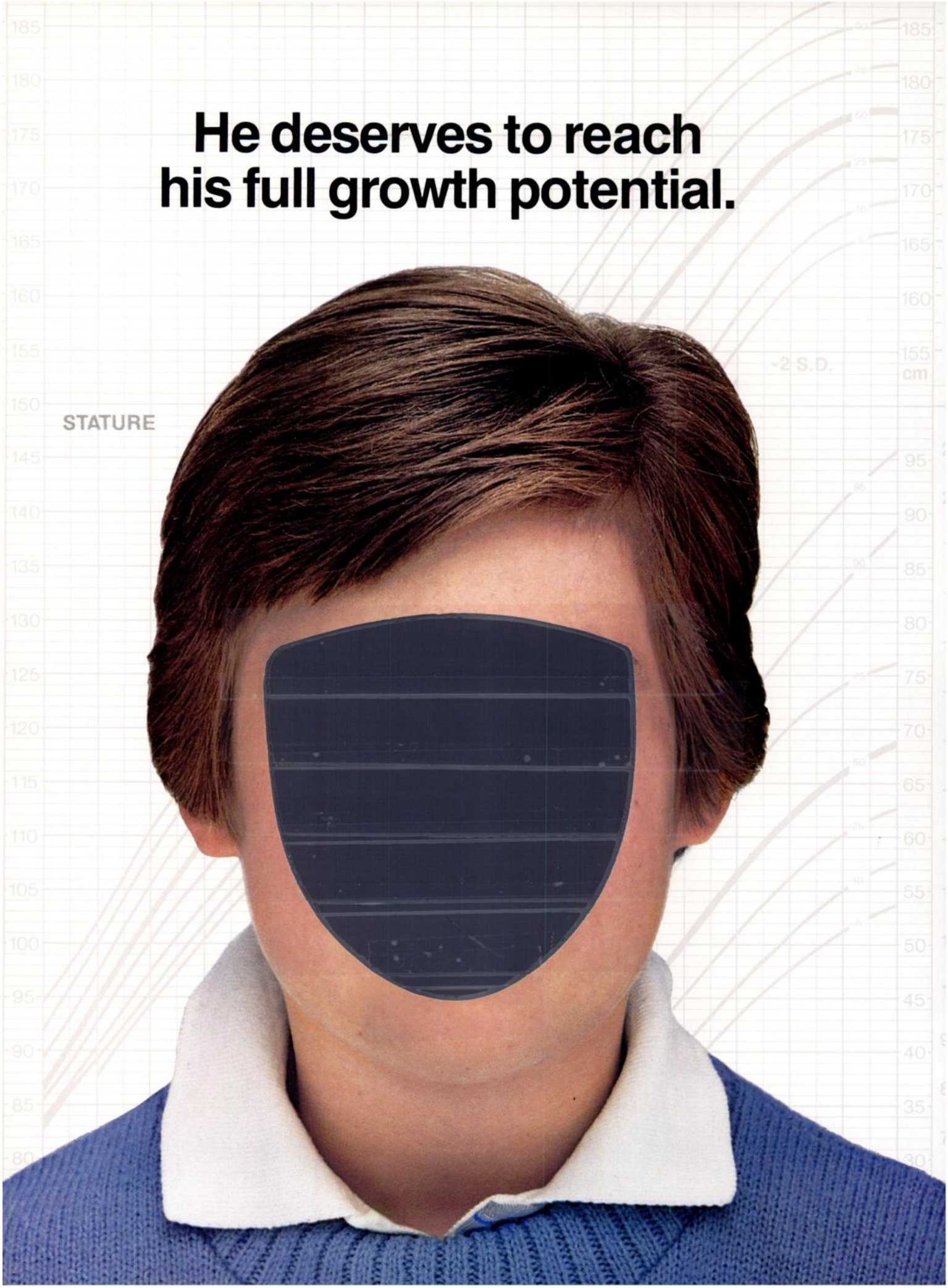
Address _____

City _____ State _____ Zip _____

☐ AAP Member ☐ Non-member

PED

He deserves to reach his full growth potential.



Physicians involved in child growth and development are aware of the importance of measuring and evaluating linear growth as one of the most sensitive means for assessing a child's overall well-being.[1]

Only Half as Many Girls as Boys Are Treated

Yet traditionally, among children with growth hormone inadequacy, only half as many girls as boys receive treatment—a fact that is borne out in an ongoing national study of Protropin® (somatrem for injection) in over 1,700 children with growth hormone inadequacy.[2]

Recognizing a Growth Problem

Short stature may result from a variety of causes. Girls and boys who fit the following criteria deserve to be evaluated further.[3,4]

- a growth rate of less than 5 cm (2 in) per year before age 5
- a growth rate of less than 4.5 cm (1.8 in) per year after age 5
- progressive deviation from the normal growth curve
- a decline in growth rate based on measurements made over four to six months

Early Referral for Greater Long-Term Growth

Early identification and referral of boys and girls can be especially beneficial because early treatment of a growth hormone inadequate child results in a greater clinical response to Protropin growth hormone therapy.[2]

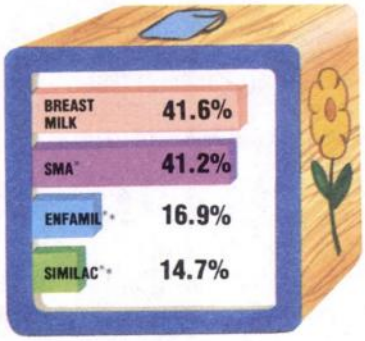
For more information, please call toll-free: 1-800-821-8590 or 1-800-551-2231.

Protropin®
[somatrem for injection]
Growth Hormone
from
Genentech®, Inc.

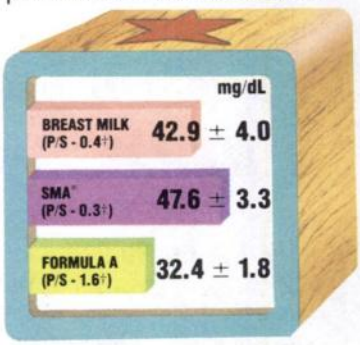
A NEW FACE...

A FAMILIAR PROFILE

Higher monounsaturated fat levels

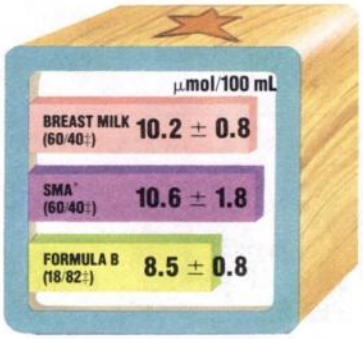


Higher levels of cardio-protective HDL cholesterol[1]

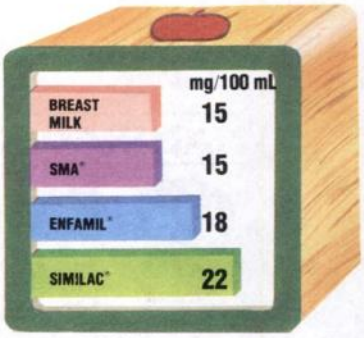


Lift label for contents

Higher levels of cystine



Natural sodium content



*All data for competitive products derived from product labels, *PDR*®, or analyses.
†Polyunsaturated/saturated fat ratio. ‡Whey/casein ratio.

NATURAL SODIUM LEVEL

S·M·A™ Infant Formula

The nutritional profile closest to breast milk

Wyeth

Behind our new labels... the building blocks of good nutrition

Higher monounsaturated fat lowers total and LDL cholesterol, maintains HDL cholesterol levels[2]
Diets high in monounsaturated fats have been effective in lowering total and LDL cholesterol levels while not causing a statistically significant decrease in HDL cholesterol in adults.[2]

Higher levels of cardio-protective HDL cholesterol[1]
Infants fed SMA maintained the high levels of protective HDL cholesterol characteristic of those receiving breast milk. Formula with a higher P/S ratio significantly lowered HDL levels.[1]

Higher levels of cystine
A whey-predominant formula, SMA, like breast milk, produces higher plasma concentrations of cystine than a casein-predominant formula.[3] Cystine is an amino acid considered essential to newborn growth and development.

The sodium content closest to mother's milk...important because a naturally low sodium diet is prudent for infants
Infants fed a higher sodium diet showed an increase in blood pressure compared to those fed a diet lower in sodium for the first 6 months of life.[4]

Note: Based on ingredients statements from product labels, *PDR*®, or analyses compared to average values of mature breast milk determined in 11 recent studies.

NATURAL SODIUM LEVEL

S·M·A™ Infant Formula

The nutritional profile closest to breast milk

References: 1. Carlson SE, De Voe PW, Barness LA: Effect of infant diets with different polyunsaturated to saturated fat ratios on circulating high-density lipoproteins. *J Ped Gastroenterol Nutr 1*:303-309, 1982. **2.** Mattson FH, Grundy SM: Comparison of effects of dietary saturated, monounsaturated, and polyunsaturated fatty acids on plasma lipids and lipoproteins in man. *J Lipid Res 26*:194-202, 1985. **3.** Järvenpää AL, *et al:* Milk protein quantity and quality in the term infant. II. Effects on acidic and neutral amino acids. *Pediatrics 70*:221-230, 1982. **4.** Hofman A, Hazebroek A, Valkenburg HA: A randomized trial of sodium intake and blood pressure in newborn infants. *JAMA 250*:370-373, 1983.

Wyeth Laboratories
Philadelphia, PA 19101
™

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

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

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

c. 1986, Wyeth Laboratories

So does she.

Please see Protropin® (somatrem for injection) brief summary on next page.

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Protropin®
[somatrem for injection]

Growth Hormone

A Pure Product of Biotechnology

Because *All* Children Deserve to Reach Their Full Growth Potential

- Growth hormone in almost limitless supply, for the treatment of *all* children lacking adequate endogenous growth hormone
- Safety and efficacy confirmed in the most complete clinical studies conducted for any growth hormone product

References:

1. Underwood LE, Van Wyk JJ: Normal and aberrant growth, in Wilson JD, Foster DW (eds) *Textbook of Endocrinology*, ed 7. Philadelphia, WB Saunders Co, 1985, p 175.
2. *National Cooperative Growth Study*. Data on file, Genentech, Inc, San Francisco, CA.
3. Underwood LE, Rosenfeld RG, Hintz RL: *Human Growth and Growth Disorders: An Update*. University of North Carolina School of Medicine and Stanford University School of Medicine, October 1985.
4. Kaplan SA: Growth and growth hormone: Disorders of the anterior pituitary, in Kaplan SA (ed) *Clinical Pediatric and Adolescent Endocrinology*. Philadelphia, WB Saunders Co, 1982.

Brief summary of prescribing information

PROTROPIN® (somatrem for injection)

INDICATIONS AND USAGE Protropin (somatrem for injection) is indicated only for the long term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion. Other etiologies of short stature should be excluded.

CONTRAINDICATIONS Protropin (somatrem for injection) should not be used in subjects with closed epiphyses. Protropin growth hormone should not be used when there is evidence of any progression of underlying intracranial lesion. Intracranial lesions must be inactive and antitumor therapy complete prior to instituting therapy. Protropin growth hormone should be discontinued if there is evidence of recurrent tumor growth. Protropin growth hormone, when reconstituted with Bacteriostatic Water for Injection, USP (Benzyl Alcohol Preserved) should not be used in patients with a known sensitivity to benzyl alcohol.

