JULY 1988

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NUMBER 1

Pediatrics

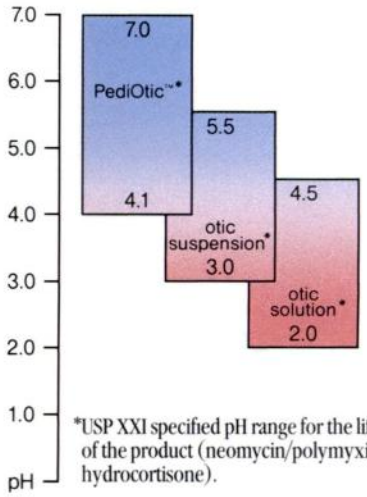
AMERICAN ACADEMY OF PEDIATRICS ELK GROVE VILLAGE IL 60009–0927

PEDIAU 82(1) pp. 1–138 (1988)

NEW PediOtic™ suspension sterile

Formulated to be less acidic to help minimize irritation.

A more normal pH range means less potential for painful irritation.



*USP XXI specified pH range for the life of the product (neomycin/polymyxin B/hydrocortisone).

Formulated to help take the sting out of otitis externa therapy

New PediOtic™ suspension is specially formulated to have a higher pH range than conventional otics.

Children may be less likely to resist its instillation, and their parents will appreciate the ease of compliance.

And you can prescribe new PediOtic suspension with confidence, knowing it contains the same proven antibiotic/anti-inflammatory combination physicians have trusted for years.

Now there's a gentle effective treatment for "swimmer's ear" to please patient, parent, *and* physician.

PediOtic™ suspension sterile

Wellcome

(polymyxin B sulfate-neomycin sulfate-hydrocortisone)

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brief summary

NEW PediOtic™ suspension sterile

(polymyxin B sulfate-neomycin sulfate-hydrocortisone)

DESCRIPTION: Pediotic suspension (polymyxin B sulfate-neomycin sulfate-hydrocortisone) is a sterile antibacterial and anti-inflammatory suspension for otic use. Each ml contains: Aerosporin* (polymyxin B sulfate) 10,000 units, neomycin sulfate equivalent to 3.5 mg neomycin base, and hydrocortisone 10 mg (1%). The vehicle contains thimerosal 0.001% (added as a preservative) and the inactive ingredients cetyl alcohol, glyceryl monostearate, mineral oil, polyoxyl 40 stearate, propylene glycol, and Water for Injection. Sulfuric acid may be added to adjust pH. Pediotic suspension has a minimum pH of 4.1, which is less acidic than the minimum pH of 3.0 for Cortisporin* Otic Suspension. **INDICATIONS AND USAGE:** For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics, and for the treatment of infections of mastoidectomy and fenestration cavities caused by organisms susceptible to the antibiotics. **CONTRAINDICATIONS:** This product is contraindicated in those individuals who have shown hypersensitivity to any of its components, and in herpes simplex, vaccinia, and varicella infections. **WARNINGS:** This product should be used with care in cases of perforated eardrum and in longstanding cases of chronic otitis media because of the possibility of ototoxicity. Neomycin sulfate may cause cutaneous sensitization. A precise incidence of hypersensitivity reactions (primarily skin rash) due to topical neomycin is not known. When using neomycin-containing products to control secondary infection in the chronic dermatoses, such as chronic otitis externa or stasis dermatitis, it should be borne in mind that the skin in these conditions is more liable than is normal skin to become sensitized to many substances, including neomycin. The manifestation of sensitization to neomycin is usually a low-grade reddening with swelling, dry scaling and itching; it may be manifest simply as a failure to heal. Periodic examination for such signs is advisable, and the patient should be told to discontinue the product if they are observed. These symptoms regress quickly on withdrawing the medication. Neomycin-containing applications should be avoided for the patient thereafter. **PRECAUTIONS:** As with other antibacterial preparations, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If the infection is not improved after one week, cultures and susceptibility tests should be repeated to verify the identity of the organism and to determine whether therapy should be changed. Treatment should not be continued for longer than ten days. Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin. **ADVERSE REACTIONS:** Neomycin occasionally causes skin sensitization. Ototoxicity and nephrotoxicity have also been reported (see WARNINGS section). Adverse reactions have occurred with topical use of antibiotic combinations including neomycin and polymyxin B. Exact incidence figures are not available since no denominator of treated patients is available. The reaction occurring most often is allergic sensitization. In one clinical study, using a 20% neomycin patch, neomycin-induced allergic skin reactions occurred in two of 2,175 (0.09%) individuals in the general population.[1] In another study, the incidence was found to be approximately 1%.[2] The following local adverse reactions have been reported with topical corticosteroids, especially under occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. Stinging and burning have been reported rarely when this drug gained access to the middle ear. **HOW SUPPLIED:** Bottle of 7.5 ml with sterilized dropper. NDC 0081-0910-02. Store at 15° to 25°C (59° to 77°F).

REFERENCES: 1. Leyden JJ, Kligman AM: Contact dermatitis to neomycin sulfate. *JAMA* 1979;242:1276-1278. 2. Prystowsky SD, Allen AM, Smith RW, et al: Allergic contact hypersensitivity to nickel, neomycin, ethylenediamine, and benzocaine. *Arch Dermatol* 1979;115:959-962.

