DECEMBER 1986

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NUMBER 6

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Pediatrics

AMERICAN ACADEMY OF PEDIATRICS ELK GROVE VILLAGE ILLINOIS 60007

Children's Sudafed®

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Clears his stuffy nose without making him drowsy on the job

Good-tasting Children's SUDAFED Liquid unstops stuffy noses due to colds or allergies... without antihistamines to cause drowsiness. Also available for children 6 years and older — SUDAFED Tablets.

Now included — convenient dosage cup.

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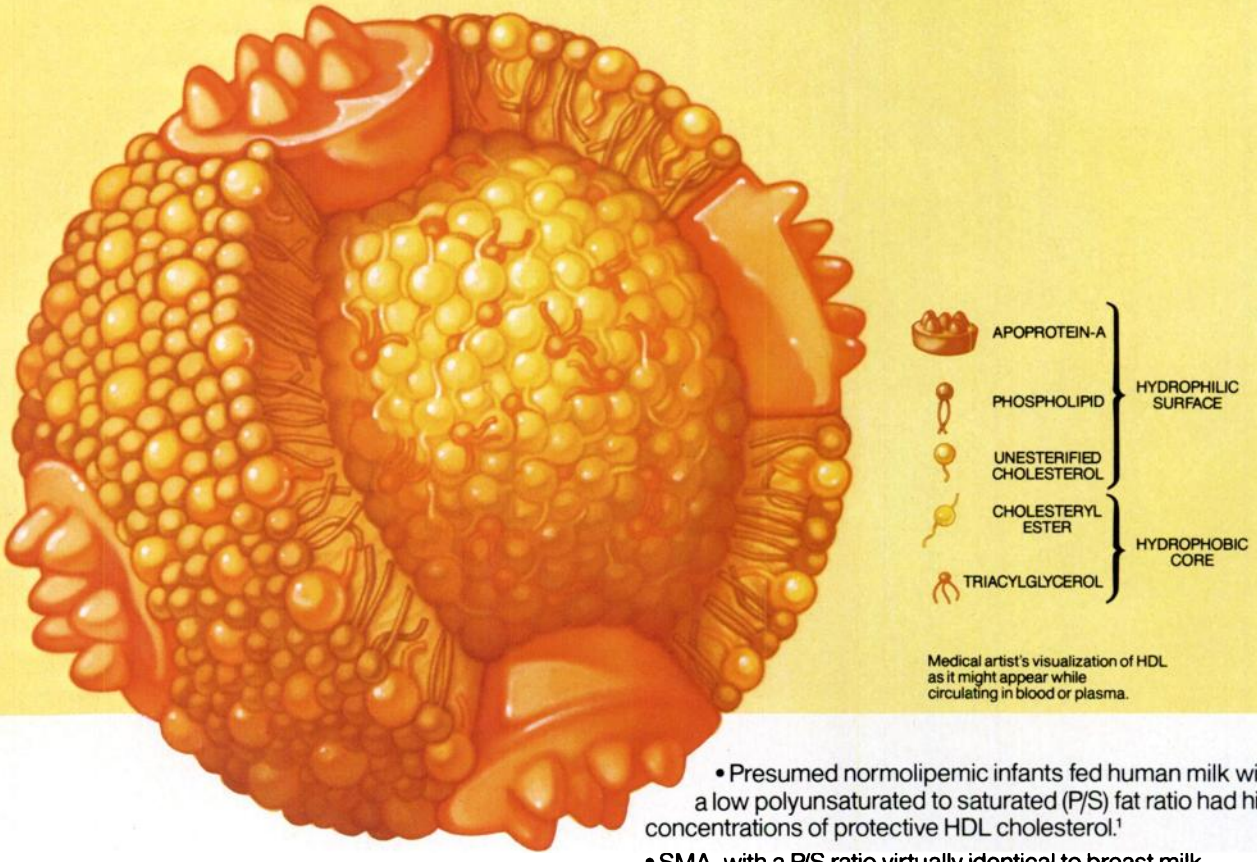
HDL: the protective lipoprotein

HDL (high-density lipoprotein) has been called the "good" lipoprotein because unlike LDL (low-density lipoprotein), which promotes fatty deposits in the blood vessels, HDL helps eliminate cholesterol from the body. Because of this, researchers have noted that persons with higher levels of HDL have a lower rate of heart disease.



Medical artist's visualization of HDL as it might appear while circulating in blood or plasma.

Clinical study: SMA® produces high HDL levels virtually identical to breast milk.

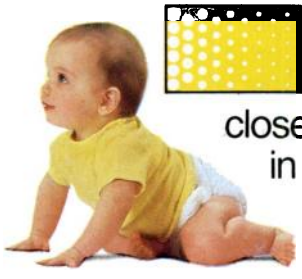
- Presumed normolipemic infants fed human milk with a low polyunsaturated to saturated (P/S) fat ratio had high concentrations of protective HDL cholesterol.[1]
- SMA, with a P/S ratio virtually identical to breast milk, maintained the high level of HDL cholesterol closest to that of human milk.
- Infant formula with a high P/S ratio significantly lowered the level of HDL cholesterol compared with human milk and SMA.

Reference:
1. Carlson SE, DeVoe PW, Barness LA: Effect of infant diets with different polyunsaturated to saturated fat ratios on circulating high-density lipoproteins. J Pediatr Gastroenterol Nutr 1:303-309, 1982.

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.



SMA® INFANT FORMULA

closest to breast milk in all nutritional components

Wyeth Laboratories
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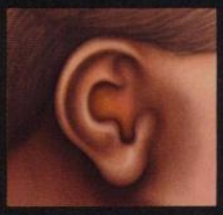
Pioneers in Infant Nutrition™

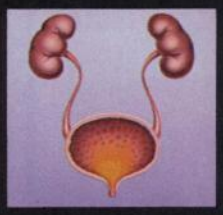
Burning questions in pediatric practice

How do you treat:

Eye infections?



Ear infections?



Urinary infections?

Gantrisin®
(sulfisoxazole diolamine/Roche)
Ophthalmic Solution

For conjunctivitis, bacterial corneal ulcers and other superficial eye infections
The Ophthalmic Solution—a sterile, isotonic preparation containing 4% (40 mg/ml) sulfisoxazole diolamine—is a highly effective answer to superficial pediatric eye infections caused by susceptible microorganisms, such as *Staphylococcus aureus*. It's easy to administer (two or three drops, three or more times daily), usually without significant stinging or burning.

Gantrisin®
(acetyl sulfisoxazole/Roche) 0.5 Gm/5 ml
Pediatric Suspension and Syrup

For acute otitis media and for acute cystitis
For children with acute nonobstructed cystitis, the Pediatric Suspension offers prompt, effective control of most common pathogens, such as susceptible strains of *E. coli* and *Klebsiella-Aerobacter*. Used concomitantly, the Suspension is also an excellent "working partner" for penicillin when *H. influenzae* is implicated in acute otitis media. As with all sulfonamides, adequate fluid intake should be maintained. Gantrisin should not be given to infants under two months of age.

Gantrisin®
sulfisoxazole/Roche
has an answer!

Please see summary of product information on the following page.

ROCHE®

GANTRISIN® (sulfisoxazole diolamine/Roche)
Ophthalmic Solution, Ophthalmic Ointment

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

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

Contraindications: Hypersensitivity.

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

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

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

GANTRISIN® (sulfisoxazole/Roche) Tablets
GANTRISIN® (acetyl sulfisoxazole/Roche) Pediatric Suspension

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

Indications: Nonobstructed urinary tract infections (mainly cystitis, pyelitis, pyelonephritis) due to susceptible organisms (usually *E. coli, Klebsiella-Aerobacter*, staphylococcus, *P. mirabilis, P. vulgaris*). Acute otitis media due to *H. influenzae* (concomitantly with adequate doses of penicillin or erythromycin; see appropriate erythromycin labeling for prescribing information). IMPORTANT NOTE: *In vitro* sensitivity tests not always reliable; must be coordinated with bacteriological and clinical response. Add aminobenzoic acid to follow-up culture media. Increasing frequency of resistant organisms limits usefulness of antibacterial agents, especially in chronic and recurrent urinary infections. Maximum safe total sulfonamide blood level, 20 mg/100 ml; measure levels as variations may occur.

Contraindications: Hypersensitivity to sulfonamides, infants less than 2 months of age; pregnancy at term and during the nursing period.

Warnings: Safety in pregnancy not established. Do not use for group A beta-hemolytic streptococcal infections, as sequelae (rheumatic fever, glomerulonephritis) are not prevented. Deaths reported from hypersensitivity reactions, hepatocellular necrosis, agranulocytosis, aplastic anemia and other blood dyscrasias. Sore throat, fever, pallor, purpura or jaundice may be early indications of serious blood disorders. CBC and urinalysis with careful microscopic examination should be performed frequently.

Precautions: Use cautiously in patients with impaired renal or hepatic function, severe allergy or bronchial asthma. Hemolysis, frequently dose-related, may occur in glucose-6-phosphate dehydrogenase-deficient patients. Maintain adequate fluid intake to prevent crystalluria and stone formation.

Adverse Reactions: *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, hepatocellular necrosis, diarrhea, anorexia, pancreatitis and stomatitis; *C.N.S. reactions:* Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia; *Miscellaneous reactions:* Drug fever, chills and toxic nephrosis with oliguria and anuria. Periarteritis nodosa and L.E. phenomenon have occurred. Due to certain chemical similarities with some goitrogens, diuretics (acetazolamide, thiazides) and oral hypoglycemic agents, sulfonamides have caused rare instances of goiter production, diuresis and hypoglycemia as well as thyroid malignancies in rats following long-term administration. Cross-sensitivity with these agents may exist.

Dosage: Contraindicated in infants under 2 months except in the treatment of congenital toxoplasmosis as adjunctive therapy with pyrimethamine.

Usual adult dosage—2 to 4 Gm initially, then 4 to 8 Gm/24 hrs. in 4 to 6 doses. *Usual dosage for infants over 2 months and children*—½ 24-hr dose initially, then 150 mg/kg/24 hrs. in 4 to 6 doses, not over 6 Gm/24 hrs.

How Supplied: Tablets containing 0.5 Gm sulfisoxazole, white, scored—bottles of 100, 500 and 1000; Tel-E-Dose® packages of 100, Prescription Paks of 100.

Pediatric Suspension, containing, in each teaspoonful (5 ml), the equivalent of approximately 0.5 Gm sulfisoxazole in the form of acetyl sulfisoxazole, raspberry flavored—bottles of 4 oz and 16 oz (1 pint).

Syrup, containing, in each teaspoonful (5 ml), the equivalent of approximately 0.5 Gm sulfisoxazole in the form of acetyl sulfisoxazole, chocolate flavored—bottles of 16 oz (1 pint).

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References must be numbered consecutively according to their citation in the text. Abbreviations for journals should be those listed in *Index Medicus*. The following reference style (a modified form of that shown in "Uniform Requirements for Manuscripts Submitted to Biomedical Journals") will appear in the journal effective with volume 71 (January 1983 issue):

Journal (list first three authors then et al):
1. Starzl TE, Klintmalm GBG, Porter KA, et al: Liver transplantation with use of cyclosporin A and prednisone. *N Engl J Med* 1981; 305:266-269

Book
1. Kavet J: Trends in the utilization of influenza vaccine: An examination of the implementation of public policy in the United States, in Selby P (ed): *Influenza: Virus, Vaccines, and Strategy*. New York, Academic Press Inc, 1976, pp 297-308

Tables must be comprehensible to the reader without reference to the text and typed (double-spaced) rather than photographed. Each table should be typed on a separate sheet, be numbered consecutively, and have a brief title. Care should be taken to make tables as concise and brief as possible.

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Revised, July 1985

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E COLI K1–OR GROUP B STREP?

Four out of 10 neonatal meningitis cases are caused by *E coli* K1. Another four are caused by Group B Strep.[1] But until now, there was no proven latex method for identifying both of these important causes of life-threatening disease—until WELLCOGEN.[2]

Only WELLCOGEN confirms a full range of meningitis pathogens—including Group B Strep and now, *E coli* K1. And you can count on WELLCOGEN to be sensitive, specific, and 15 minutes fast.

So the next time you suspect neonatal meningitis, be sure to specify WELLCOGEN. It's the *only* truly complete neonatal meningitis testing panel.