WARNINGS Benzyl alcohol as a preservative in Bacteriostatic Water for Injection has been associated with toxicity in newborns. When administering Protropin to newborns, reconstitute with Water for Injection, USP USE ONLY ONE DOSE PER VIAL AND DISCARD THE UNUSED PORTION.

PRECAUTIONS Protropin (somatrem for injection) should be used only by physicians experienced in the diagnosis and management of patients with pituitary growth hormone deficiency. Patients with growth hormone deficiency secondary to an intracranial lesion should be examined frequently for progression or recurrence of the underlying disease process. Because Protropin growth hormone may induce a state of insulin resistance, patients should be observed for evidence of glucose intolerance. Concomitant glucocorticoid therapy may inhibit the growth promoting effect of Protropin growth hormone. Patients with coexisting ACTH deficiency should have their glucocorticoid replacement dose carefully adjusted to avoid an inhibitory effect on growth. Hypothyroidism may develop during Protropin treatment. Untreated hypothyroidism prevents optimal response to Protropin growth hormone. Therefore, patients should have periodic thyroid function tests and should be treated with thyroid hormone when indicated. Slipped capital femoral epiphysis may occur more frequently in patients with endocrine disorders. Physicians and parents should be alert to the development of a limp or complaints of hip or knee pain in Protropin-treated patients. As for any protein, a systemic allergic reaction may occur. See WARNINGS for use of Bacteriostatic Water for Injection, USP (Benzyl Alcohol Preserved) in newborns.

ADVERSE REACTIONS

A. Protropin (somatrem for injection) Approximately 30 percent of all Protropin treated patients developed persistent antibodies to growth hormone. In patients who had been previously treated with pituitary-derived growth hormone, one of twenty-two subjects developed persistent antibodies to growth hormone in response to Protropin therapy. In children not previously treated with any exogenous growth hormone approximately 40 percent developed persistent antibodies to growth hormone. In general, the growth hormone antibodies are not neutralizing and do not interfere with the growth response to Protropin growth hormone. One of eighty-four subjects treated with Protropin growth hormone for 6 to 36 months developed antibodies associated with high binding capacities and failed to respond to treatment with Protropin growth hormone. In addition to an evaluation of compliance with treatment program and thyroid status, testing for antibodies to human growth hormone should be carried out in any patient who fails to respond to therapy. Additional short term immunologic and renal function studies were carried out in a group of patients after approximately two years of treatment to detect other potential adverse effects of antibodies to growth hormone. The antibody was determined to be of the IgG class; no antibodies to growth hormone of the IgE class were detected. Testing included immune complex determination, measurement of total hemolytic complement and specific complement components, and immunochemical analyses. No adverse effects of growth hormone antibody formation were observed. These findings are supported by a toxicity study conducted in a primate model in which a similar antibody response to growth hormone was observed. Protropin (somatrem for injection), administered to monkeys by intramuscular injection at doses of 125 and 625 μg/kg t.i.w., was compared to pituitary-human growth hormone at the same doses and with placebo over a period of 90 days. Most monkeys treated with high-dose Protropin growth hormone developed persistent antibodies at week four. There were no biologically significant drug related changes in standard laboratory variables. Histopathologic examination of the kidney and other selected organs (pituitary, lungs, liver and pancreas) showed no treatment related toxicity. There was no evidence of immune complexes or immune complex toxicity when the kidney was also examined for the presence of immune complexes and possible toxic effects of immune complexes by immunohistochemistry and electron microscopy.

B. Bacteriostatic Water for Injection, USP (Benzyl Alcohol Preserved) Toxicity in newborns has been associated with benzyl alcohol as a preservative (see WARNINGS).

OVERDOSAGE The recommended dosage of up to 0.1 mg (0.2 IU) per kg body weight three times per week should not be exceeded due to the potential risk of side effects.

DOSAGE AND ADMINISTRATION The Protropin (somatrem for injection) dosage must be individualized for each patient. A dosage and schedule of up to 0.1 mg/kg (0.2 IU/kg) body weight administered three times per week (t.i.w.) by intramuscular injection is recommended. After the dose has been determined, reconstitute each 5 mg vial with 1-5 mL of Bacteriostatic Water for Injection, USP (Benzyl Alcohol Preserved) only. For use in newborns see WARNINGS. The pH of Protropin after reconstitution is approximately 7.8. To prepare the Protropin solution, inject the Bacteriostatic Water for Injection, USP (Benzyl Alcohol Preserved) into the vial of Protropin growth hormone, aiming the stream of liquid against the glass wall. Then swirl the product vial with a GENTLE rotary motion until the contents are completely dissolved. DO NOT SHAKE. Because Protropin growth hormone is a protein, shaking can result in a cloudy solution. Immediately after reconstitution, the Protropin solution should be clear. Occasionally, after refrigeration, you may notice that small colorless particles of protein are present in the Protropin solution. This is not unusual for proteins like Protropin growth hormone. If the solution is cloudy immediately after reconstitution or refrigeration the contents MUST NOT be injected. Before and after injections the septum of the vial should be wiped with an antiseptic solution to prevent contamination of the contents after repeated needle insertions. It is recommended that Protropin growth hormone be administered using sterile, disposable syringes and needles. The syringes should be of small enough volume that the prescribed dose can be drawn from the vial with reasonable accuracy. The needle should be of sufficient length (usually 1 inch or more) to ensure that the injection reaches the muscular layer.

Genentech®, Inc.
460 Point San Bruno Blvd.
South San Francisco, CA 94080

NOW... The standard ADD medication in once-a-day dosage

One 20-mg sustained-release Ritalin-SR tablet given at breakfast provides a therapeutic effect equivalent to that of the standard 10-mg tablet given twice daily.[1]

Eliminates the need to take medication in school

"The availability of a sustained-release (SR) formulation of methylphenidate would greatly improve patient compliance and lessen school-related dosing problems..."[1]

Improves compliance... affords greater convenience and greater privacy

Ritalin is indicated as adjunctive therapy to other remedial measures (psychological, educational, social) for ADD in children. Drug treatment is not indicated for all children with ADD. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or primary psychiatric disorders, including psychosis.

Also available: Regular tablets of 5, 10 and 20 mg.

Before prescribing, please consult Brief Summary of Prescribing Information on next page.

RITALIN-SR®

methylphenidate

20-mg sustained-release tablets

© 1985, CIBA 174-2492-A

CIBA

Now— a standard therapy for ADD becomes more convenient... more simple... more private...

RITALIN-SR®

methylphenidate

20-mg sustained-release tablets

Reference

1. Whitehouse D, Shah U, Palmer FB: *J Clin Psychiatry* 1980 (Aug); 41(8):282-285.

Part of the ADD management team— only when medication is indicated

C85-55 (Rev. 11/85)
665615

Ritalin® hydrochloride
methylphenidate hydrochloride
tablets USP

C II

Ritalin-SR®
methylphenidate hydrochloride USP
sustained-release tablets

C II

BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE INSERT)

CONTRAINDICATIONS

Marked anxiety, tension, and agitation are contraindications to Ritalin, since the drug may aggravate these symptoms. Ritalin is contraindicated also in patients known to be hypersensitive to the drug, in patients with glaucoma, and in patients with motor tics or with a family history or diagnosis of Tourette's syndrome.

WARNINGS

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

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

Ritalin should not be used for severe depression of either exogenous or endogenous origin. Clinical experience suggests that in psychotic children, administration of Ritalin may exacerbate symptoms of behavior disturbance and thought disorder.

Ritalin should not be used for the prevention or treatment of normal fatigue states.

There is some clinical evidence that Ritalin may lower the convulsive threshold in patients with prior history of seizures, with prior EEG abnormalities in absence of seizures, and, very rarely, in absence of history of seizures and no prior EEG evidence of seizures. Safe concomitant use of anticonvulsants and Ritalin has not been established. In the presence of seizures, the drug should be discontinued.

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

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

Drug Interactions

Ritalin may decrease the hypotensive effect of guanethidine. Use cautiously with pressor agents and MAO inhibitors.

Human pharmacologic studies have shown that Ritalin may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (phenobarbital, diphenylhydantoin, primidone), phenylbutazone, and tricyclic antidepressants (imipramine, desipramine). Downward dosage adjustments of these drugs may be required when given concomitantly with Ritalin.

Usage in Pregnancy

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

Drug Dependence

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

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

PRECAUTIONS

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

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

Drug treatment is not indicated in all cases of this behavioral syndrome and should be considered only in light of the complete history and evaluation of the child. The decision to prescribe Ritalin should depend on the physician's assessment of the chronicity and severity of the child's symptoms and their appropriateness for his/her age. Prescription should not depend solely on the presence of one or more of the behavioral characteristics.

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

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

ADVERSE REACTIONS

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

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

DOSAGE AND ADMINISTRATION

Dosage should be individualized according to the needs and responses of the patient.

Adults

Tablets: Administer in divided doses 2 or 3 times daily, preferably 30 to 45 minutes before meals. Average dosage is 20 to 30 mg daily. Some patients may require 40 to 60 mg daily. In others, 10 to 15 mg daily will be adequate. Patients who are unable to sleep if medication is taken late in the day should take the last dose before 6 p.m.

SR Tablets: Ritalin-SR tablets have a duration of action of approximately 8 hours. Therefore, Ritalin-SR tablets may be used in place of Ritalin tablets when the 8-hour dosage of Ritalin-SR corresponds to the titrated 8-hour dosage of Ritalin. Ritalin-SR tablets must be swallowed whole and never crushed or chewed.

Children (6 years and over)

Ritalin should be initiated in small doses, with gradual weekly increments. Daily dosage above 60 mg is not recommended.

If improvement is not observed after appropriate dosage adjustment over a one-month period, the drug should be discontinued.

Tablets: Start with 5 mg twice daily (before breakfast and lunch) with gradual increments of 5 to 10 mg weekly.

SR Tablets: Ritalin-SR tablets have a duration of action of approximately 8 hours. Therefore, Ritalin-SR tablets may be used in place of Ritalin tablets when the 8-hour dosage of Ritalin-SR corresponds to the titrated 8-hour dosage of Ritalin. Ritalin-SR tablets must be swallowed whole and never crushed or chewed.

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

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

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

OVERDOSAGE

Signs and symptoms of acute overdosage, resulting principally from overstimulation of the central nervous system and from excessive sympathomimetic effects, may include the following: vomiting, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitations, cardiac arrhythmias, hypertension, mydriasis, and dryness of mucous membranes.

Treatment consists of appropriate supportive measures. The patient must be protected against self-injury and against external stimuli that would aggravate overstimulation already present. If signs and symptoms are not too severe and the patient is conscious, gastric contents may be evacuated by induction of emesis or gastric lavage. In the presence of severe intoxication, use a carefully titrated dosage of a *short-acting* barbiturate *before* performing gastric lavage.

Intensive care must be provided to maintain adequate circulation and respiratory exchange; external cooling procedures may be required for hyperpyrexia.

Efficacy of peritoneal dialysis or extracorporeal hemodialysis for Ritalin overdosage has not been established.

HOW SUPPLIED

Tablets 5 mg — round, yellow
(imprinted CIBA 7)
Bottles of 100 ..... NDC 0083-0007-30
Bottles of 500 ..... NDC 0083-0007-35
Bottles of 1000 ..... NDC 0083-0007-40

Tablets 10 mg — round, pale green, scored
(imprinted CIBA 3)
Bottles of 100 ..... NDC 0083-0003-30
Bottles of 500 ..... NDC 0083-0003-35
Bottles of 1000 ..... NDC 0083-0003-40
Accu-Pak® Unit Dose (blister pack)
Box of 100 (strips of 10) ..... NDC 0083-0003-32

Tablets 20 mg — round, pale yellow, scored
(imprinted CIBA 34)
Bottles of 100 ..... NDC 0083-0034-30
Bottles of 1000 ..... NDC 0083-0034-40

Protect from light.
Dispense in tight, light-resistant container (USP).

SR Tablets 20 mg — round, white, coated
(imprinted CIBA 16)
Bottles of 100 ..... NDC 0083-0016-30

Note: SR Tablets are color-additive free.

Do not store above 86°F (30°C). Protect from moisture.
Dispense in tight, light-resistant container (USP).

C85-55 (Rev. 11/85)

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May 9-14, 1987

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The full meeting program and registration materials will be sent to all AAP members in January. Non-members can call or write for a free program. Mark your calendar now! Don't miss this important event.

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American Academy of Pediatrics

HEALTH OF AMERICAN DAUGHTERS (1841)

During the mid 1840s a number of American authors commented about the poor state of health of American daughters. None wrote more fervently about this than Mrs Sigourney of Hartford, Connecticut.

In 1841 she wrote as follows:

Mothers, is there any thing we can do, to acquire for our daughters a good constitution? Is there truth in the sentiment sometimes repeated, that our sex is becoming more and more effeminate? Are we capable of enduring hardship as our grandmothers were? Are we as well versed in the details of housekeeping, as able to bear them without fatigue, as our mothers? Have our daughters as much stamina of constitution, as much aptitude for domestic duty, as we ourselves possess? These questions are not interesting to us simply as individuals. They affect the welfare of the community.

Tenderly interested as we are for the health of our offspring, let us devote peculiar attention to that of our daughters. Their delicate frames require more care, in order to become vigorous, and in more danger through the prevalence of fashion. Frequent and thorough ablutions, a simple and nutritious diet, we should secure for all our children.

But I plead for the little girl, that she may have air and exercise, as well as her brother, and that she may not be too much blamed, if in her earnest play, she happen to tear or soil her apron. I plead that she not be punished as a romp, if she keenly enjoy those activities, which city gentility proscribes. I plead that the ambition to make her accomplished, do not chain her to her piano, till the spinal column which should consolidate her frame, starts aside like a broken reed; nor bow her over her book, till the vital energy, which ought to pervade the whole system, mounts into the brain, and kindles the death-fever.

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

REFERENCE

1. Sigourney LH: Health of daughters. *The Parents Magazine.* Concord, NH, James Thompson, 1841, vol 2, pp 63–64.

W. H. AUDEN ON MEDICINE

W. H. Auden (1907–1973), the Anglo-American poet, wrote the following provocative description of physicians.

I can remember my father, who was a physician, quoting to me when I was a young boy an aphorism by Sir William Osler: "Care more for the individual patient than for the special features of his disease." In other words, a doctor, like anyone else who has to deal with human beings, each of them unique, cannot be a scientist; he is either, like the surgeon, a craftsman, or, like the physician and the psychologist, an artist. As Novalis (a German romantic poet) wrote: "Every sickness is a musical problem, every cure a musical solution . . . . " This means that in order to be a good doctor a man must also have a good character, that is to say, whatever weaknesses and foibles he may have, he must love his fellow human beings in the concrete and desire their good before his own. A doctor, like a politician, who loves other men only in the abstract or regards them only in the abstract or regards them simply as a source of income can, however clever, do nothing but harm.

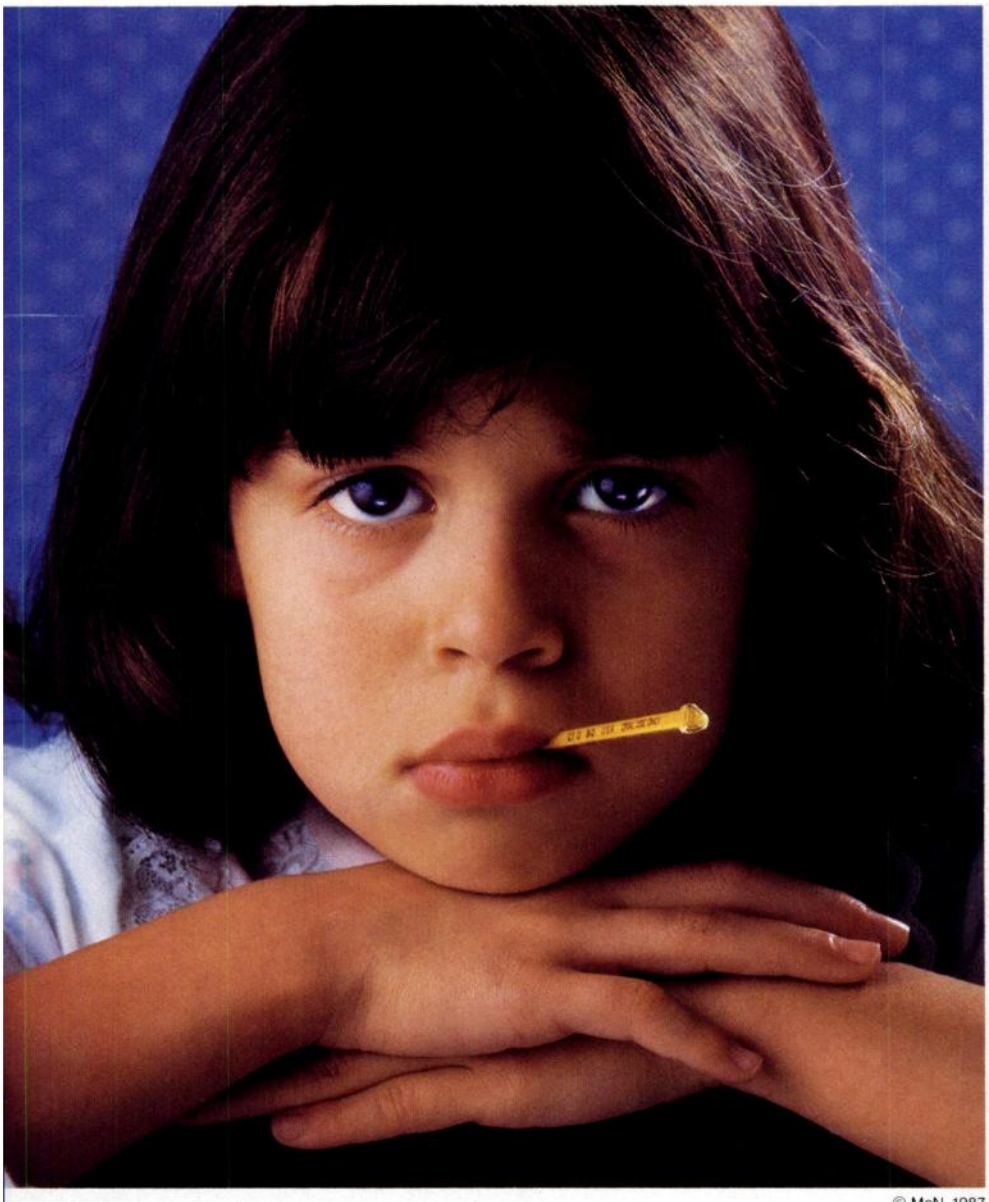
It is precisely those members of the medical profession who make the bogus claim that they are "scientific" who are most likely to refuse to consider new evidence. To its shame, the profession has always had its acknowledged "Holy Office," which has dealt with the heterodox, like Kasper Wolff and Semmelweis, every bit as unscrupulously and ruthlessly as the Inquisition ever dealt with heretics.

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

REFERENCE

1. Auden WH: *A Certain World.* New York, Viking Press, 1970, pp 256–257.

Bring back the smiles fever took away.



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When the aches and pains of fever turned Maria's smile into a frown, relieving her discomfort was a key concern. That's why her pediatrician recommended rest, liquids, and Children's TYLENOL® acetaminophen.

Equally effective as aspirin

Milligram for milligram, acetaminophen is as effective an antipyretic as aspirin.[1] And, like aspirin, TYLENOL® products promptly reduce the aches and pains that so often accompany fever.[2]

With a superior safety profile

While aspirin therapy may be associated with frequent GI upset or hypersensitivity reactions, these complications are rare with Children's TYLENOL® products.[3]

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Next time fever takes away your patients' smiles, you can help them feel better fast—by recommending Children's TYLENOL® products.

References: 1. Tarlin L, et al: *Am J Dis Child* 1972; 124:880-882. **2.** Cooper SA: *Arch Intern Med* 1981; 141:282-285. **3.** Lorin MI: *Contemp Pediatr* 1986; 3:35-46.

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The drug of choice[1-3] for absence (petit mal) seizures

*Minor alterations have been observed in some hepatic and renal function tests. Ethosuximide should therefore be administered with extreme caution to patients with known hepatic or renal disease.

REFERENCES: 1. Wilder BJ, Bruni J: *Seizure Disorders: A Pharmacological Approach to Treatment*. New York, Raven Press, 1981, p 98. 2. Green JB: Epilepsy in adolescents and adults, in Conn HF (ed): *Current Therapy 1982*. Philadelphia, WB Saunders Co, 1982, pp 720-726. 3. Fernandez RJ, Samuels MA: Epilepsy, in Samuels MA (ed): *Manual of Neurologic Therapeutics with Essentials of Diagnosis*. Boston, Little Brown & Co, 1981, pp 75-117.

PARKE-DAVIS

Please see next page for brief summary of prescribing information.

ZARONTIN® (ethosuximide capsules, USP)

Before prescribing, please see full prescribing information.
A Brief Summary follows.

INDICATION: Zarontin is indicated for the control of absence (petit mal) epilepsy.
CONTRAINDICATION: Ethosuximide should not be used in patients with a history of hypersensitivity to succinimides.
WARNINGS: Blood dyscrasias, including some with fatal outcome, have been reported to be associated with the use of ethosuximide; therefore, periodic blood counts should be performed.

Ethosuximide is capable of producing morphological and functional changes in the animal liver. In humans, abnormal liver and renal function studies have been reported.

Ethosuximide should be administered with extreme caution to patients with known liver or renal disease. Periodic urinalysis and liver function studies are advised for all patients receiving the drug.

Cases of systemic lupus erythematosus have been reported with the use of ethosuximide. The physician should be alert to this possibility.

Usage in Pregnancy: The effects of Zarontin in human pregnancy and nursing infants are unknown.

Recent reports suggest an association between the use of anticonvulsant drugs by women with epilepsy and an elevated incidence of birth defects in children born to these women. Data are more extensive with respect to phenytoin and phenobarbital, but these are also the most commonly prescribed anticonvulsants; less systematic or anecdotal reports suggest a possible similar association with the use of all known anticonvulsant drugs.