Only one panel can make the distinction

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THE neonatal meningitis panel

References: 1. Silverblatt FJ, Weinstein R: Enterobacteriaceae, in Mandell GL, Douglas RG Jr, Bennett JE (eds): *Principles and Practice of Infectious Diseases*, ed 2. New York, John Wiley & Sons, 1985, p 1230 **2.** Data on file. Wellcome Diagnostics

Wellcome Diagnostics
A Division of Burroughs Wellcome Co.
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DECEMBER 1986 VOL. 78 NO. 6

Pediatrics

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CONTRIBUTORS SECTION

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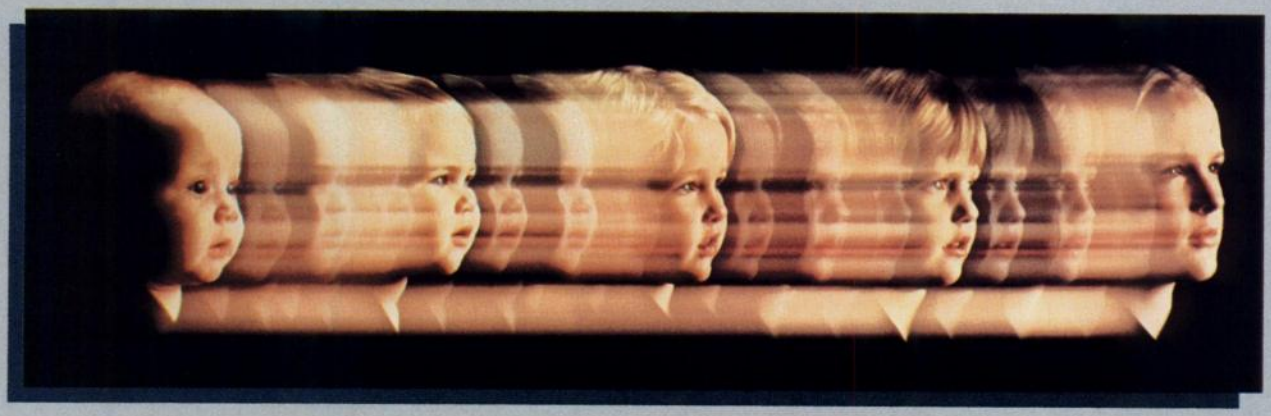
SPECIAL ARTICLE

ARTICLES continued

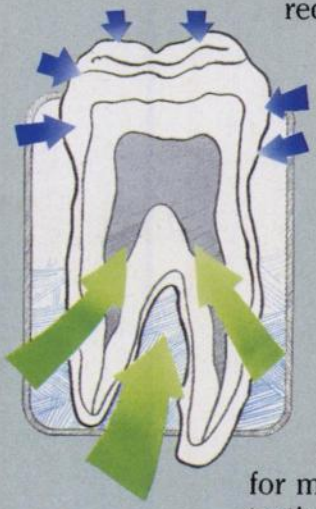
Fluoride

To Meet A Growing Need



Dental Caries Can Be Reduced 50-80%

Developing primary and permanent teeth supplied with systemic fluoride are so much stronger that later caries can be reduced 50-80%.[1,2]



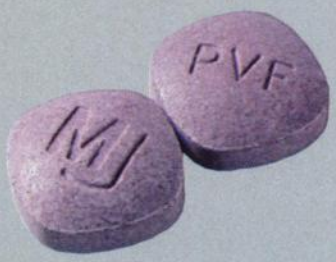
Since pre-eruptive and newly erupted teeth incorporate fluoride more easily than older teeth,[3] systemic fluoride is required every day–from birth until final molars appear (around age 13).

After teeth appear, systemic and topical fluoride work together for maximum protection from caries.

Vi-Flor® Vitamin/ Fluoride Combination Enhances Compliance

Daily vitamins already containing fluoride make compliance easy and economical for parents.

Regular fluoride updates in the office remind parents of the importance of daily systemic fluoride.



Meet the growing need for fluoride. Prescribe Vi-Flor fluoride vitamins.

See attached statement for full prescribing information.

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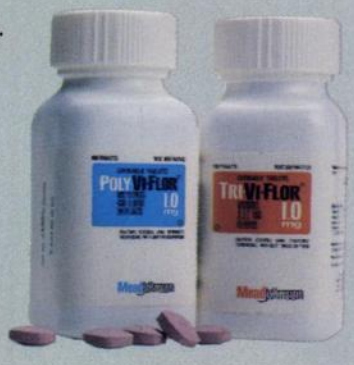

REFERENCES:
[1]Aasenden R and Peebles T: Effects of Fluoride Supplementation From Birth on Human Deciduous and Permanent Teeth. Arch Oral Biol 19:321, 1974.
[2]Hambert L: Controlled Trial of Fluoride in Vitamin Drops for Prevention of Caries in Children. Lancet Feb. 27, 1971, p. 442.
[3]Newbrun, E.: How Fluoride Works: Topical vs. Systemic Action, in Mead Johnson Clinical Report Series, Clinical Importance of Fluoride Nutrition in Infants, Children and Young Adults, Chicago, Pragmaton®, 1985, p. 7.

LK-0197-3-86

Routine VI-FLOR®

supplementation

to help you guard appropriate patients against caries risk and nutritional risk.

INDICATIONS AND USAGE: Prophylaxis of vitamin deficiencies and dental caries in children and adults when fluoride of water supply does not exceed 0.7 ppm.[1,2,3] And, in the case of TRI-VI-FLOR* 0.25 mg Drops with Iron and POLY-VI-FLOR* Drops and Chewable Tablets with Iron, prophylaxis against iron deficiencies. Note: VI-FLOR Drops do not contain folic acid because the vitamin is not stable in liquid form.

PRECAUTIONS: Do not exceed recommended dose or give concurrently with other medications containing significant amounts of fluoride. Prolonged excessive fluoride intake may cause dental fluorosis. All VI-FLOR* with Iron products: as with all products containing iron, parents should be warned against excessive dosage. The bottle should be kept out of reach of children.

Keep all VI-FLOR with Iron products tightly closed and away from direct light.

VI-FLOR Drops should be dispensed in the original plastic container, since contact with glass leads to instability and precipitation.

ADVERSE REACTIONS: Allergic rash has rarely been reported.

DOSAGE AND ADMINISTRATION:

Supplemental Fluoride Dosage Schedule (mg/day)*

Age	Concentration of Fluoride in Drinking Water (ppm)		
	<0.3	0.3-0.7	>0.7
2 wk-2 yr**	0.25	0	0
2-3 yr	0.5	0.25	0
3-16 yr	1.0	0.5	0

*From the American Academy of Pediatrics Committee on Nutrition statement, Fluoride Supplementation: Revised Dosage Schedule. Pediatrics 63(1):150-152, 1979.

**The Committee favors initiating fluoride supplementation shortly after birth in breast-fed infants (0.25 mg F/day). In formula-fed infants, fluoride supplementation should be according to the fluoride content of the water used to prepare formula.

PRODUCT	FORM	SIZE	FLUORIDE mg/dose
POLY-VI-FLOR 0.25 mg	Drops	50 ml Bottle	0.25
POLY-VI-FLOR 0.25 mg with Iron	Drops	50 ml Bottle	0.25
POLY-VI-FLOR 0.5 mg	Drops	50 ml Bottle	0.5
POLY-VI-FLOR 0.5 mg with Iron	Drops	50 ml Bottle	0.5
POLY-VI-FLOR 0.5 mg	Tablets	Bottle of 100	0.5
POLY-VI-FLOR 0.5 mg with Iron	Tablets	Bottle of 100	0.5
POLY-VI-FLOR 1.0 mg	Tablets	Bottle of 100	1.0
POLY-VI-FLOR 1.0 mg with Iron	Tablets	Bottle of 100	1.0
TRI-VI-FLOR 0.25 mg	Drops	50 ml Bottle	0.25
TRI-VI-FLOR 0.25 mg with Iron	Drops	50 ml Bottle	0.25
TRI-VI-FLOR 0.5 mg	Drops	50 ml Bottle	0.5
TRI-VI-FLOR 1.0 mg	Tablets	Bottle of 100	1.0

REFERENCES:

1. Hennon DK, Stookey GK and Muhler JC: The Clinical Anticariogenic Effectiveness of Supplementary Fluoride-Vitamin Preparations—Results at the End of Four Years. J Dentistry for Children 34:439-443 (Nov) 1967.
2. Hennon DK, Stookey GK and Muhler JC: The Clinical Anticariogenic Effectiveness of Supplementary Fluoride-Vitamin Preparations—Results at the End of Five and a Half Years. Pharmacology and Therapeutics in Dentistry 1:1-6 (Oct) 1970.
3. Hennon DK, Stookey GK and Muhler JC: Prophylaxis of Dental Caries: Relative Effectiveness of Chewable Fluoride Preparations With and Without Added Vitamins. J Pediatrics 80:1018-1021 (June) 1972.

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(For complete details, please consult full prescribing information.)

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10. ***Tubersol®*** *(Tuberculin Purified Protein Derivative, Mantoux) (PPD)*
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1987
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October 31–November 5

1988
San Francisco
October 22–27

1989
Chicago
October 21–26

1990
Boston
October 6–11

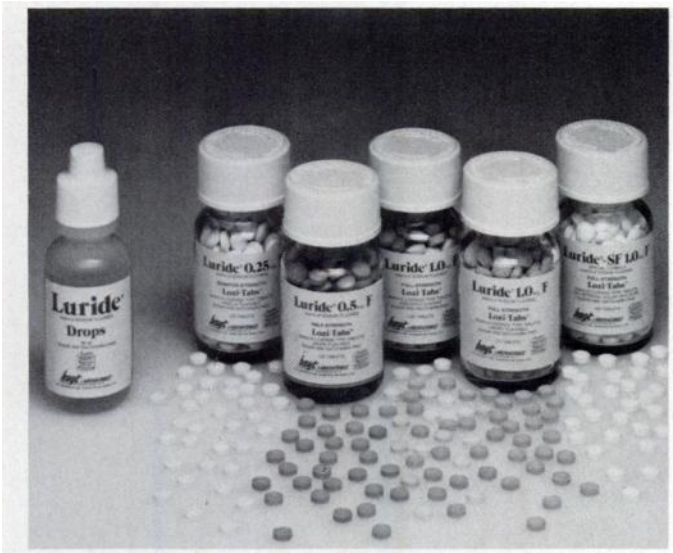
1991
New Orleans
October 26–31

1992
San Francisco
October 10–15

SPRING SESSIONS

1987
San Francisco
May 9–14

1988
New York City
May 14–19



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.

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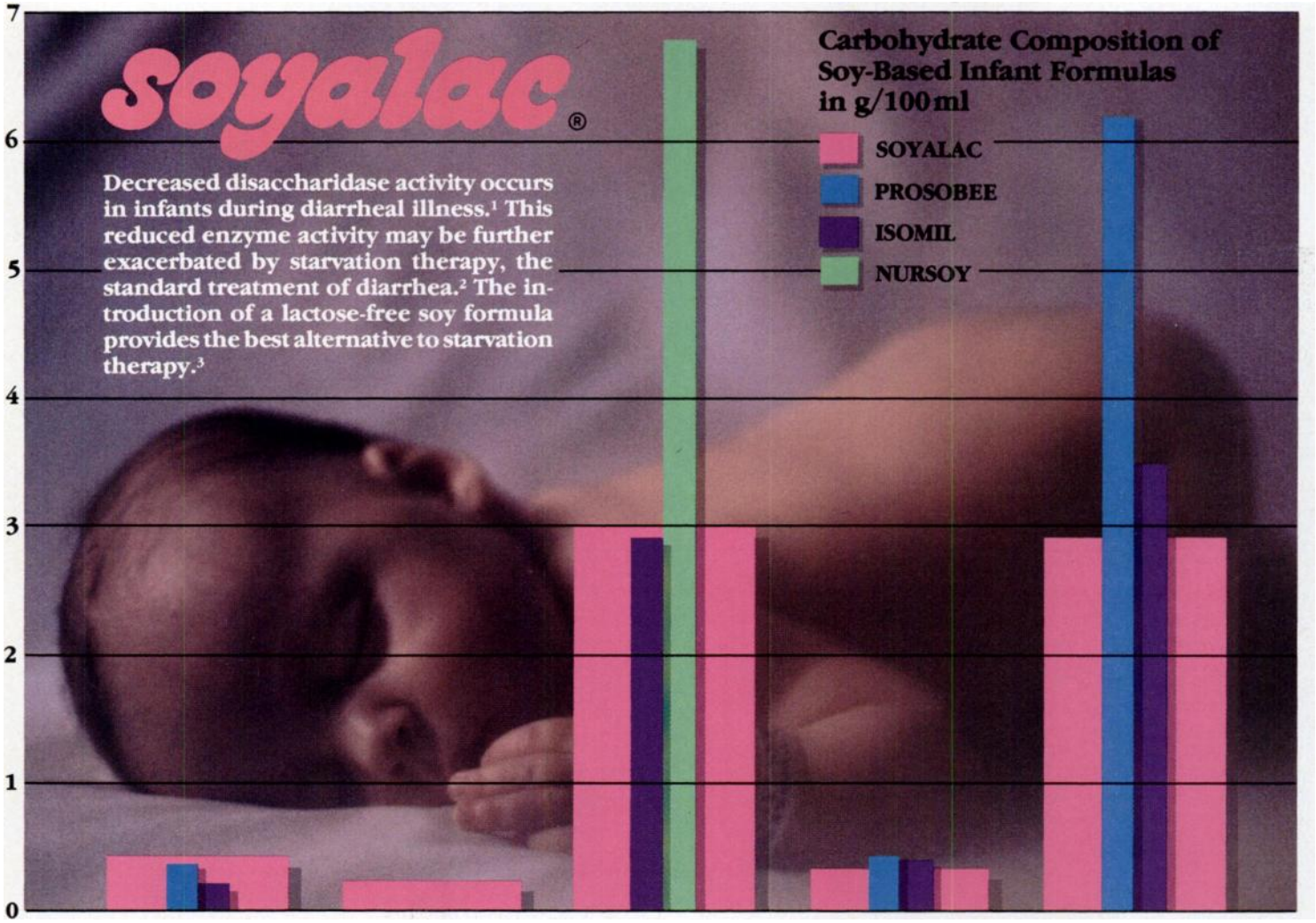
PEDIATRICS IN REVIEW: February 1987 Contents