The reports suggesting an elevated incidence of birth defects in children of drug-treated epileptic women cannot be regarded as adequate to prove a definite cause and effect relationship. There are intrinsic methodologic problems in obtaining adequate data on drug teratogenicity in humans; the possibility also exists that other factors, eg, genetic factors or the epileptic condition itself, may be more important than drug therapy in leading to birth defects. The great majority of mothers on anticonvulsant medication deliver normal infants. It is important to note that anticonvulsant drugs should not be discontinued in patients in whom the drug is administered to prevent major seizures because of the strong possibility of precipitating status epilepticus with attendant hypoxia and threat to life. In individual cases where the severity and frequency of the seizure disorder are such that the removal of medication does not pose a serious threat to the patient, discontinuation of the drug may be considered prior to and during pregnancy, although it cannot be said with any confidence that even minor seizures do not pose some hazard to the developing embryo or fetus.

The prescribing physician will wish to weigh these considerations in treating or counseling epileptic women of childbearing potential.

Hazardous Activities: Ethosuximide may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a motor vehicle or other such activity requiring alertness; therefore, the patient should be cautioned accordingly.
PRECAUTIONS: Ethosuximide, when used alone in mixed types of epilepsy, may increase the frequency of grand mal seizures in some patients.

As with other anticonvulsants, it is important to proceed slowly when increasing or decreasing dosage, as well as when adding or eliminating other medication. Abrupt withdrawal of anticonvulsant medication may precipitate absence (petit mal) status.
ADVERSE REACTIONS: Gastrointestinal System: Gastrointestinal symptoms occur frequently and include anorexia, vague gastric upset, nausea and vomiting, cramps, epigastric and abdominal pain, weight loss, and diarrhea.

Hemopoietic System: Hemopoietic complications associated with the administration of ethosuximide have included leukopenia, agranulocytosis, pancytopenia, aplastic anemia, and eosinophilia.

Nervous System: Neurologic and sensory reactions reported during therapy with ethosuximide have included drowsiness, headache, dizziness, euphoria, hiccups, irritability, hyperactivity, lethargy, fatigue, and ataxia. Psychiatric or psychological aberrations associated with ethosuximide administration have included disturbances of sleep, night terrors, inability to concentrate, and aggressiveness. These effects may be noted particularly in patients who have previously exhibited psychological abnormalities. There have been rare reports of paranoid psychosis, increased libido, and increased state of depression with overt suicidal intentions.

Integumentary System: Dermatologic manifestations which have occurred with the administration of ethosuximide have included urticaria, Stevens-Johnson syndrome, systemic lupus erythematosus, and pruritic erythematous rashes.

Miscellaneous: Other reactions reported have included myopia, vaginal bleeding, swelling of the tongue, gum hypertrophy, and hirsutism.

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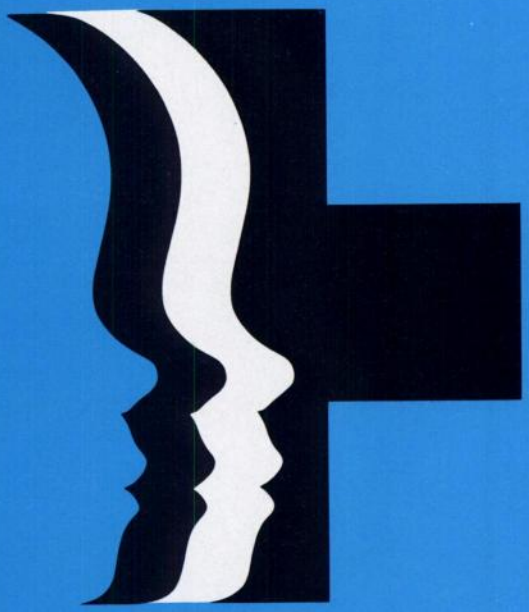

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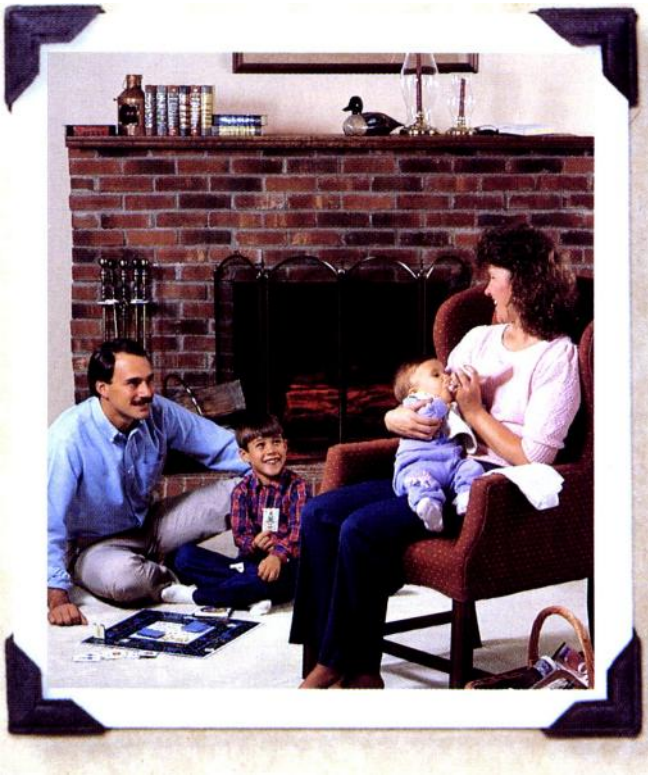

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Allergy is more common in families of milk-allergic infants. In fact, in a study of 206 milk-allergic infants, atopy was reported in 85% of the families.[1] And, the type of feeding has been shown to affect the development of atopic disease.[2]

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References

1. Clein NW: Cow's milk allergy in infants and children. *Int Arch Allergy* 13:245-256, 1958.
2. Businco L, Marchetti F, Pellegrini G, et al: Prevention of atopic disease in "at-risk newborns" by prolonged breast-feeding. *Ann Allergy* 51:296-299, 1983.
3. Harris NJ, Petts V, Penny R: Cow's milk allergy as a cause of infantile colic: Immunofluorescent studies on jejunal mucosa. *Aust Paediatr J* 13:276-281, 1977.
4. Cowan CC Jr, Brownlee RC Jr, De Loache WR, et al: A soy protein isolate formula in the management of allergy in infants and children. *South Med J* 62:389-393, 1969.

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Please see next page for brief summary of prescribing information.

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LIQUID

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PHENYLEPHRINE HYDROCHLORIDE	5 mg
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GUAIFENESIN	100 mg
ALCOHOL	5%

Before prescribing or administering, see package circular for full product information. The following is a brief summary.

INDICATIONS AND USAGE: ENTEX LIQUID is indicated for the symptomatic relief of sinusitis, bronchitis, pharyngitis, and coryza when these conditions are associated with nasal congestion and inspissated mucus in the lower respiratory tract.

CONTRAINDICATIONS: ENTEX LIQUID is contraindicated in individuals with hypersensitivity to sympathomimetics, severe hypertension, or in patients receiving monoamine oxidase inhibitors.

WARNINGS: Sympathomimetic amines should be used with caution in patients with hypertension, diabetes mellitus, heart disease, peripheral vascular disease, increased intraocular pressure, hyperthyroidism, or prostatic hypertrophy.

PRECAUTIONS: Drug Interactions: ENTEX LIQUID should not be used in patients taking monoamine oxidase inhibitors or other sympathomimetics.

Drug/Laboratory Test Interactions: Guaifenesin has been reported to interfere with clinical laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and urinary vanilmandelic acid (VMA).

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

Nursing Mothers: It is not known whether the drugs in ENTEX LIQUID are excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the product, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of ENTEX LIQUID in children below the age of 2 have not been established.

ADVERSE REACTIONS: Possible adverse reactions include nervousness, insomnia, restlessness, headache, nausea, or gastric irritation. These reactions seldom, if ever, require discontinuation of therapy. Urinary retention may occur in patients with prostatic hypertrophy.

OVERDOSAGE: The treatment of overdosage should provide symptomatic and supportive care. If the amount ingested is considered dangerous or excessive, induce vomiting with ipecac syrup unless the patient is convulsing, comatose, or has lost the gag reflex, in which case perform gastric lavage using a large-bore tube. If indicated, follow with activated charcoal and a saline cathartic.

DOSAGE AND ADMINISTRATION:
All dosage should be administered four times daily (every 6 hours).

Children:

2 to under 4 years	½ teaspoonful (2.5 ml)
4 to under 6 years	1 teaspoonful (5.0 ml)
6 to under 12 years	1½ teaspoonfuls (7.5 ml)

Adults and children 12 years of age and older: 2 teaspoonfuls (10.0 ml)

NDC 0149-0414-16 16 FL. OZ. (1 Pint) bottle

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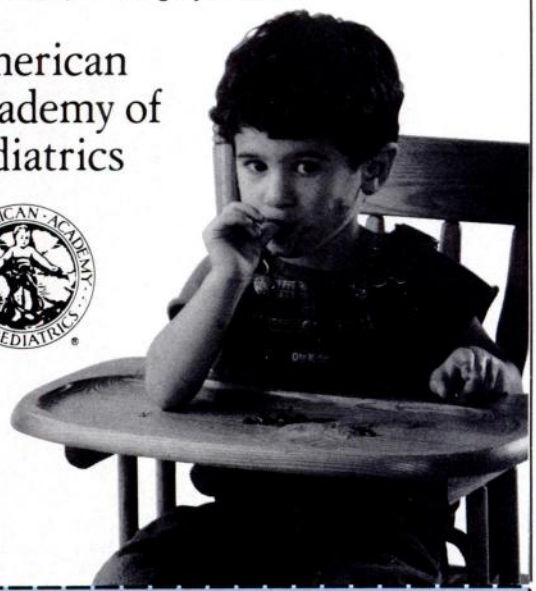

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Tuberculin, Old, TINE TEST®
Tuberculin Purified
Protein Derivative
TINE TEST® PPD

Brief Summary
Please see package insert for full prescribing information.

INDICATIONS: For screening for tuberculosis.

PRECAUTIONS: Use with caution in persons with acute tuberculosis (activation of quiescent lesions is rare); and in patients with known allergy to acacia. Reactivity to the test may be suppressed in those receiving corticosteroids or immunosuppressive agents, or those who have recently been vaccinated with live virus vaccine such as measles, mumps, rubella, polio, etc. With a positive reaction, further diagnostic procedures must be considered, ie, chest x-ray, microbiologic examinations of sputum and other specimens, confirmation of positive tine test (except vesiculation reactions) by Mantoux method. When vesiculation occurs, the reaction is to be interpreted as strongly positive and a repeat test by the Mantoux method must not be attempted. If a patient has a history of occurrence of vesiculation and necrosis with a previous tuberculin test by any method, tuberculin testing should be avoided. Similar or more severe vesiculation with or without necrosis is likely to occur.

Pregnancy Category C: Animal reproduction studies have not been conducted; whether these tuberculin tests can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity is unknown. Tuberculin, Old, TINE TEST or Tuberculin, Purified Protein Derivative TINE TEST PPD should be given to a pregnant woman only if clearly needed. During pregnancy, known positive reactors may demonstrate a negative response.