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]

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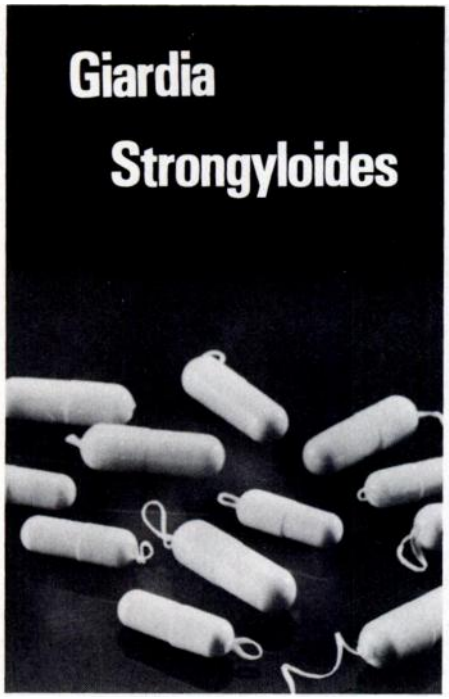

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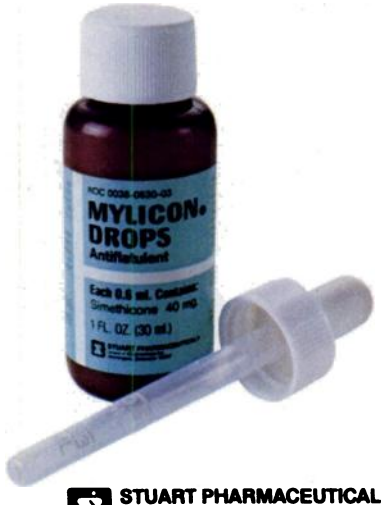

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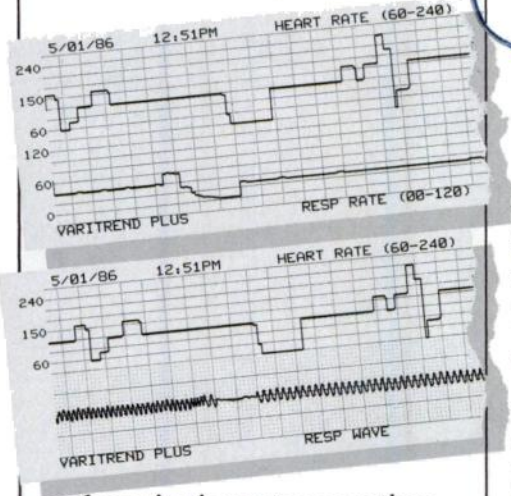

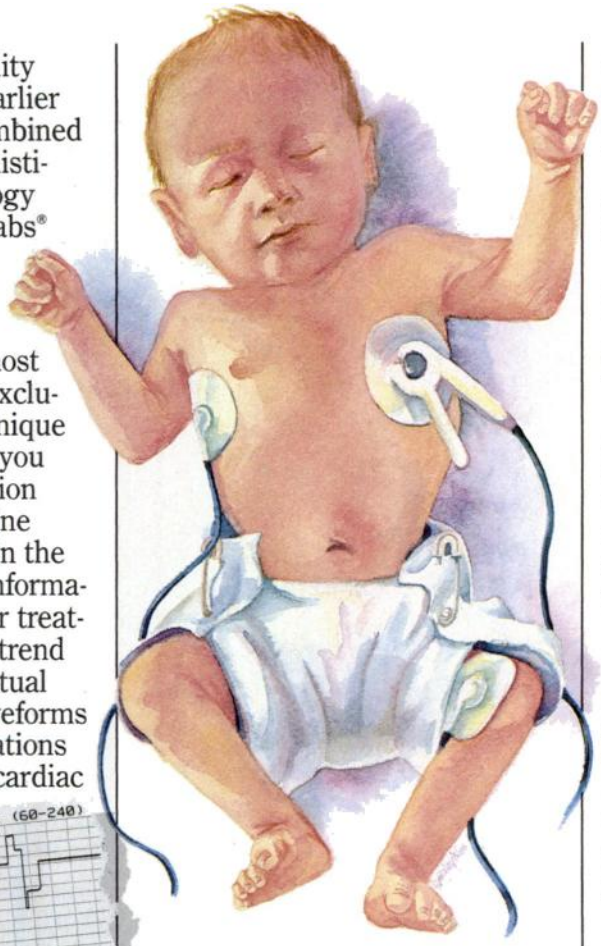

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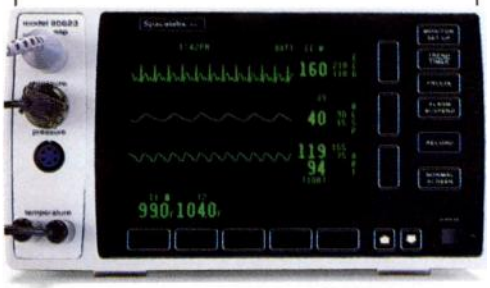

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"The availability of a sustained-release (SR) formulation of methylphenidate would greatly improve patient compliance and lessen school-related dosing problems...."[1]

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.

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Reference

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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.
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C85-55 (Rev. 11/85)

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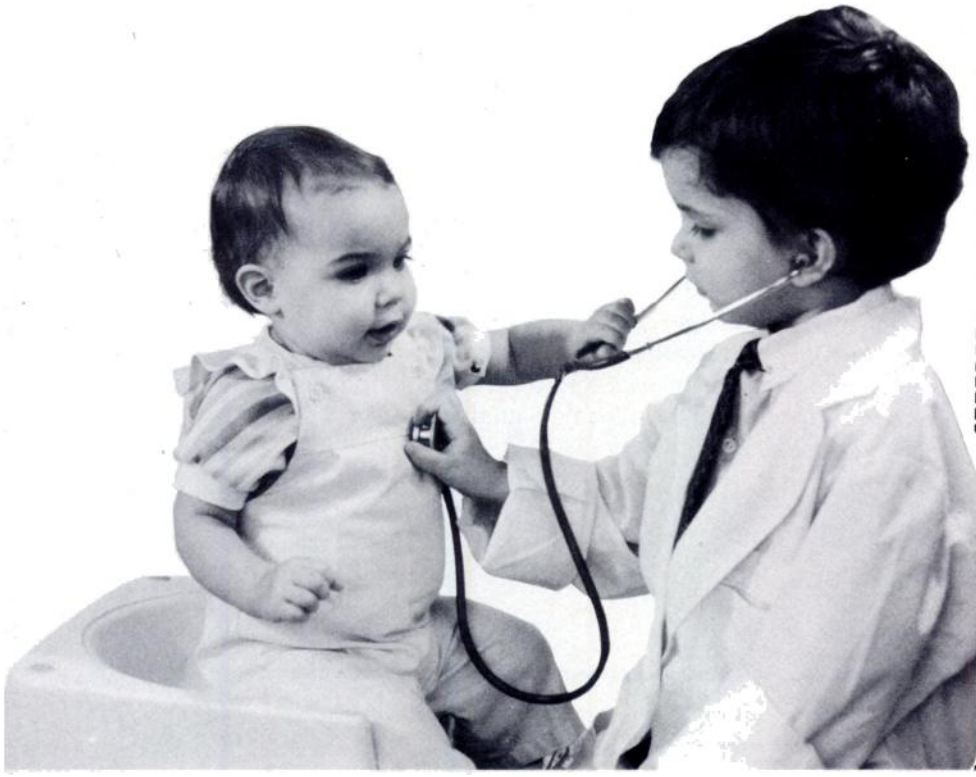

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PEDS

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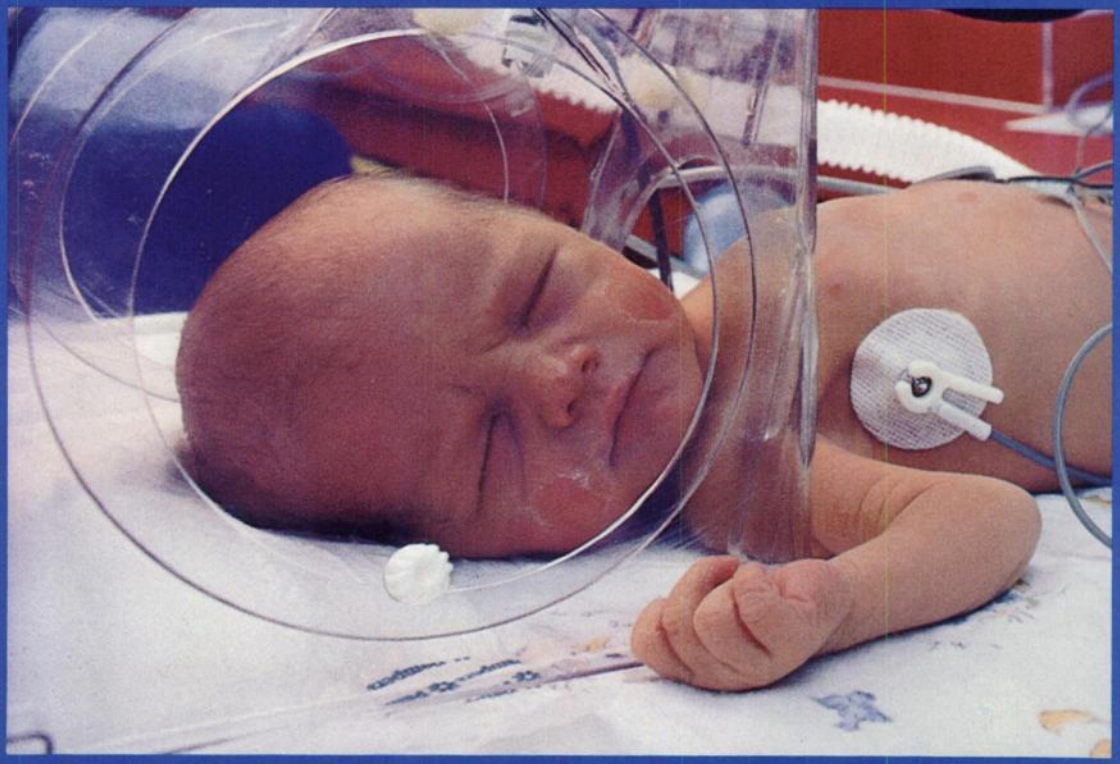

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Rapid diagnostic procedures (2 to 5 hours) now make it possible to confirm your diagnosis of

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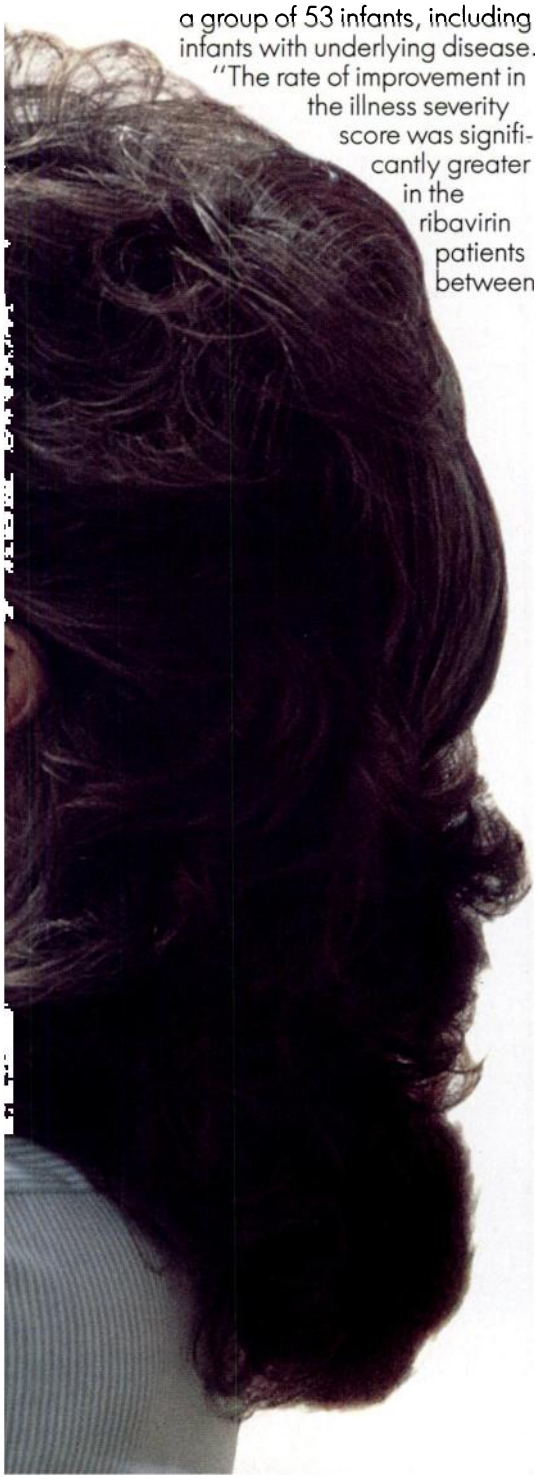
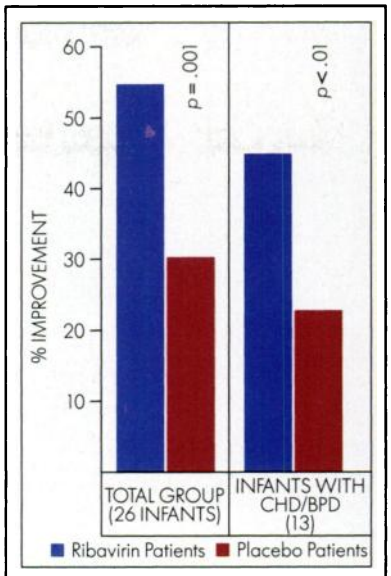
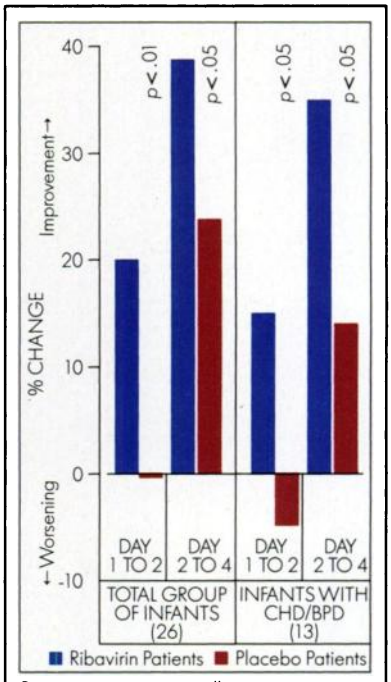
RECENT STUDY[4] FURTHER DEMONSTRATES EFFECTIVENESS OF VIRAZOLE (RIBAVIRIN) THERAPY IN RSV

Hall and associates measured the effects of Virazole therapy in the treatment of RSV disease in a group of 53 infants, including infants with underlying disease. "The rate of improvement in the illness severity score was significantly greater in the ribavirin patients between day 1 and each subsequent day of therapy...the difference in improvement between the ribavirin- and placebo-treated patients was most noticeable during the first 24 hours of therapy. In infants with bronchopulmonary dysplasia and congenital heart disease, this may be particularly important in preventing the cascade of complications that are more likely to ensue because of the underlying disease.[2,3]...Significantly greater improvement was also demonstrated in their arterial blood gas values and in the amount of virus shed."[4]





Percent improvement in illness severity score from start to end of therapy in infants with RSV infection who received ribavirin compared with those who received placebo for total group of infants (left two bars) and for those infants with congenital heart disease (CHD) and bronchopulmonary dysplasia (BPD) (right two bars).[4]



Percent improvement in illness severity score from day 1 to day 2 and from day 2 to day 4 in infants with RSV infection who received ribavirin compared with those who received placebo for total group of infants (left bars) and for those infants with congenital heart disease (CHD) and bronchopulmonary dysplasia (BPD) (right bars).[4]

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Virazole®
(Ribavirin)
lyophilized for aerosol administration

Please see prescribing information on next page for warnings and contraindications.

Virazole®
(Ribavirin)

lyophilized for aerosol administration

PRESCRIBING INFORMATION

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

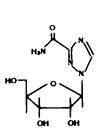
Deterioration of respiratory function has been associated with ribavirin use in infants, and in adults with chronic obstructive lung disease or asthma. Respiratory function should be carefully monitored during treatment. If initiation of ribavirin aerosol treatment appears to produce sudden deterioration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

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

DESCRIPTION:

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

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



Ribavirin, a synthetic nucleoside, is a stable, white, crystalline compound with a maximum solubility in water of 142 mg/ml at 25 °C and with only a slight solubility in ethanol. The empirical formula is $C_8H_{12}N_4O_5$ and the molecular weight is 244.2 Daltons.

CLINICAL PHARMACOLOGY:

Antiviral effects:

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

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

Immunologic effects:

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

Microbiology:

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

Pharmacokinetics:

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

Ribavirin administered by aerosol is absorbed systemically. Four pediatric patients inhaling ribavirin aerosol administered by face mask for 2.5 hours each day for 3 days had plasma concentrations ranging from 0.44 to 1.55 μM, with a mean concentration of 0.76 μM. The plasma half-life was reported to be 9.5 hours. Three pediatric patients inhaling ribavirin aerosol administered by face mask or mist tent for 20 hours each day for 5 days had plasma concentrations ranging from 1.5 to 14.3 μM, with a mean concentration of 6.8μM.

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

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

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

INDICATIONS AND USAGE:

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

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

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

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

Diagnosis:

RSV infection should be documented by a rapid diagnostic method such as demonstration of viral antigen in respiratory tract secretions by immunofluorescence[3,4] or ELISA[5] before or during the first 24 hours of treatment. Ribavirin aerosol is indicated only for lower respiratory tract infection due to RSV. Treatment may be initiated while awaiting rapid diagnostic test results. However, treatment should not be continued without documentation of RSV infection.

CONTRAINDICATIONS:

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

WARNINGS:

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

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

PRECAUTIONS:

General:

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

Drug Interactions:

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

Carcinogenesis, mutagenesis, impairment of fertility:

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

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

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

Pregnancy:

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

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

ADVERSE REACTIONS:

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

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

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

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

Cardiovascular: Cardiac arrest, hypotension, and digitalis toxicity.

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

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

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

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

Overdosage:

No overdosage with ribavirin by aerosol administration has been reported in the human. The LD_{50} in mice is 2 gm orally. Hypoactivity and gastrointestinal symptoms occurred. In man, ribavirin is sequestered in red blood cells for weeks after dosing.

DOSAGE AND ADMINISTRATION

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

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

Treatment is carried out for 12-18 hours per day for at least 3 and no more than 7 days, and is part of a total treatment program. The aerosol is delivered to an infant oxygen hood from the SPAG-2 aerosol generator. Administration by face mask or oxygen tent may be necessary if a hood cannot be employed (see SPAG-2 manual). However, the volume of distribution and condensation area are larger in a tent and efficacy of this method of administering the drug has been evaluated in only a small number of patients. Ribavirin aerosol is not to be administered with any other aerosol generating device or together with other aerosolized medications. Ribavirin aerosol should not be used for patients requiring simultaneous assisted ventilation (see Boxed Warnings).

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

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

HOW SUPPLIED:

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

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5. Hendry RM, McIntosh K, Fahnestock ML, and Pierik LT. Enzyme-linked immunosorbent assay for detection of respiratory syncytial virus infection. *J Clin Microbiol* 16:329-33, 1982.

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(griseofulvin microsize)
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Indications

Major indications for GRIFULVIN V griseofulvin microsize are

Tinea capitis	Tinea unguium
Tinea corporis	Tinea cruris
Tinea pedis	Tinea barbae

GRIFULVIN V (griseofulvin microsize) inhibits the growth of those genera of fungi that commonly cause ringworm infections of the hair, skin, and nails, such as:

Trichophyton rubrum	Microsporum audouini
Trichophyton tonsurans	Microsporum canis
Trichophyton mentagrophytes	Microsporum gypseum
Trichophyton interdigitalis	Epidermophyton floccosum
Trichophyton verrucosum	Trichophyton megnini
Trichophyton sulphureum	Trichophyton gallinae
Trichophyton schoenleini	Trichophyton crateriform

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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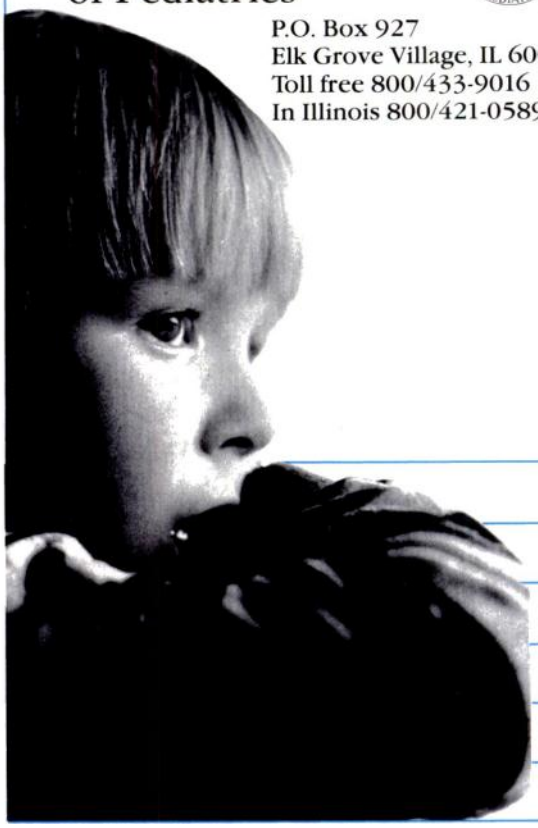


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THESE INCIDENTS USUALLY HAVE OCCURRED DURING THE FIRST SIX MONTHS OF TREATMENT. SERIOUS OR FATAL HEPATOTOXICITY MAY BE PRECEDED BY NON-SPECIFIC SYMPTOMS SUCH AS LOSS OF SEIZURE CONTROL, MALAISE, WEAKNESS, LETHARGY, FACIAL EDEMA, ANOREXIA AND VOMITING. PATIENTS SHOULD BE MONITORED CLOSELY FOR APPEARANCE OF THESE SYMPTOMS. LIVER FUNCTION TESTS SHOULD BE PERFORMED PRIOR TO THERAPY AND AT FREQUENT INTERVALS THEREAFTER, ESPECIALLY DURING THE FIRST SIX MONTHS.

DESCRIPTION: Divalproex sodium is a stable co-ordination compound comprised of sodium valproate and valproic acid in a 1:1 molar relationship and formed during the partial neutralization of valproic acid with 0.5 equivalent of sodium hydroxide. Chemically it is designated as sodium hydrogen bis(2-propylpentanoate).

Divalproex sodium has a molecular weight of 310.41 and occurs as a white powder with a characteristic odor.

DEPAKOTE is an oral antiepileptic supplied as enteric-coated tablets in three dosage strengths containing divalproex sodium equivalent to 125 mg, 250 mg or 500 mg of valproic acid.

Inactive Ingredients
125 mg tablets: cellulosic polymers, diacetylated monoglycerides, FD&C Blue No. 1, FD&C Red No. 40, povidone, pregelatinized starch (contains corn starch), silica gel, talc, titanium dioxide, vanillin and other ingredients.

250 mg tablets: cellulosic polymers, diacetylated monoglycerides, FD&C Yellow No. 6, iron oxide, povidone, pregelatinized starch (contains corn starch), silica gel, talc, titanium dioxide, vanillin and other ingredients.

500 mg tablets: cellulosic polymers, diacetylated monoglycerides, D&C Red No. 30, FD&C Blue No. 2, iron oxide, povidone, pregelatinized starch (contains corn starch), silica gel, talc, titanium dioxide, vanillin and other ingredients.

CLINICAL PHARMACOLOGY: DEPAKOTE is an antiepileptic agent which is chemically related to valproic acid. It has no nitrogen or aromatic moiety characteristic of other antiepileptic drugs. The mechanism by which DEPAKOTE exerts its antiepileptic effects has not been established. It has been suggested that its activity is related to increased brain levels of gamma-aminobutyric acid (GABA). The effect on the neuronal membrane is unknown. DEPAKOTE dissociates into valproate in the gastrointestinal tract.

Because of the enteric coating of DEPAKOTE, absorption is delayed one hour following oral administration. Thereafter, DEPAKOTE is uniformly and reliably absorbed, as shown by studies in normal volunteers. Peak serum levels of valproate occur in 3 to 4 hours. Bioavailability of divalproex sodium tablets was found to be equivalent to that of DEPAKENE® (valproic acid) capsules. Concomitant administration with food would be expected to slow absorption but not affect the extent of absorption. The serum half-life of valproate is typically in the range of six to sixteen hours. Half-lives in the lower part of the above range are usually found in patients taking other antiepileptic drugs capable of enzyme induction.

Enteric-coated divalproex sodium may reduce the incidence of the irritative gastrointesnal effects of valproate as compared to valproic acid capsules.

Valproate is rapidly distributed and at therapeutic drug concentrations, drug is highly bound (90%) to human plasma proteins. Increases in dose may result in decreases in the extent of protein binding and increased valproate clearance and elimination.