ADVERSE REACTIONS: Vesiculation, ulceration, or necrosis may appear at test site in highly sensitive persons. Pain, pruritus and discomfort at test site may be relieved by cold packs or by topical glucocorticoid ointment or cream. Any transient bleeding at puncture site is not significant.

Rev. 3/86

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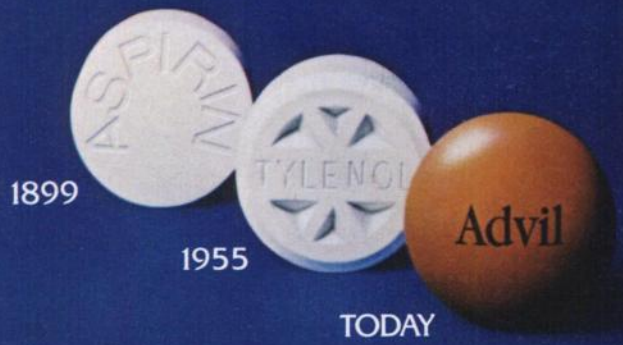

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200 MG

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A NEW STANDARD FOR OTC ANALGESIA™

Many adolescents 12 years and older tend to stay with their pediatricians. When these patients or their parents describe these symptoms, that's one time when your recommendation for ADVIL is particularly appropriate. However, please remind parents that ADVIL should not be given to children under 12 without the advice and supervision of a doctor.

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

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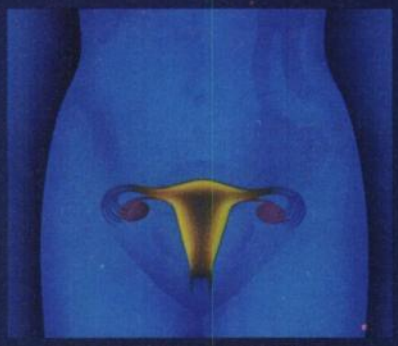
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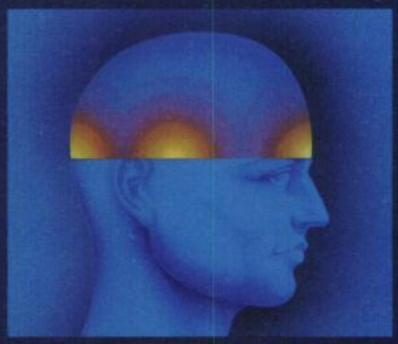
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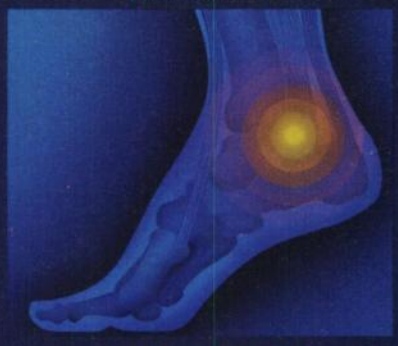
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a new age in
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TWO AND OLDER

VENTOLIN® SYRUP

(ALBUTEROL SULFATE/GLAXO)

2mg*/5ml

Ventolin Syrup for children two and older...

The only β_2-adrenergic bronchodilator recommended for children as young as 2 years old. VENTOLIN Syrup extends the benefits of VENTOLIN therapy to pediatric patients:

- **Rapid, effective relief of bronchospasm within 30 minutes**
- **Control for up to 6 hours**
- **Continued effectiveness with long-term use**
- **A simple dosage regimen**
- **Side effects reported with VENTOLIN Syrup are similar to those of other sympathomimetic amines**

*Potency expressed as albuterol.

Strawberry flavor enhances compliance

Strawberry flavor is favored by children. And VENTOLIN Syrup is free of sugar, alcohol, tartrazine dye (yellow dye #5) and bisulfites.

Please see brief summary of Prescribing Information on following page.

Glaxo a world leader in respiratory care
Glaxo Inc., Research Triangle Park, NC 27709

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VENTOLIN® SYRUP
(ALBUTEROL SULFATE/GLAXO) 2mg*/5ml

*Potency expressed as albuterol
Brief summary of prescribing information

INDICATIONS AND USAGE: VENTOLIN® 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 VENTOLIN (albuterol sulfate) Syrup. Peak improvement of pulmonary function occurred between two to three hours. In a controlled clinical trial involving 55 children, clinically significant improvement (defined as maintenance of mean values over baseline of 15% to 20% or more in the FEV_1 and MMEF, respectively) continued to be recorded up to six hours. No decrease in the effectiveness was reported in one uncontrolled study of 32 children who took VENTOLIN Syrup for a three-month period.

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 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 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, 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, 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 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 were 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 VENTOLIN 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 VENTOLIN® 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, and 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 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.

Glaxo R-500

Manufactured for Glaxo Inc., Research Triangle Park, NC 27709 by Schering Corporation, Kenilworth, NJ 07033

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Pediatric health supervision isn't child's play

From toddlers to teenagers, the needs of your pediatric patients are as diverse as their ages. Now there's one reference manual that covers all aspects of pediatric care—**Guidelines for Health Supervision** from the American Academy of Pediatrics (AAP).

It provides detailed formats for children's regular health checkups, from infancy through age 20, with age-specific information and suggested guidelines for the pediatric visit, including:

- Physical and emotional development
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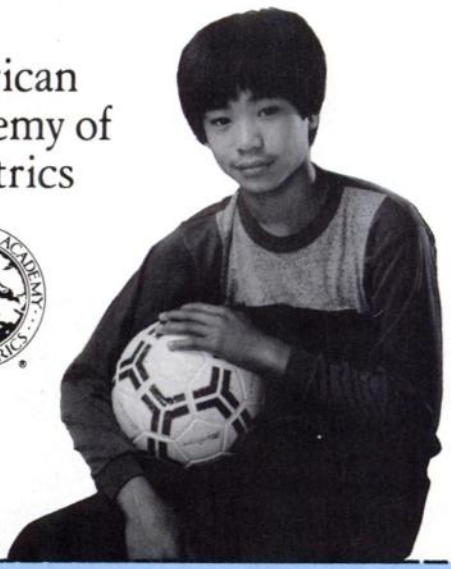
Also included are reference cards which highlight suggested topics for each check-up.

The complete **Guidelines for Health Supervision** package—117-page manual and reference cards—is available from the American Academy of Pediatrics for $25. Return the attached coupon, or charge your order by calling, toll free, **800-433-9016.**

American Academy of Pediatrics



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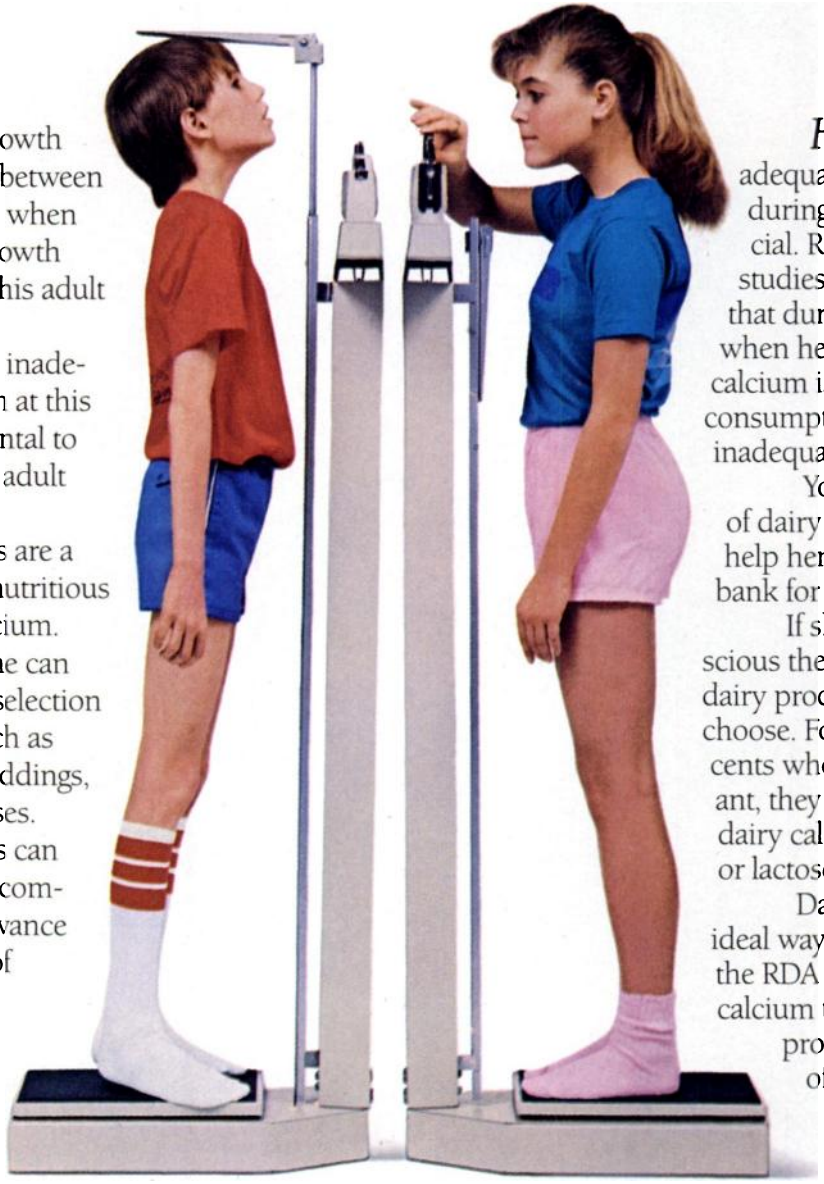
Inadequate Dairy Calcium, lifelong implications

HIS major growth spurt usually occurs between the ages of 12 and 16 when dimensional bone growth accounts for 45% of his adult peak bone mass.[1,2]

In some cases, inadequate dietary calcium at this time may be detrimental to attaining his optimal adult height.[2]

Dairy products are a rich, complete, and nutritious source of dietary calcium. In addition to milk, he can choose from a wide selection of dairy products such as yogurt, ice cream, puddings, and all types of cheeses.

Dairy products can help him meet the recommended dietary allowance (RDA) of 1,200 mg. of calcium for healthy bones and teeth.



HER need for adequate dietary calcium during adolescence is crucial. Recent epidemiologic studies have demonstrated that during adolescence, when her need for dietary calcium is at its highest, her consumption is grossly inadequate.[1]

Your recommendation of dairy calcium <u>now</u> can help her build her calcium bank for the future.

If she's weight-conscious there are many low-fat dairy products from which to choose. For those few adolescents who are lactose-intolerant, they can still benefit from dairy calcium through yogurt or lactose-free products.

Dairy foods are an ideal way to help her meet the RDA of 1,200 mg. of calcium to start on a lifelong program of prevention of osteoporosis.

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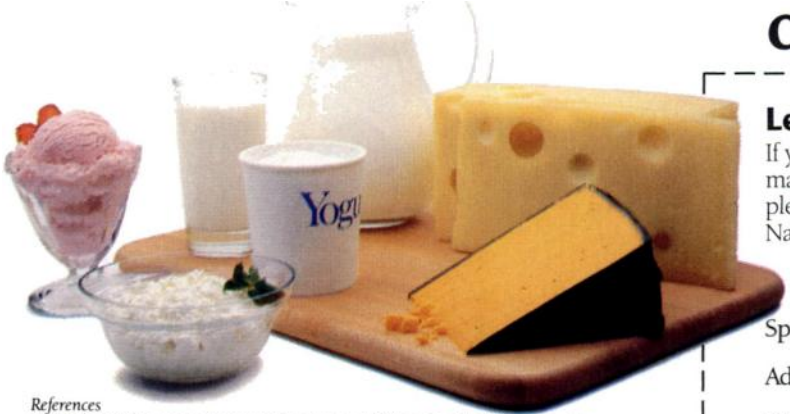
Calcium the way nature intended.™



References
1. Rubin K: Osteoporosis prevention during childhood and adolescence—the ultimate form of preventative medicine. Pediatric By-Line 4(3): 1–6, 1985.
2. Greenwood CT, Richardson DP: Nutrition during adolescence. Wld Rev Nutr Diet 33:1–41, 1979.

PED 3/87

Let us help you teach the children

If you would like a free kit containing patient education materials on dairy calcium's role in adolescent nutrition, please clip and mail this coupon to: Adolescent Nutrition, National Dairy Board, P.O. Box 1063, Fairview, NJ 07022.

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You chose it because it works!

Providing therapy for children that tastes good is a good idea. But, prescribing a medication that works is essential. That's why doctors prescribed Dimetapp® 200 million times and made it the #1 cold and allergy brand*...because it works.

So, recommend the same name you've been prescribing for years,...Dimetapp® Elixir...now in the non-Rx formula that provides the effective antihistamine relief of brompheniramine plus the proven nasal decongestant action of phenylpropanolamine. Kids know Dimetapp for its "great grape taste".

Each teaspoonful of Dimetapp Elixir delivers: 2 mg. Brompheniramine Maleate, USP, 12.5 mg. Phenylpropanolamine Hydrochloride, USP, with 2.3% alcohol.

For your patients who prefer to take a tablet, you can recommend Dimetapp Extentabs.® They provide B.I.D. convenience and relief that lasts a full 12 hours per dose. And, now, for additional dosage flexibility, there are 4-hour Dimetapp® Tablets.

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Antihistamine/Nasal Decongestant

The brand with over 200 million prescriptions to its name.

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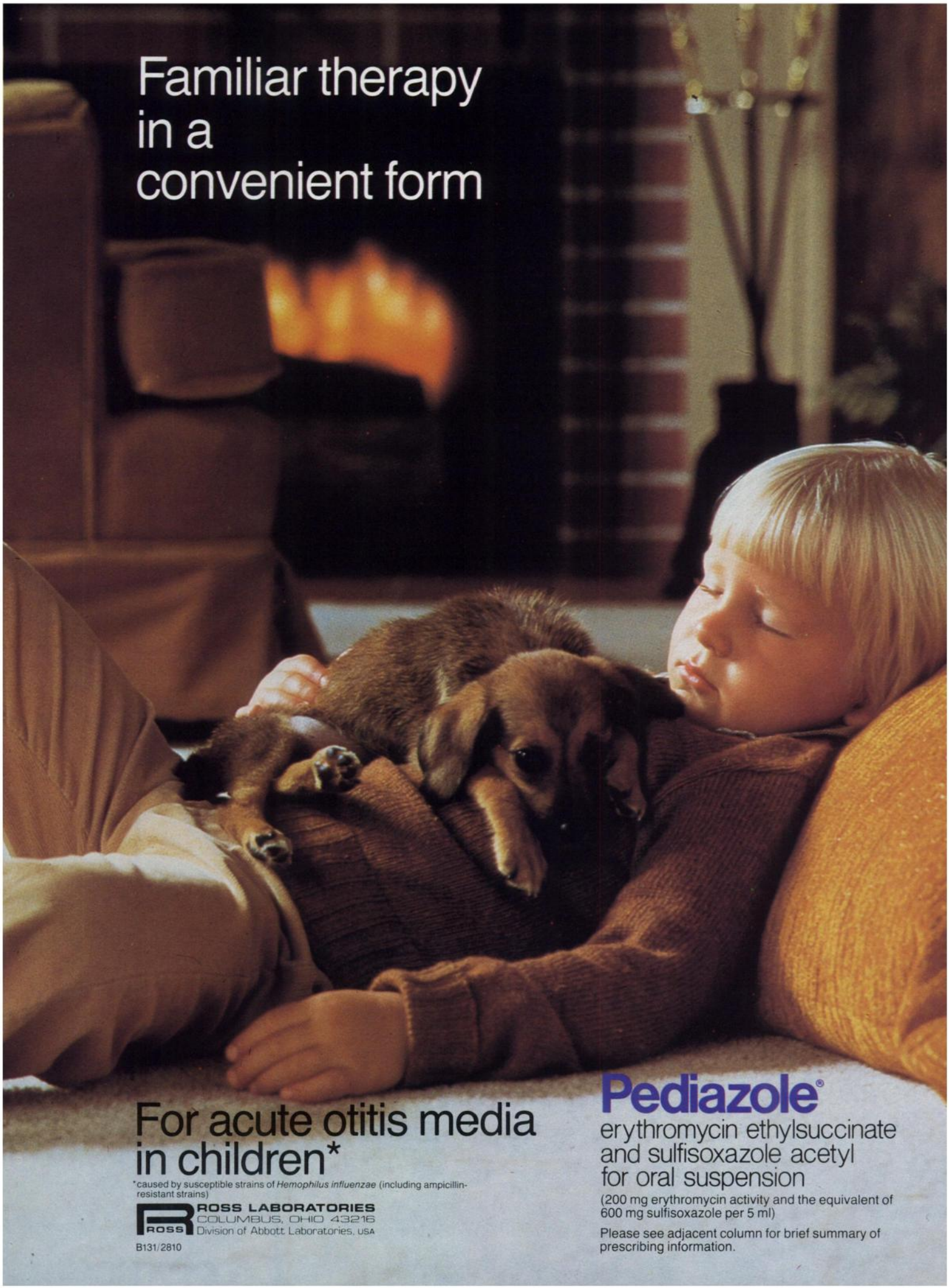

For acute otitis media in children*

*caused by susceptible strains of *Hemophilus influenzae* (including ampicillin-resistant strains)

ROSS LABORATORIES
COLUMBUS, OHIO 43216
Division of Abbott Laboratories, USA

B131/2810

Pediazole®

erythromycin ethylsuccinate and sulfisoxazole acetyl for oral suspension

(200 mg erythromycin activity and the equivalent of 600 mg sulfisoxazole per 5 ml)

Please see adjacent column for brief summary of prescribing information.

Pediazole®

erythromycin ethylsuccinate and sulfisoxazole acetyl for oral suspension

(200 mg erythromycin activity and the equivalent of 600 mg sulfisoxazole per 5 ml)

BRIEF SUMMARY: Please see package enclosure for full prescribing information.

Indication

For treatment of ACUTE OTITIS MEDIA in children that is caused by susceptible strains of *Hemophilus influenzae*.

Contraindications

Known hypersensitivity to either erythromycin or sulfonamides.

Infants less than 2 months of age.

Pregnancy at term and during the nursing period, because sulfonamides pass into the placental circulation and are excreted in human breast milk and may cause kernicterus in the infant.

Warnings

FATALITIES ASSOCIATED WITH THE ADMINISTRATION OF SULFONAMIDES, ALTHOUGH RARE, HAVE OCCURRED DUE TO SEVERE REACTIONS INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA, AND OTHER BLOOD DYSCRASIAS.

Clinical signs such as sore throat, fever, pallor, rash, purpura, or jaundice may be early indications of serious reactions.

PEDIAZOLE SHOULD BE DISCONTINUED AT THE FIRST APPEARANCE OF SKIN RASH OR ANY SIGN OF ADVERSE REACTION. In some instances a skin rash may be followed by a more severe reaction, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatic necrosis and serious blood disorders.

COMPLETE BLOOD COUNT SHOULD BE DONE FREQUENTLY IN PATIENTS RECEIVING SULFONAMIDES.

Usage in Pregnancy (SEE ALSO: CONTRAINDICATIONS): The safe use of erythromycin or sulfonamides in pregnancy has not been established. The teratogenic potential of most sulfonamides has not been thoroughly investigated in either animals or humans. However, a significant increase in the incidence of cleft palate and other bony abnormalities of offspring has been observed when certain sulfonamides of the short, intermediate and long-acting types were given to pregnant rats and mice at high oral doses (7 to 25 times the human therapeutic dose).

The frequency of renal complications is considerably lower in patients receiving the most soluble sulfonamides such as sulfisoxazole. Urinalysis with careful microscopic examination should be obtained frequently in patients receiving sulfonamides.

Precautions

Erythromycin is principally excreted by the liver. Caution should be exercised in administering the antibiotic to patients with impaired hepatic function. There have been reports of hepatic dysfunction, with or without jaundice occurring in patients receiving oral erythromycin products.

Recent data from studies of erythromycin reveal that its use in patients who are receiving high doses of theophylline may be associated with an increase of serum theophylline levels and potential theophylline toxicity. In case of theophylline toxicity and/or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy.

Surgical procedures should be performed when indicated.

Sulfonamide therapy should be given with caution to patients with impaired renal or hepatic function and in those patients with a history of severe allergy or bronchial asthma. In the presence of a deficiency in the enzyme glucose-6-phosphate dehydrogenase, hemolysis may occur. This reaction is frequently dose-related. Adequate fluid intake must be maintained in order to prevent crystalluria and renal stone formation.

Adverse Reactions

The most frequent side effects of oral erythromycin preparations are gastrointestinal, such as abdominal cramping and discomfort, and are dose-related. Nausea, vomiting and diarrhea occur infrequently with usual oral doses. During prolonged or repeated therapy, there is a possibility of overgrowth of nonsusceptible bacteria or fungi. If such infections occur, the drug should be discontinued and appropriate therapy instituted. The overall incidence of these latter side effects reported for the combined administration of erythromycin and a sulfonamide is comparable to those observed in patients given erythromycin alone. Mild allergic reactions such as urticaria and other skin rashes have occurred. Serious allergic reactions, including anaphylaxis, have been reported with erythromycin.

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

The following untoward effects have been associated with the use of sulfonamides:

Blood Dyscrasias: Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, hemolytic anemia, purpura, hypoprothrombinemia and methemoglobinemia.

Allergic Reactions: Erythema multiforme (Stevens-Johnson syndrome), generalized skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritus, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia and allergic myocarditis.

Gastrointestinal Reactions: Nausea, emesis, abdominal pains, hepatitis, diarrhea, anorexia, pancreatitis and stomatitis.

CNS Reactions: Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia.

Miscellaneous Reactions: Drug fever, chills and toxic nephrosis with oliguria or anuria. Periarteritis nodosa and LE phenomenon have occurred.

The sulfonamides bear certain chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents. Goiter production, diuresis and hypoglycemia have occurred rarely in patients receiving sulfonamides. Cross-sensitivity may exist with these agents.

Rats appear to be especially susceptible to the goitrogenic effects of sulfonamides, and long-term administration has produced thyroid malignancies in the species.