Elimination of DEPAKOTE and its metabolites occurs principally in the urine, with minor amounts in the feces and expired air. Very little unmetabolized parent drug is excreted in the urine. The drug is primarily metabolized in the liver and is excreted as the glucuronide conjugate. Other metabolites in the urine are products of beta, omega-1, and omega oxidation (C-3, C-4 and C-5 positions). The major oxidative metabolite in the urine is 2-propyl-3-keto-pentanoic acid; minor metabolites are 2-propyl-glutaric acid, 2-propyl-5-hydroxypentanoic acid, 2-propyl-3-hydroxypentanoic acid and 2-propyl-4-hydroxypentanoic acid.

INDICATIONS AND USAGE: DEPAKOTE (divalproex sodium) is indicated for use as sole and adjunctive therapy in the treatment of simple (petit mal) and complex absence seizures. DEPAKOTE may also be used adjunctively in patients with multiple seizure types which include absence seizures.

In accordance with the International Classification of Seizures, simple absence is defined as very brief clouding of the sensorium or loss of consciousness (lasting usually 2-15 seconds), accompanied by certain generalized epileptic discharges without other detectable clinical signs. Complex absence is the term used when other signs are also present.

SEE "WARNINGS" SECTION FOR STATEMENT REGARDING FATAL HEPATIC DYSFUNCTION.

CONTRAINDICATIONS: DEPAKOTE (DIVALPROEX SODIUM) SHOULD NOT BE ADMINISTERED TO PATIENTS WITH HEPATIC DISEASE OR SIGNIFICANT DYSFUNCTION.

DEPAKOTE is contraindicated in patients with known hypersensitivity to the drug.

WARNINGS: Hepatic failure resulting in fatalities has occurred in patients receiving valproic acid. These incidents usually have occurred during the first six months of treatment. Serious or fatal hepatotoxicity may be preceded by non-specific symptoms such as loss of seizure control, malaise, weakness, lethargy, facial edema, anorexia and vomiting. Patients should be monitored closely for appearance of these symptoms. Liver function tests should be performed prior to therapy and at frequent intervals thereafter, especially during the first six months. However, physicians should not rely totally on serum biochemistry since these tests may not be abnormal in all instances, but should also consider the results of careful interim medical history and physical examination. Caution should be observed when administering DEPAKOTE to patients with a prior history of hepatic disease. Patients on multiple anticonvulsants, children, those with congenital metabolic disorders, those with severe seizure disorders accompanied by mental retardation, and those with organic brain disease may be at particular risk. Experience has indicated that children under the age of two years are at a considerably increased risk of developing fatal hepatotoxicity, especially those with the aforementioned conditions. When DEPAKOTE is used in this patient group, it should be used with extreme caution and as a sole agent. The benefits of seizure control should be weighed against the risks. Above this age group, experience has indicated that the incidence of fatal hepatotoxicity decreases considerably in progressively older patient groups.

The drug should be discontinued immediately in the presence of significant hepatic dysfunction, suspected or apparent. In some cases, hepatic dysfunction has progressed in spite of discontinuation of drug.

The frequency of adverse effects (particularly elevated liver enzymes) may be dose-related. The benefit of improved seizure control which may accompany the higher doses should therefore be weighed against the possibility of a greater incidence of adverse effects.

Usage in Pregnancy: ACCORDING TO PUBLISHED AND UNPUBLISHED REPORTS, VALPROIC ACID MAY PRODUCE TERATOGENIC EFFECTS IN THE OFFSPRING OF HUMAN FEMALES RECEIVING THE DRUG DURING PREGNANCY.

THERE ARE MULTIPLE REPORTS IN THE CLINICAL LITERATURE WHICH INDICATE THAT THE USE OF ANTIEPILEPTIC DRUGS DURING PREGNANCY RESULTS IN AN INCREASED INCIDENCE OF BIRTH DEFECTS IN THE OFFSPRING. ALTHOUGH DATA ARE MORE EXTENSIVE WITH RESPECT TO TRIMETHADIONE, PARAMETHADIONE, PHENYTOIN, AND PHENOBARBITAL, REPORTS INDICATE A POSSIBLE SIMILAR ASSOCIATION WITH THE USE OF OTHER ANTIEPILEPTIC DRUGS. THEREFORE, ANTIEPILEPTIC DRUGS SHOULD BE ADMINISTERED TO WOMEN OF CHILDBEARING POTENTIAL ONLY IF THEY ARE CLEARLY SHOWN TO BE ESSENTIAL IN THE MANAGEMENT OF THEIR SEIZURES.

THE INCIDENCE OF NEURAL TUBE DEFECTS IN THE FETUS MAY BE INCREASED IN MOTHERS RECEIVING VALPROATE DURING THE FIRST TRIMESTER OF PREGNANCY. THE CENTERS FOR DISEASE CONTROL (CDC) HAS ESTIMATED THE RISK OF VALPROIC ACID EXPOSED WOMEN HAVING CHILDREN WITH SPINA BIFIDA TO BE APPROXIMATELY 1 TO 2%.[1] THIS RISK IS SIMILAR TO THAT FOR NONEPILEPTIC WOMEN WHO HAVE HAD CHILDREN WITH NEURAL TUBE DEFECTS (ANENCEPHALY AND SPINA BIFIDA).

ANIMAL STUDIES ALSO HAVE DEMONSTRATED VALPROIC ACID INDUCED TERATOGENICITY. Studies in rats and human females demonstrated placental transfer of the drug. Doses greater than 65 mg/kg/day given to pregnant rats and mice produced skeletal abnormalities in the offspring, primarily involving ribs and vertebrae; doses greater than 150 mg/kg/day given to pregnant rabbits produced fetal resorptions and (primarily) soft-tissue abnormalities in the offspring. In rats a dose-related delay in the onset of parturition was noted. Postnatal growth and survival of the progeny were adversely affected, particularly when drug administration spanned the entire gestation and early lactation period.

Antiepileptic 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.

PRECAUTIONS: *Hepatic Dysfunction:* See "Boxed Warning," "Contraindications" and "Warnings" sections.

General: Because of reports of thrombocytopenia, inhibition of the secondary phase of platelet aggregation, and abnormal coagulation parameters, platelet counts and coagulation tests are recommended before initiating therapy and at periodic intervals. It is recommended that patients receiving DEPAKOTE (divalproex sodium) be monitored for platelet count and coagulation parameters prior to planned surgery. Evidence of hemorrhage, bruising or a disorder of hemostasis/coagulation is an indication for reduction of DEPAKOTE dosage or withdrawal of therapy.

Hyperammonemia with or without lethargy or coma has been reported and may be present in the absence of abnormal liver function tests. If clinically significant elevation occurs, DEPAKOTE should be discontinued.

Since DEPAKOTE (divalproex sodium) may interact with concurrently administered antiepileptic drugs, periodic serum level determinations of concomitant antiepileptic drugs are recommended during the early course of therapy. (See "Drug Interactions" section).

Valproate is partially eliminated in the urine as a keto-metabolite which may lead to a false interpretation of the urine ketone test.

There have been reports of altered thyroid function tests associated with valproate. The clinical significance of these is unknown.

Information for Patients: Since DEPAKOTE may produce CNS depression, especially when combined with another CNS depressant (e.g., alcohol), patients should be advised not to engage in hazardous occupations, such as driving an automobile or operating dangerous machinery, until it is known that they do not become drowsy from the drug.

Drug Interactions: Valproic acid may potentiate the CNS depressant activity of alcohol.

The concomitant administration of valproic acid with drugs that exhibit extensive protein binding (e.g., aspirin, carbamazepine, and diclumarol) may result in alteration of serum drug levels.

THERE IS EVIDENCE THAT VALPROIC ACID CAN CAUSE AN INCREASE IN SERUM PHENOBARBITAL LEVELS BY IMPAIRMENT OF NON-RENAL CLEARANCE. THIS PHENOMENON CAN RESULT IN SEVERE CNS DEPRESSION. THE COMBINATION OF VALPROIC ACID AND PHENOBARBITAL HAS ALSO BEEN REPORTED TO PRODUCE CNS DEPRESSION WITHOUT SIGNIFICANT ELEVATIONS OF BARBITURATE OR VALPROATE SERUM LEVELS. ALL PATIENTS RECEIVING CONCOMITANT BARBITURATE THERAPY SHOULD BE CLOSELY MONITORED FOR NEUROLOGICAL TOXICITY. SERUM BARBITURATE LEVELS SHOULD BE OBTAINED, IF POSSIBLE, AND THE BARBITURATE DOSAGE DECREASED, IF APPROPRIATE.

Primidone is metabolized into a barbiturate and, therefore, may also be involved in a similar or identical interaction.

THERE HAVE BEEN REPORTS OF BREAKTHROUGH SEIZURES OCCURRING WITH THE COMBINATION OF VALPROIC ACID AND PHENYTOIN. MOST REPORTS HAVE NOTED A DECREASE IN TOTAL PLASMA PHENYTOIN CONCENTRATION. HOWEVER, INCREASES IN TOTAL PHENYTOIN SERUM CONCENTRATION HAVE BEEN REPORTED, AN INITIAL FALL IN TOTAL PHENYTOIN LEVELS WITH SUBSEQUENT INCREASE IN PHENYTOIN LEVELS HAS ALSO BEEN REPORTED. IN ADDITION, A DECREASE IN TOTAL SERUM PHENYTOIN WITH AN INCREASE IN THE FREE VS. PROTEIN BOUND PHENYTOIN LEVELS HAS BEEN REPORTED. THE DOSAGE OF PHENYTOIN SHOULD BE ADJUSTED AS REQUIRED BY THE CLINICAL SITUATION.

THE CONCOMITANT USE OF VALPROIC ACID AND CLONAZEPAM MAY PRODUCE ABSENCE STATUS.

There is inconclusive evidence regarding the effect of valproate on serum ethosuximide levels. Patients receiving valproate and ethosuximide, especially along with other anticonvulsants, should be monitored for alterations in serum concentrations of both drugs.

Caution is recommended when DEPAKOTE (divalproex sodium) is administered with drugs affecting coagulation, e.g., aspirin and warfarin. (See "Adverse Reactions" section).

Carcinogenesis: Valproic acid was administered to Sprague Dawley rats and ICR (HA/ICR) mice at doses of 0, 80 and 170 mg/kg/day for two years. Although a variety of neoplasms were observed in both species, the chief findings were a statistically significant increase in the incidence of subcutaneous fibrosarcomas in high dose male rats receiving valproic acid and a statistically significant dose-related trend for benign pulmonary adenomas in male mice receiving valproic acid. The significance of these findings for man is unknown at present.

Mutagenesis: Studies on valproic acid have been performed using bacterial and mammalian systems. These studies have provided no evidence of a mutagenic potential for DEPAKOTE.

Fertility: Chronic toxicity studies in juvenile and adult rats and dogs demonstrated reduced spermatogenesis and testicular atrophy at doses greater than 200 mg/kg/day in rats and greater than 90 mg/kg/day in dogs. Segment I fertility studies in rats have shown doses up to 350 mg/kg/day for 60 days to have no effect on fertility. THE EFFECT OF DEPAKOTE (DIVALPROEX SODIUM) ON THE DEVELOPMENT OF THE TESTES AND ON SPERM PRODUCTION AND FERTILITY IN HUMANS IS UNKNOWN.

Pregnancy: Pregnancy Category D: See "Warnings" section.

Nursing Mothers: Valproate is excreted in breast milk. Concentrations in breast milk have been reported to be 1-10% of serum concentrations. It is not known what effect this would have on a nursing infant. Caution should be exercised when DEPAKOTE is administered to a nursing woman.

ADVERSE REACTIONS: Since valproic acid and its derivatives have usually been used with other antiepileptic drugs, it is not possible, in most cases, to determine whether the following adverse reactions can be ascribed to valproic acid alone, or the combination of drugs.

Gastrointestinal: The most commonly reported side effects at the initiation of therapy are nausea, vomiting and indigestion. These effects are usually transient and rarely require discontinuation of therapy. Diarrhea, abdominal cramps and constipation have been reported. Both anorexia with some weight loss and increased appetite with weight gain have also been reported. The administration of enteric-coated divalproex sodium may result in reduction of gastrointestinal side effects in some patients.[2]

CNS Effects: Sedative effects have been noted in patients receiving valproic acid alone but are found most often in patients receiving combination therapy. Sedation usually disappears upon reduction of other antiepileptic medication. Tremor has been reported in patients receiving valproate and may be dose-related. Ataxia, headache, nystagmus, diplopia, asterixis, "spots before eyes," dysarthria, dizziness, and incoordination have rarely been noted. Rare cases of coma have been noted in patients receiving valproic acid alone or in conjunction with phenobarbital.

Dermatologic: Transient increases in hair loss have been observed. Skin rash and erythema multiforme rarely have been noted.

Psychiatric: Emotional upset, depression, psychosis, aggression, hyperactivity and behavioral deterioration have been reported.

Musculoskeletal: Weakness has been reported.

Hematologic: Thrombocytopenia has been reported. Valproic acid inhibits the secondary phase of platelet aggregation. (See "Drug Interactions" section). This may be reflected in altered bleeding time. Petechiae, bruising, hematoma formation, and frank hemorrhage have been reported. (See "Precautions" section). Relative lymphocytosis and hypofibrinogenemia have been noted. Leukopenia and eosinophilia have also been reported. Anemia and bone marrow suppression have been reported.

Hepatic: Minor elevations of transaminases (e.g., SGOT and SGPT) and LDH are frequent and appear to be dose related. Occasionally, laboratory test results include, as well, increases in serum bilirubin and abnormal changes in other liver function tests. These results may reflect potentially serious hepatotoxicity. (See "Warnings" section).

Endocrine: There have been reports of irregular menses and secondary amenorrhea, and rare reports of breast enlargement and galactorrhea occurring in patients receiving valproic acid and its derivatives.

Abnormal thyroid function tests have been reported. (See "Precautions" section).

Pancreatic: There have been reports of acute pancreatitis, including rare fatal cases, occurring in patients receiving valproic acid and its derivatives.

Metabolic: Hyperammonemia. (See "Precautions" section).

Hyperglycinemia has been reported and has been associated with a fatal outcome in a patient with preexistent nonketotic hyperglycinemia.

Other: Edema of the extremities has been reported.

OVERDOSAGE: Overdosage with valproic acid may result in deep coma.

Since DEPAKOTE tablets are enteric-coated, the benefit of gastric lavage or emesis will vary with the time since ingestion. General supportive measures should be applied with particular attention being given to the maintenance of adequate urinary output.

Naloxone has been reported to reverse the CNS depressant effects of valproate overdosage. Because naloxone could theoretically also reverse the antiepileptic effects of DEPAKOTE it should be used with caution.

DOSAGE AND ADMINISTRATION: DEPAKOTE is administered orally. The recommended initial dose is 15 mg/kg/day, increasing at one week intervals by 5 to 10 mg/kg/day until seizures are controlled or side effects preclude further increases. The maximum recommended dosage is 60 mg/kg/day. If the total daily dose exceeds 250 mg, it should be given in a divided regimen.

Conversion from DEPAKENE to DEPAKOTE: In patients previously receiving DEPAKENE (valproic acid) therapy, DEPAKOTE should be initiated at the same total daily dose and dosing schedule.[3] After the patient is stabilized on DEPAKOTE, a twice-a-day or three-times-a-day schedule may be instituted in selected patients.

The frequency of adverse effects (particularly elevated liver enzymes) may be dose-related. The benefit of improved seizure control which may accompany higher doses should therefore be weighed against the possibility of a greater incidence of adverse reactions.

A good correlation has not been established between daily dose, serum level and therapeutic effect. However, therapeutic valproate serum levels for most patients will range from 50 to 100 mcg/ml. Occasional patients may be controlled with serum levels lower or higher than this range.

As the DEPAKOTE dosage is titrated upward, blood levels of phenobarbital and/or phenyton may be affected. (See "Precautions" section).

Patients who experience G. I. irritation may benefit from administration of the drug with food or by slowly building up the dose from an initial low level.

HOW SUPPLIED: DEPAKOTE (divalproex sodium enteric-coated tablets) are supplied as:

125 mg salmon pink-colored tablets:
Bottles of 100 ..... (**NDC** 0074-6212-13)

250 mg peach-colored tablets:
Bottles of 100 ..... (**NDC** 0074-6214-13)
Abbo-Pac® unit dose packages of 100 ..... (**NDC** 0074-6214-11)

500 mg lavender-colored tablets:
Bottles of 100 ..... (**NDC** 0074-6215-13)
Abbo-Pac® unit dose packages of 100 ..... (**NDC** 0074-6215-11)

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3. Wilder, B.J., et al, Twice-Daily Dosing of Valproate with Divalproex, *Clin Pharmacol Ther* 34(4):501-504, 1983.

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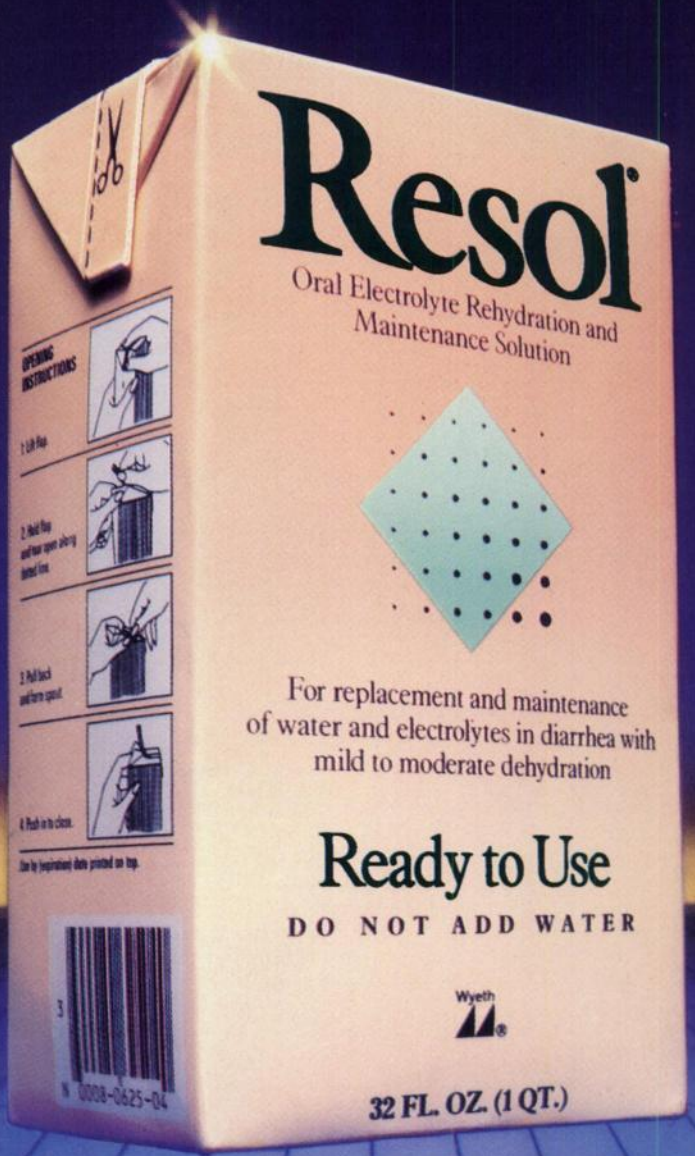

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References: 1. Committee on Nutrition, American Academy of Pediatrics: Oral fluid therapy and posttreatment feeding following enteritis, chap 31 in Forbes GB, ed, and Woodruff CW, assoc ed: *Pediatric Nutrition Handbook*, 2nd ed, American Academy of Pediatrics, Elk Grove Village, Illinois, 1985, pp 274-280.
2. *Seminar on Oral Rehydration for Diarrheal Disease*, Johns Hopkins School of Medicine, March 15-17, 1982.

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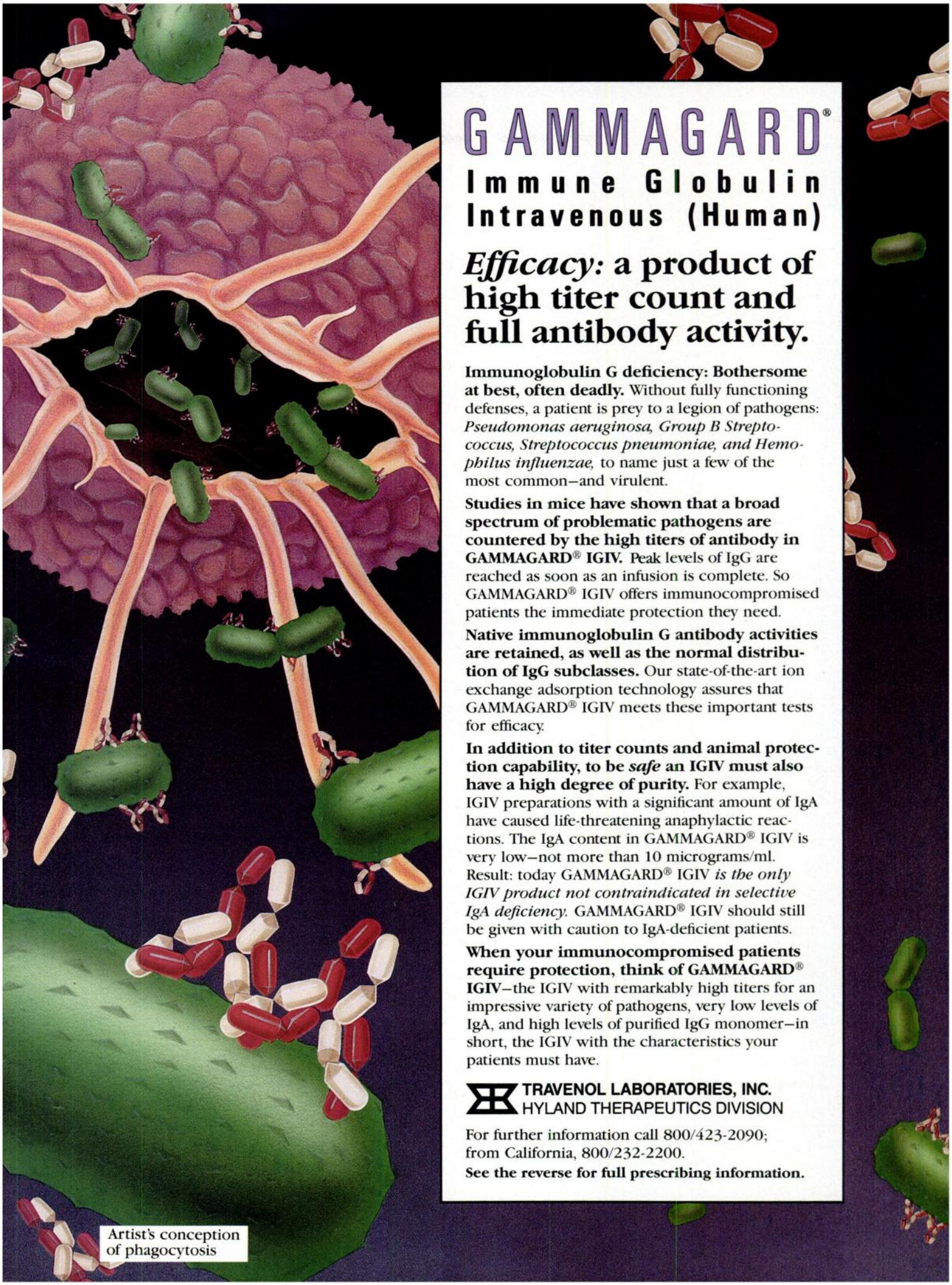

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Artist's conception of phagocytosis

DIRECTION INSERT

Immune Globulin Intravenous (Human) GAMMAGARD®

DESCRIPTION

Immune Globulin Intravenous (Human), GAMMAGARD® * is a sterile, dried, highly purified preparation of immunoglobulin which is derived from the cold ethanol fractionation process and is further purified using ultrafiltration and ion exchange adsorption. When reconstituted with the appropriate volume of diluent, this preparation contains approximately 50 mg of protein per mL, of which at least 90% is gamma globulin. The reconstituted product contains approximately 1% sodium chloride, not more than 20 mg/mL glucose, not more than 0.2 g/dL PEG, and 0.3M glycine as a stabilizing agent. It has a pH of 6.8±0.4.

The manufacturing process for Immune Globulin Intravenous (Human), GAMMAGARD, isolates gamma globulin without additional chemical or enzymatic modification and the Fc portion is maintained intact. Immune Globulin Intravenous (Human), GAMMAGARD contains all the immunoglobulin G antibody activities which are present in the donor population. On the average, the distribution of IgG subclasses present in this product is the same as is present in normal plasma.[1] Immune Globulin Intravenous (Human), GAMMAGARD contains only trace amounts of IgM and IgA.

Immune Globulin Intravenous (Human), GAMMAGARD contains no preservative.

This product has been prepared from large pools of human plasma which was taken only from plasma units found to have normal levels of alanine aminotransferase (ALT). Each unit of plasma used in the manufacture of this product has been found to be nonreactive for HBsAg and HTLV-III antibody by FDA approved tests.

CLINICAL PHARMACOLOGY

Immune Globulin Intravenous (Human), GAMMAGARD contains a broad spectrum of IgG antibodies against bacterial and viral agents that are capable of opsonization and neutralization of microbes and toxins.

Peak levels of IgG are reached immediately after infusion of Immune Globulin Intravenous (Human), GAMMAGARD. It has been shown that IgG is distributed relatively rapidly between plasma and extravascular fluid until approximately half of the total body pool is partitioned in the extravascular space. A rapid initial drop in serum levels is, therefore, to be expected.[2]

As a class, IgG survives longer *in vivo* than other serum proteins.[2,3] Studies show that the half-life of Immune Globulin Intravenous (Human), GAMMAGARD is approximately 24 days. These findings are consistent with reports of a 21 to 25 day half-life for IgG.[2,3,4] The half-life of IgG can vary considerably from person to person, however. In particular, high concentrations of IgG and hypermetabolism associated with fever and infection have been seen to coincide with a shortened half-life of IgG.[2,3,4,5]

INDICATIONS AND USAGE

Antibody Deficiency

Immune Globulin Intravenous (Human), GAMMAGARD is efficacious in the treatment of primary immunodeficient states in which severe impairment of antibody forming capacity has been shown, such as: congenital agammaglobulinemias, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.[4,5]

Immune Globulin Intravenous (Human), GAMMAGARD is especially useful when high levels or rapid elevation of circulating gamma globulins are desired or when intramuscular injections are contraindicated.