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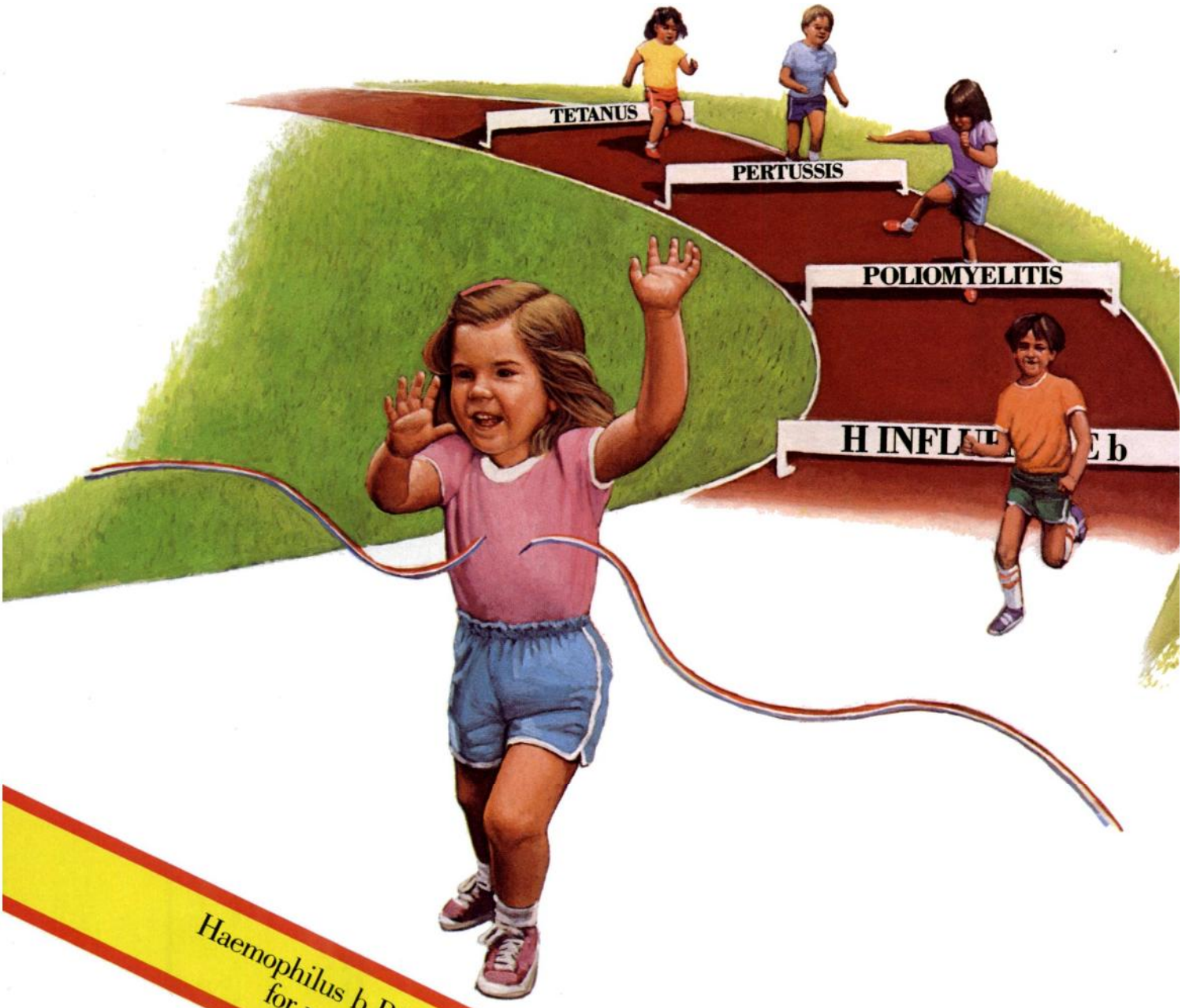
Help kids clear the hurdl
Haemophilus Influenza



Haemophilus b Polysaccharide Vaccine recommended for routine use by the AAP and CDC[1,2]

# of invasive type b diseases

Indicated for:

- Routine immunization of children at 24 months of age.
- Immunization of children 2 through 5 years of age who have not previously received Hib polysaccharide vaccine.
- Immunization of high-risk children at 18 months, particularly those who attend day-care facilities or have chronic illnesses.*

*Anatomic or functional asplenia such as sickle cell anemia or splenectomy, and malignancies associated with immunosuppression.

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Experience—

For over 75 years Lederle has been meeting your vaccine needs and continues to do so when other companies have discontinued.

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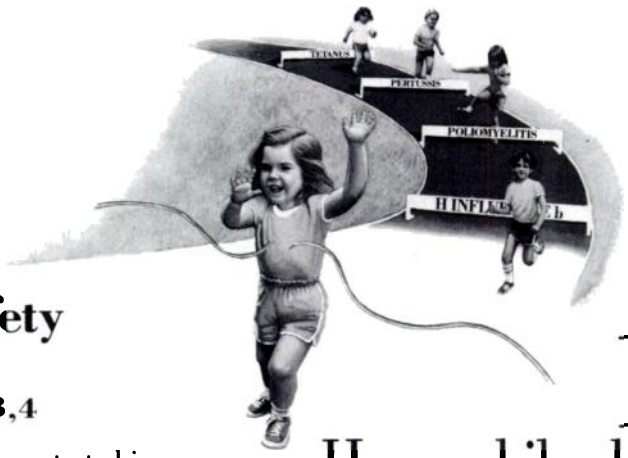
Haemophilus b Polysaccharide Vaccine/Lederle

Please see Brief Summary of prescribing information on next page.



HIB-IMUNE™

Haemophilus b Polysaccharide Vaccine/Lederle

Efficacy and Safety Documented in Clinical Trials[1,3,4]

- 90% protective efficacy demonstrated in a controlled clinical trial involving over 75,000 children 18-71 months of age during a 4-year follow-up.[4]
- Low reported incidence of adverse reactions.[1,3]

References:
1. U.S. Dept. Health and Human Services: Polysaccharide vaccine for prevention of *Haemophilus influenzae* type b disease. *Morbidity and Mortality Weekly Report* 1985; 34(15):201-205.
2. Committee on Infectious Diseases. Haemophilus Type b Polysaccharide Vaccine. *Pediatrics* 1985; 76(2):322-324.
3. Data on file. Lederle Laboratories, Pearl River, NY.
4. Peltola H, Kayhty H, Virtanen M, *et al:* Prevention of *Haemophilus influenzae* type b bacteremic infections with the capsular polysaccharide vaccine. *N Engl J Med* 1984; 310:1561-1566.

Brief Summary
Before prescribing, consult the complete package circular.

INDICATIONS AND USAGE: HIB-IMUNE is indicated for immunization against the invasive disease caused by *H influenzae* type b in children from 24 months through 5 years of age. Routine revaccination of these children is not recommended at this time. Immunization of children 18 through 23 months of age, particularly those in known high-risk groups, may be considered. Initial vaccination at 18 months is specifically recommended for the following groups: (1) children attending day care facilities; (2) children with chronic illnesses known to be associated with an increased risk of Hib disease, eg, anatomic or functional asplenia such as sickle cell anemia or splenectomy, and malignancies associated with immunosuppression. The precise efficacy of the vaccine among children 18-23 months of age is not known; however, this age group accounts for approximately 12% of all invasive Hib disease among children under 5 years of age, and Hib vaccine has been shown by serologic methods to be immunogenic in most children of this age group. Physicians and parents should be informed that the vaccine is not likely to be as effective in this age group as in older children. These younger children may need a second dose of vaccine within 18 months following the initial dose to ensure protection.

CONTRAINDICATIONS: Hypersensitivity to any component of the vaccine, including thimerosal, a mercury derivative.

WARNINGS: HIB-IMUNE will not protect children younger than 18 months of age and will not protect against *Haemophilus influenzae* other than type b or other microorganisms that cause meningitis or septic disease.

The expected antibody response may not be obtained in patients with impaired immune responsiveness, which may be due to a genetic defect or use of immunosuppressive agents. A temporal association of neurologic disorders has been reported following the parenteral injection of many biological products and should always be carefully considered when an immunization is indicated.

PRECAUTIONS: *General:* As with any parenteral vaccine, epinephrine (1:1000) should be available for immediate use should an anaphylactoid reaction occur. HIB-IMUNE should be injected intramuscularly. Do not inject intravenously. Any febrile illness or acute infection is reason for delaying use of HIB-IMUNE™ Haemophilus b Polysaccharide Vaccine.

When administering HIB-IMUNE, a separate sterile syringe and needle should be used for each patient to prevent transmission of hepatitis B (homologous serum hepatitis) or other infectious agents. *Pregnancy:* Pregnancy Category C: Animal reproduction studies have not been conducted with HIB-IMUNE. It is not known whether HIB-IMUNE can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. HIB-IMUNE is not recommended for use in a pregnant woman. *Nursing Mothers:* It is not known whether this vaccine is secreted in human milk. HIB-IMUNE is not recommended for use in a nursing mother. *Infants:* The use of HIB-IMUNE in children younger than 18 months of age is not recommended. Please see Indications and Usage Section.

ADVERSE REACTIONS: Different preparations of Haemophilus b Polysaccharide Vaccine produced by different procedures and administered at different doses have been evaluated in several field studies in a total of over 60,000 children. Objectively observed side effects, eg, erythema and induration at the injection site and fever, have generally been minor and lasted 24 hours or less. In the Finnish field trial, one child had a possible anaphylactoid reaction; following an injection of epinephrine, the child recovered rapidly and without complications.

In clinical trials involving the administration of HIB-IMUNE, reconstituted with phosphate buffered saline, to over 300 children (18 months of age and older), local adverse reactions such as erythema, warmth, swelling and tenderness at the site of injection were observed. There were no incidences of significant erythema, and swelling was considered significant in 0.3% of subjects. Local reactions have been mild with a peak occurrence at approximately 6 hours and resolution within 24 hours.

Systemic reactions observed included fever, irritability, anorexia, and sleep disturbance. Fever exceeding 38.5°C (101.3°F) was observed in 1.5% of subjects within 24 hours after immunization. There were no episodes of fever exceeding 38.5°C (101.3°F) reported in children 24 months of age or older.

As with any vaccine, there is the possibility that broad use of the vaccine could reveal rare adverse reactions not observed in the clinical trials.

Since the introduction of Haemophilus b Polysaccharide Vaccine in the U.S., a number of infrequent adverse reactions have been reported temporally associated with administration of the vaccine, including seizures, rashes, and sleep disturbance. A cause and effect relationship has not been established.

A temporal association of neurologic disorders has been reported following the parenteral injection of many biological products and should always be carefully considered when an immunization is indicated.