CONTRAINDICATIONS

None known.

WARNINGS

Immune Globulin Intravenous (Human), GAMMAGARD should only be administered intravenously. Other routes of administration have not been evaluated.

Immune Globulin Intravenous (Human), GAMMAGARD contains very low quantities of IgA (not more than 10 μg/mL) and although no instances of anaphylaxis associated with the use of this product have been observed during the clinical trials, such reactions have been observed with other immunoglobulin products.[5,6] Immune Globulin Intravenous (Human), GAMMAGARD should be given with caution to patients with antibodies to IgA or selective IgA deficiencies.

PRECAUTIONS

Drug Interaction

Admixtures of Immune Globulin Intravenous (Human), GAMMAGARD with other drugs have not been evaluated. It is recommended that Immune Globulin Intravenous (Human), GAMMAGARD be administered separately from other drugs or medication which the patient may be receiving.

Pregnancy Category C

Animal reproduction studies have not been conducted with Immune Globulin Intravenous (Human), GAMMAGARD. It is also not known whether Immune Globulin Intravenous (Human), GAMMAGARD can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Immune Globulin Intravenous (Human), GAMMAGARD should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

The incidence of untoward reactions to Immune Globulin Intravenous (Human), GAMMAGARD is low, although various minor reactions, such as headache, fatigue, chills, backache, lightheadedness, fever and nausea may occasionally occur. The incidence of these reactions during the clinical trials was less than 6%. Slowing or stopping the infusion usually allows the symptoms to disappear promptly.

Immediate anaphylactic and hypersensitivity reactions due to previous sensitization, although they have not been observed during the clinical trials, are a possibility. Epinephrine should be available for treatment of any acute anaphylactoid reaction. (See WARNINGS.)

DOSAGE AND ADMINISTRATION

Antibody Deficiency

For patients with primary immunodeficiencies, monthly doses of at least 100 mg/kg are recommended. Initially, patients may receive 200-400 mg/kg. As there are significant differences in the half-life of IgG among patients with primary immunodeficiencies, the frequency and amount of immunoglobulin therapy may vary from patient to patient. The proper amount can be determined by monitoring clinical response and/or the serum IgG levels before each dose, to insure that they do not drop below 500 mg/dL.

Rate of Administration

It is recommended that initially a rate of 0.5 mL/kg per Hr be used. If infusion at this rate causes the patient no distress, the administration rate may be gradually increased but should not exceed 4 mL/kg per Hr.

A rate of administration which is too rapid may cause flushing and changes in pulse rate and blood pressure. Slowing or stopping the infusion usually allows the symptoms to disappear promptly.

Administration

Immune Globulin Intravenous (Human), GAMMAGARD should be administered as soon after reconstitution as possible. Administration should not begin more than 2 hours after reconstitution.

The reconstituted material should be at room temperature during administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Follow directions for use which accompany the administration set. If a Hyland set is not used, make sure the administration set contains an adequate filter.

How Supplied

Immune Globulin Intravenous (Human), GAMMAGARD is supplied in either 2.5 g or 5.0 g single use vials. Each vial of Immune Globulin Intravenous (Human), GAMMAGARD is furnished with a suitable volume of Sterile Water for Injection, USP, a transfer device and an administration set which contains an integral airway and a 15 micron filter.

Storage

Immune Globulin Intravenous (Human), GAMMAGARD should be stored under ordinary refrigeration, (2 to 8 °C, 36 to 46 °F). Freezing should be avoided to prevent the diluent bottle from breaking.

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1. Unpublished data in the files of Travenol Laboratories, Inc.
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1. Pediatrics 73:405-407, 1984.

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*The pediatrician's responsibility for infant nutrition. *AAP News*, Vol. 2, No. 10, October 1986.

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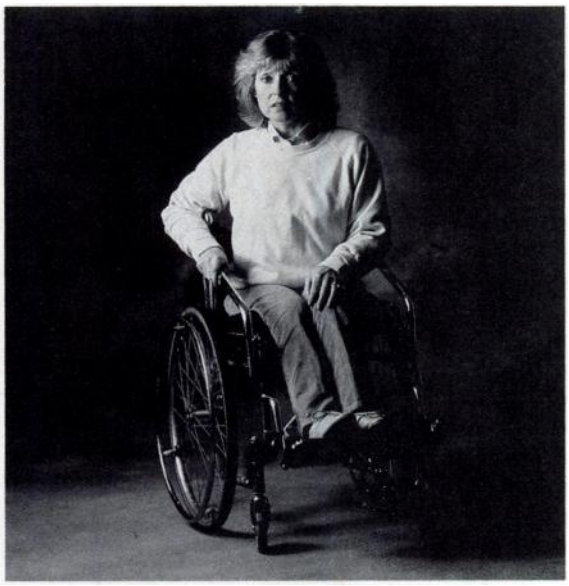

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INDICATIONS
For prevention of poliomyelitis caused by Poliovirus Types 1, 2, and 3. For complete references and Indications and Usage statement, see package insert.

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."

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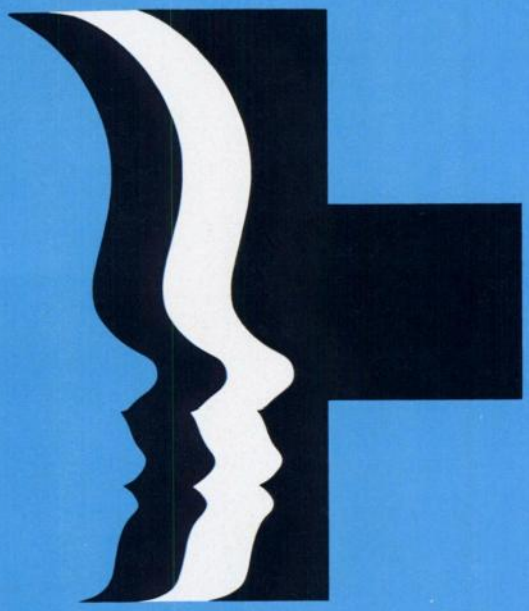

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P-1286

THE CONSEQUENCES OF A PHYSICIAN DECEIVING A CHILD (1832)

The Reverend John S. C. Abbott of Worcester, Massachusetts was one of the best known early nineteenth century authors of books written for the guidance of American mothers in "the government of their children."[1] He warned mothers about the consequences of deceiving children as follows:

A physician was once called to extract as tooth from a child. The little boy seeing the formidable instruments, and anticipating the pain, was exceedingly frightened, and refused to open his mouth. After much fruitless solicitation, the physician said, "Perhaps there is no need of drawing it. Let me rub it a little with my handkerchief, and it may be all that is necessary; it will not hurt you in the least." The boy, trusting his word, opened his mouth. The physician, concealing his instrument in his handkerchief, seized hold of the tooth and wrenched it out. The parents highly applauded his artifice. But the man cheated the child. He abused his confidence; and he inflicted an injury upon his moral feelings not soon to be effaced. Will that physician get his handkerchief into the mouth of the child again? And when told that it is wicked to say that which is not true, will not the remembrance of the doctor's falsehood be fresh in his mind? And while conscious that his parents approved of the deception, will he not feel it be right for him to deceive, that he may accomplish his desires? This practice is attended with the most ruinous consequences. It unavoidably teaches the child to despise his parents. After he has detected them in one falsehood, he will not believe them when they speak the truth. It destroys his tenderness of conscience; and it teaches arts of deception.

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

REFERENCE

1. Abbott JSC: *The Mother at Home; or the Principles of Maternal Duty.* Boston, Crocker & Brewster, 1834, pp 97–98.

IS THIS WHAT HAS HAPPENED TO US?

I do not mean merely to accuse my profession of greediness, though greed exists among doctors as among any other group. Rather, I would suggest that we physicians have been seduced by money; we have been bound by it. Money has become the measure of what we do, the yardstick of our work. Just as if we were in any other business, we physicians have capitulated to the use of economic worth as the determinant of value. In a consumer society such as ours, we doctors are not alone in our idolatry, but our seduction is such a major change from the roots of our profession that it should not go unnoticed.

Submitted by Student

From Hilfiker D: A doctor's view of modern medicine. *The New York Times Magazine*, Feb 23, 1986.

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INDICATIONS AND USAGE: ERYC 125 is indicated in children and adults for the treatment of the following conditions: Upper respiratory tract infections of mild to moderate degree caused by *Streptococcus pyogenes* (group A beta hemolytic streptococci), *Streptococcus pneumoniae (Diplococcus pneumoniae)*, *Haemophilus influenzae* (when used concomitantly with adequate doses of sulfonamides, since not all strains of *H influenzae* are susceptible at the erythromycin concentrations ordinarily achieved) (See appropriate sulfonamide labeling for prescribing information.)

Lower respiratory tract infections of mild to moderate severity caused by *Streptococcus pyogenes* (group A beta hemolytic streptococci); *Streptococcus pneumoniae (Diplococcus pneumoniae)*

Respiratory tract infections due to *Mycoplasma pneumoniae* (Eaton's agent)

Skin and skin structures infections of mild to moderate severity caused by *Streptococcus pyogenes* and *Staphylococcus aureus* (resistant staphylococci may emerge during treatment)

Pertussis (whooping cough) caused by *Bordetella pertussis*. Erythromycin is effective in eliminating the organism from the nasopharynx of infected individuals, rendering them noninfectious. Some clinical studies suggest that erythromycin may be helpful in the prophylaxis of pertussis in exposed susceptible individuals.

Diphtheria—As an adjunct to antitoxin in infections due to *Corynebacterium diphtheriae*, to prevent establishment of carriers and to eradicate the organism in carriers.

Erythrasma—In the treatment of infections due to *Corynebacterium minutissimum*.

Intestinal amebiasis caused by *Entamoeba histolytica* (oral erythromycins only). Extraenteric amebiasis requires treatment with other agents.

Infections due to *Listeria monocytogenes*.

Erythromycin is indicated for treatment of the following infections caused by *Chlamydia trachomatis*: conjunctivitis of the newborn, pneumonia of infancy and urogenital infections during pregnancy. When tetracyclines are contraindicated or not tolerated, erythromycin is indicated for the treatment of uncomplicated urethral, endocervical, or rectal infections in adults due to *Chlamydia trachomatis*.

When tetracyclines are contraindicated or not tolerated erythromycin is indicated for the treatment of nongonococcal urethritis caused by *Ureaplasma urealyticum*.

Primary syphilis caused by *Treponema pallidum*. Erythromycin (oral forms only) is an alternative choice of treatment for primary syphilis in patients allergic to the penicillins. In treatment of primary syphilis, spinal fluid should be examined before treatment and as part of the follow-up after therapy.

Legionnaires' Disease caused by *Legionella pneumophila*. Although no controlled clinical efficacy studies have been conducted, in vitro and limited preliminary clinical data suggest that erythromycin may be effective in treating Legionnaires' Disease.

Prevention of Initial Attacks of Rheumatic Fever—Penicillin is considered by the American Heart Association to be the drug of choice in the prevention of initial attacks of rheumatic fever (treatment of group A beta-hemolytic streptococcal infections of the upper respiratory tract, e.g. tonsillitis or pharyngitis).

Erythromycin is indicated for the treatment of penicillin-allergic patients. A therapeutic dose should be administered for ten days.

Prevention of Recurrent Attacks of Rheumatic Fever—Penicillin or sulfonamides are considered by the American Heart Association to be the drugs of choice in the prevention of recurrent attacks of rheumatic fever.

In patients who are allergic to penicillin and sulfonamides, oral erythromycin is recommended by the American Heart Association in the long-term prophylaxis of streptococcal pharyngitis (for the prevention of recurrent attacks of rheumatic fever).

Prevention of Bacterial Endocarditis—Although no controlled clinical efficacy trials have been conducted, oral erythromycin has been recommended by the American Heart Association for prevention of bacterial endocarditis in penicillin-allergic patients with prosthetic cardiac valves, most congenital cardiac malformations, surgically constructed systemic-pulmonary shunts, rheumatic or other acquired valvular dysfunction, idiopathic hypertrophic subaortic stenosis (IHSS), previous history of bacterial endocarditis and mitral valve prolapse with insufficiency when they undergo dental procedures and surgical procedures of the upper respiratory tract.

CONTRAINDICATION: ERYC 125 is contraindicated in patients with known hypersensitivity to this antibiotic.

WARNING: There have been a few reports of hepatic dysfunction, with or without jaundice, occurring in patients receiving erythromycin ethylsuccinate, base, estolate and stearate products.