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Lederle Biologicals
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Wayne, New Jersey 07470

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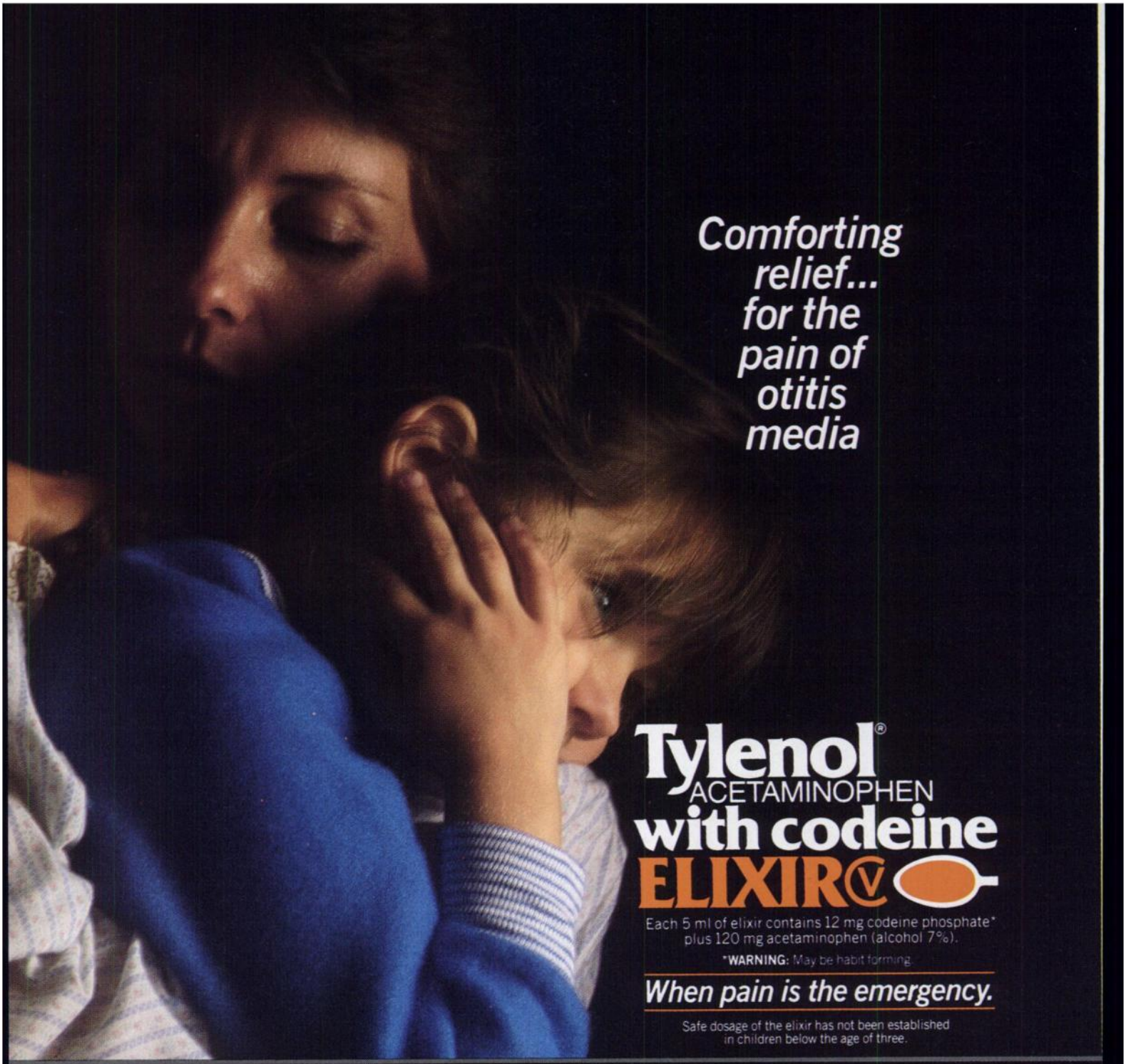

Summary of Prescribing Information
The following is a brief summary only. Before prescribing, see complete prescribing information in TYLENOL with Codeine labeling.

Description
Elixir: Each 5 mL contains 12 mg codeine phosphate* plus 120 mg acetaminophen (alcohol 7%).
***Warning:** May be habit forming.

Contraindications: Hypersensitivity to any component.

Warnings: *Drug dependence.* (see DRUG ABUSE AND DEPENDENCE)

Precautions: General — *Head injury and increased intracranial pressure.* Respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries. *Acute abdominal conditions.* Codeine or other narcotics may obscure the diagnosis or clinical course of acute abdominal conditions.
Special risk patients. Administer with caution to certain patients such as the elderly or debilitated, those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.

Information for Patients: *Usage in ambulatory patients.* Codeine may impair mental and/or physical abilities required for performance of potentially hazardous tasks such as driving a car or operating machinery.

Drug Interactions: Other narcotic analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics or other CNS depressants (including alcohol) may exhibit additive CNS depression. When such a combination is contemplated, reduce the dose of one or both agents.
MAO inhibitors or tricyclic antidepressants may increase the effect of either the antidepressant or codeine.
Anticholinergics with codeine may produce paralytic ileus.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies in animals have been performed to determine carcinogenic potential or effects on fertility.
Acetaminophen and codeine have been found to have no mutagenic potential.

Teratogenic Effects: Pregnancy Category C. Codeine has been shown to be teratogenic in mice when given in doses 17 times the maximum human daily dose. There are no adequate and well controlled studies in pregnant women. Should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether the components of this drug are excreted in human milk, caution should be exercised when administered to a nursing woman.

Pediatric Use: Safe dosage of the elixir has not been established in children below the age of three.

Adverse Reactions: *Most frequent:* Lightheadedness, dizziness, sedation, shortness of breath, nausea and vomiting; more prominent in ambulatory than in nonambulatory patients; some may be alleviated if patient lies down. *Others:* allergic reactions, euphoria, dysphoria, constipation, and pruritus.
At higher doses codeine has most of the disadvantages of morphine including respiratory depression.

Drug Abuse and Dependence: TYLENOL with Codeine elixir is a Schedule V controlled substance. Codeine can produce drug dependence of the morphine type and may be abused. Dependence and tolerance may develop upon repeated administration; prescribe and administer with same caution appropriate to other oral narcotics. Subject to the Federal Controlled Substances Act.
Full directions for use should be read before administering or prescribing.
For information on symptoms/treatment of overdosage, see full prescribing information.

5/7/86

McNEIL PHARMACEUTICAL
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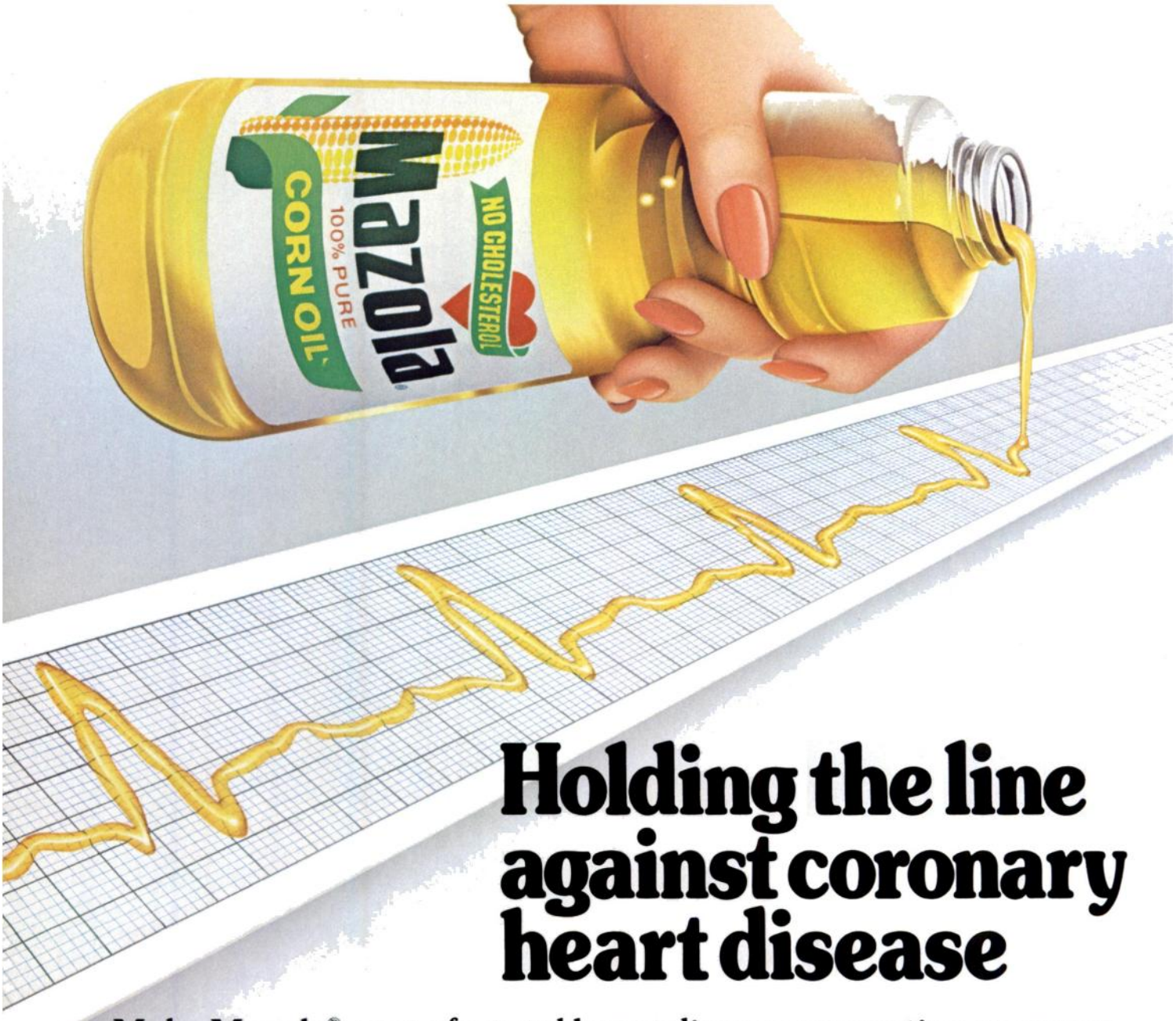

Holding the line against coronary heart disease

Make Mazola® part of a total heart disease prevention program

Mazola in the diet... clinically proven to lower serum cholesterol

Mazola 100% Pure Corn Oil was a key component of two diets clinically proven to reduce serum cholesterol.[1] In just 3 weeks, the average decrease with a moderate cholesterol-lowering diet was 17%, and 29% with a stricter diet. Substitution of Mazola Corn Oil and a corn oil margarine for shortening and butter was the essential change from the control diet.

100% pure corn oil with proven PUFA benefits

Increased intake of polyunsaturated fatty acids (PUFA) enhances the cholesterol-lowering effect of merely decreasing saturated fat intake.[1] That's why Mazola is so useful. It is higher in PUFA than the leading cooking oil and shortening, and it contains no cholesterol or salt.

Raising your patients' "cholesterol consciousness"

More patients are asking about cholesterol levels and diet.[2] To assist you in making *practical* dietary recommendations and to improve compliance, a supply of patient aid sheets highlighting fat, PUFA, and calorie content of many foods is available by writing to MAZOLA at Mazola Nutrition/Health Information Service, Dept. EWSW-JA, P.O. Box 307, Coventry, CT 06238.

References: 1. Anderson, J.T., *et al.*: Cholesterol-lowering diets. J. Am. Diet. Assoc. 62:133-142, 1973. **2.** Campaign seeks to increase U.S. "cholesterol consciousness." JAMA 255:1097-1102, 1986.

Mazola®
100% Pure Corn Oil
Corn Oil Margarines
No-Stick Spray

Good Nutrition Is Good Medicine

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