PRECAUTIONS: Caution should be exercised when erythromycin is administered to patients with impaired hepatic function (see CLINICAL PHARMACOLOGY in full prescribing information and WARNING section above).

Prolonged or repeated use of erythromycin may result in an overgrowth of nonsusceptible bacteria or fungi. If superinfection occurs, erythromycin should be discontinued and appropriate therapy instituted. When indicated, incision and drainage or other surgical procedures should be performed in conjunction with antibiotic therapy.

Laboratory Tests: Erythromycin interferes with the fluorometric determination of urinary catecholamines.

Drug Interactions: Erythromycin use in patients who are receiving high doses of theophylline may be associated with an increase in 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.

Erythromycin administration in patients receiving carbamazepine has been reported to cause increased blood levels of carbamazepine with subsequent development of signs of carbamazepine toxicity.

Pregnancy Category B—Reproduction studies have been performed in rats, mice and rabbits using erythromycin and its various salts and esters, at doses which were several times the usual human dose. No evidence of impaired fertility or harm to the fetus that appeared related to erythromycin was reported in these studies. There are, however, no adequate well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery—The effect of ERYC 125 on labor and delivery is unknown.

Nursing Mothers—Erythromycin is excreted in milk (see CLINICAL PHARMACOLOGY).

Pediatric Use—See INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION.

ADVERSE REACTIONS: The most frequent side effects of oral erythromycin preparations are gastrointestinal and are dose-related. They include nausea, vomiting, abdominal pain, diarrhea and anorexia. Symptoms of hepatic dysfunction and/or abnormal liver function test results may occur (see WARNING).

Mild allergic reactions such as rashes with or without pruritus, urticaria, bullous fixed eruptions, and eczema have been reported with erythromycin. Serious allergic reactions, including anaphylaxis, have been reported.

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

DOSAGE AND ADMINISTRATION: The entire contents of an ERYC 125 (erythromycin capsules, USP) Capsule should be sprinkled on a small amount of apple sauce immediately prior to ingestion. SUBDIVIDING THE CONTENTS OF A CAPSULE IS NOT RECOMMENDED. If desired ERYC 125 Capsule may be swallowed whole.

Optimum and uniform serum levels of erythromycin are obtained when ERYC 125 is administered in the fasting state (at least 1 hour before meals).

ADULTS: The usual dose is 250 mg every 6 hours. If twice-a-day dosage is desired, the recommended dose is 500 mg every 12 hours. Dosage may be increased up to 4 grams per day, according to the severity of infection. Twice-a-day dosing is not recommended when doses larger than 1 gram daily are administered.

CHILDREN: Age, weight, and severity of the infection are important factors in determining the proper dosage. The usual dosage is 30-50 mg/kg/day in equally divided doses. For the treatment of more severe infections this dosage may be doubled.

In the treatment of group A beta-hemolytic streptococcal infections of the upper respiratory tract (eg tonsillitis or pharyngitis) a therapeutic dosage of erythromycin should be administered for ten days.

The American Heart Association suggests a dosage of 250 mg of erythromycin orally twice a day in long-term prophylaxis of streptococcal upper respiratory tract infections for the prevention of recurrent attacks of rheumatic fever in patients allergic to penicillin and sulfonamide.

In prophylaxis against bacterial endocarditis (see Indications), the oral regimen for penicillin-allergic patients is erythromycin 1.0 g one hour before the procedure followed by 500 mg six hours later.

Conjunctivitis of the newborn caused by *Chlamydia trachomatis*: Oral erythromycin syrup 50 mg/kg/day in four divided doses for at least two weeks.

Pneumonia of infancy caused by *Chlamydia trachomatis*: Although the optimal duration of therapy has not been established, the recommended therapy is oral erythromycin syrup 50 mg/kg/day in four divided doses for at least three weeks.

Urogenital infections during pregnancy due to *Chlamydia trachomatis*. Although the optimal dose and duration of the therapy have not been established, the suggested treatment is erythromycin 500 mg, by mouth, four times a day on an empty stomach for at least seven days. For women who cannot tolerate this regimen, a decreased dose of 250 mg, by mouth, four times a day should be used for at least fourteen days.

For adults with uncomplicated urethral, endocervical, or rectal infections caused by *Chlamydia trachomatis* in whom tetracyclines are contraindicated or not tolerated: 500 mg, by mouth, four times a day for at least seven days.

For patients with nongonococcal urethritis caused by *Ureaplasma urealyticum* in whom tetracyclines are contraindicated or not tolerated: 500 mg, by mouth, four times a day for at least seven days.

Primary syphilis: 30-40 grams given in divided doses over a period of ten to fifteen days.

Intestinal amebiasis: 250 mg four times daily for ten to fourteen days for adults. 30 to 50 mg/kg/day in divided doses for ten to fourteen days for children.

Legionnaires' Disease: Although optimal doses have not been established, doses utilized in reported clinical data were those recommended above (1 to 4 grams daily in divided doses).

Pertussis: Although optimum dosage and duration of therapy have not been established, doses of erythromycin utilized in reported clinical studies were 40-50 mg/kg/day, given in divided doses for five to fourteen days.

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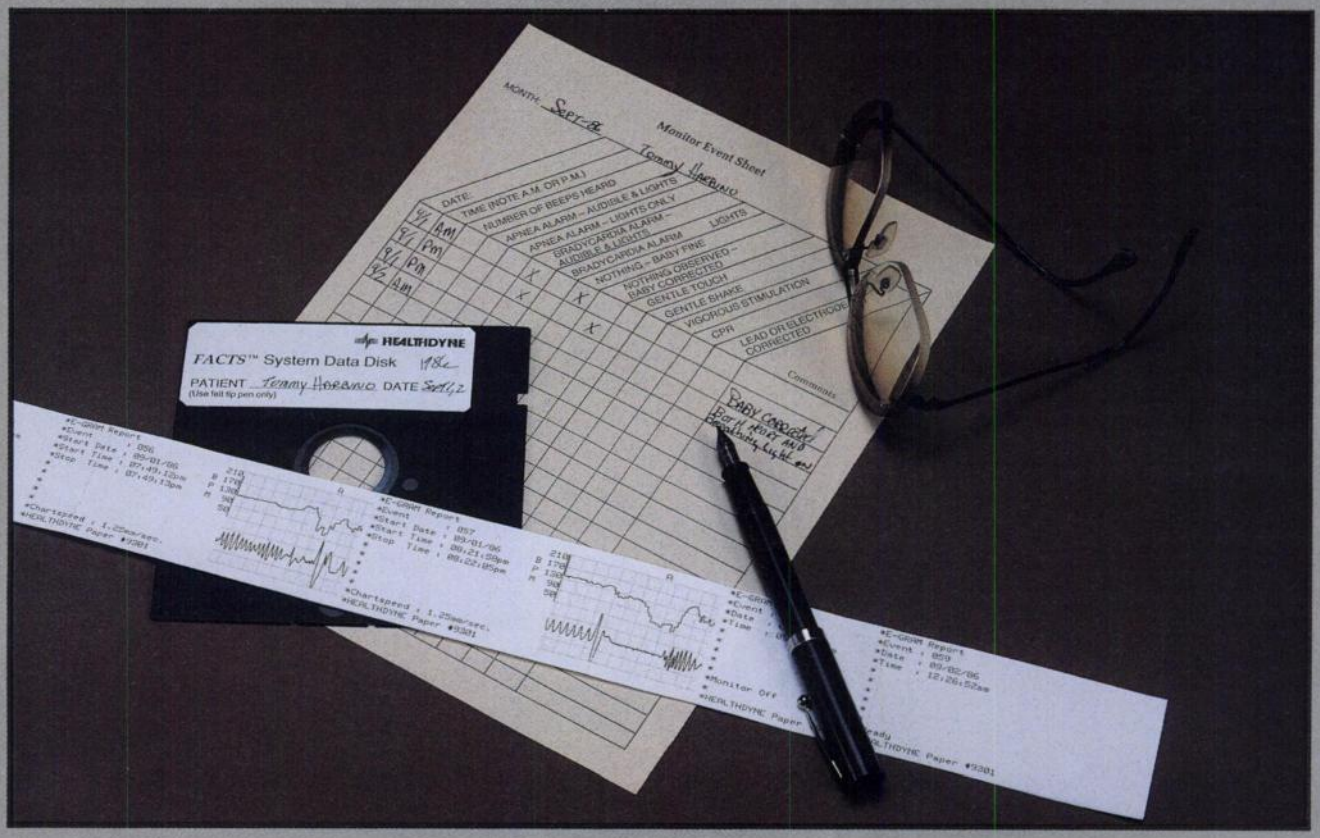

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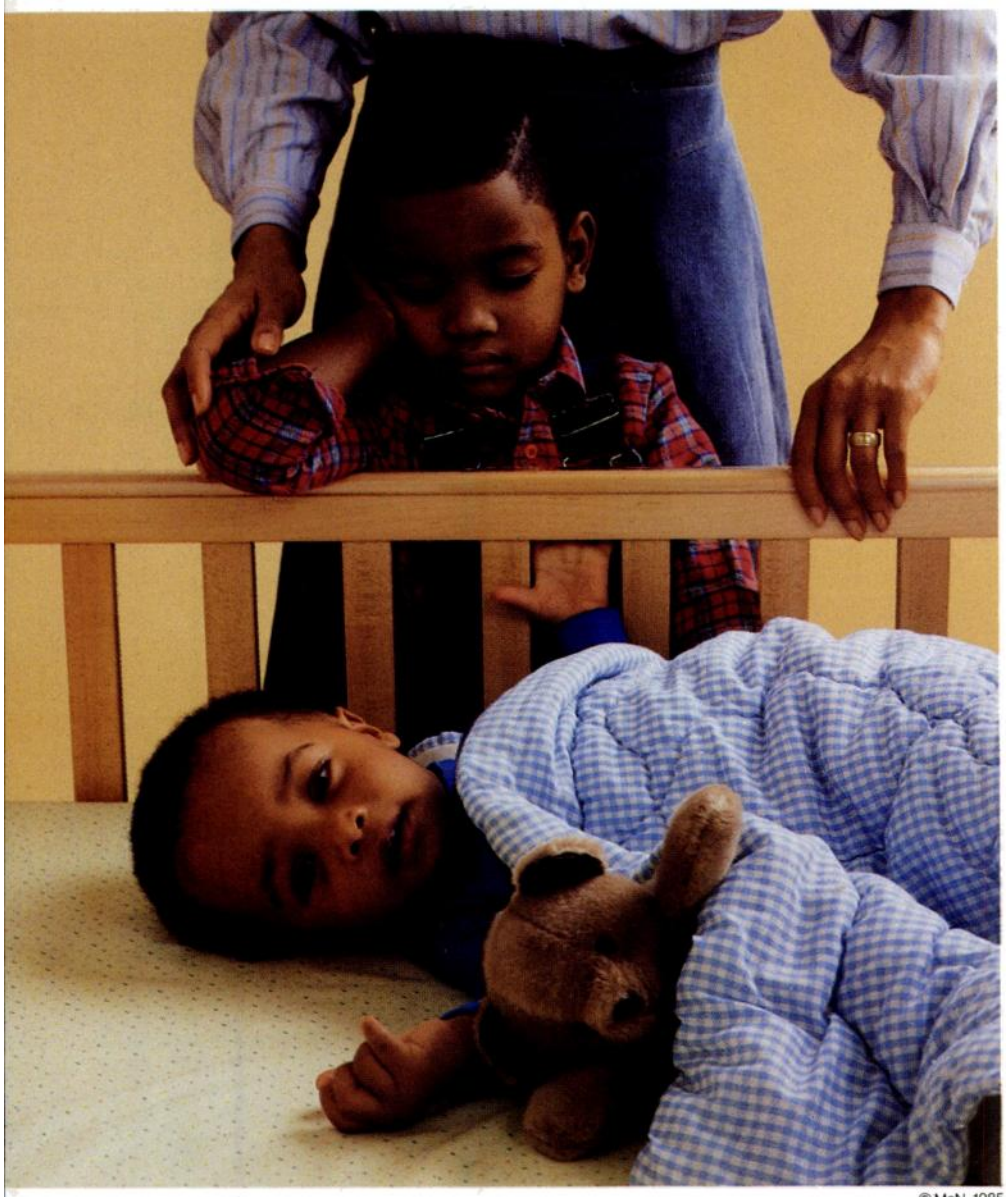

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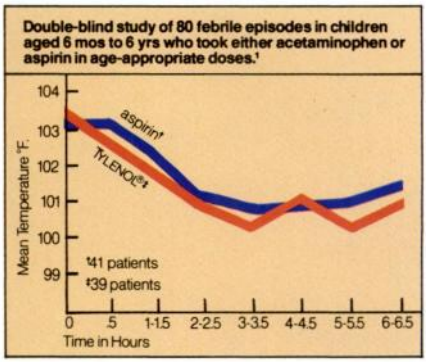

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References: 1. Tarlin L, et al: *Am J Dis Child* 124:880, 1972.
2. Aspirin or paracetamol? *Lancet* II:287, 1981.

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