BURROUGHS WELLCOME CO., Research Triangle Park, NC 27709

PED-100

Fatty streaks in the aortas of 3-year-olds Fatty streaks have been found even in the aortas of 3-year-olds. Aortic fatty streaks have been strongly related to both total- and LDL-cholesterol levels and inversely to the HDL/LDL + VLDL ratio. Expert advice suggests that a rational approach to the prevention of CVD should begin early in life.[1]

SMA® maintains high levels of cardio-protective HDL Wyeth's SMA, with a lipid profile virtually identical to mother's milk, provides infants with HDL-cholesterol plasma levels that closely approximate those found in breast-fed infants. And, like breast milk, SMA has more than twice the level of monounsaturates than the other two leading formulas. High levels of monounsaturates have been associated with higher levels of cardio-protective HDL.[2] Start them early...and start them right... with SMA.

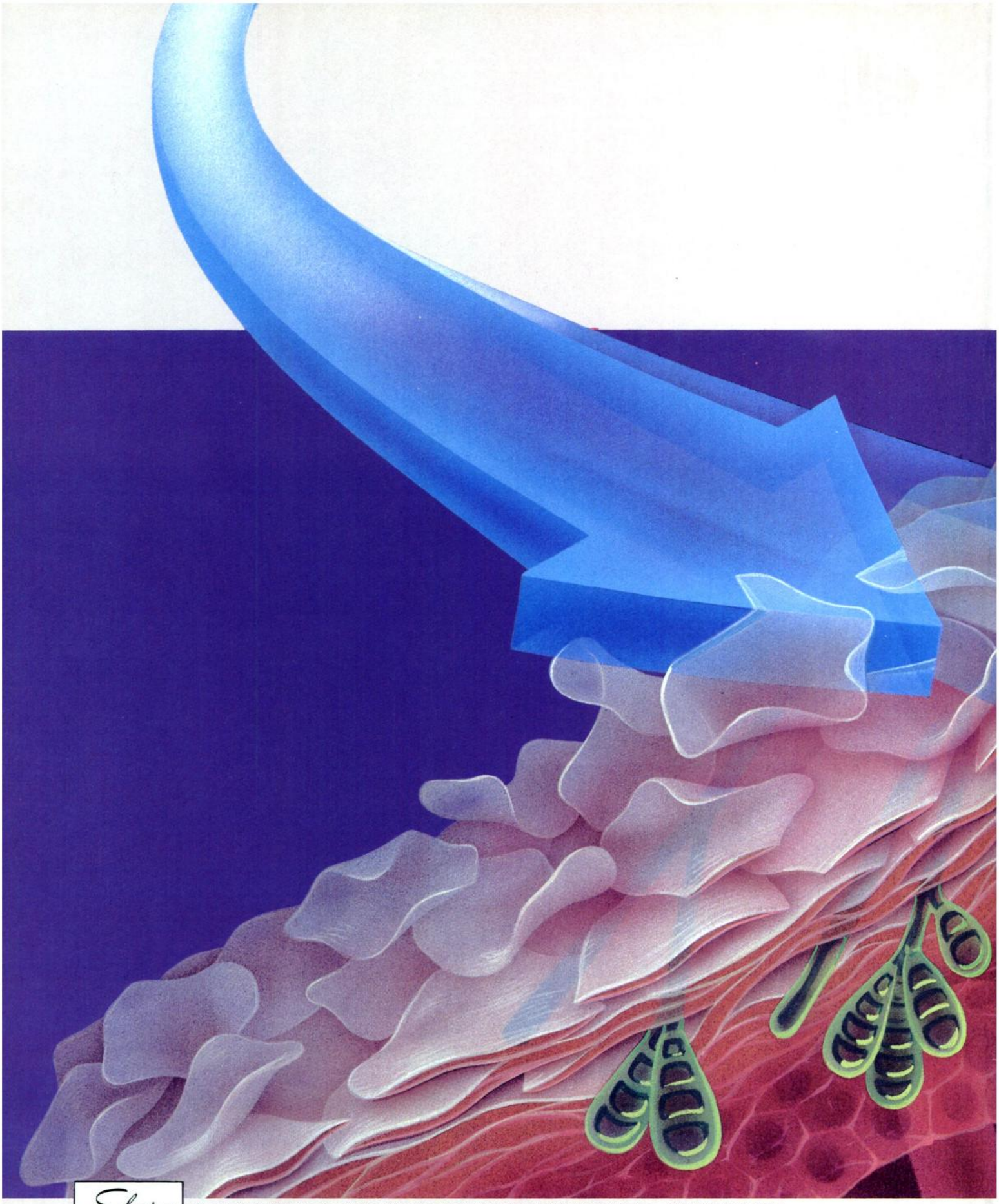
References: 1. Newman WP III, *et al:* Relation of serum lipoprotein levels and systolic blood pressure to early atherosclerosis. *N Engl J Med 314*:138-144, 1986. **2.** Mattson FH, Grundy SM: Comparison of effects of dietary saturated, monounsaturated and polyunsaturated fatty acids on plasma lipids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

S·M·A™
Infant Formula

A first step in good cardiovascular nutrition

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.

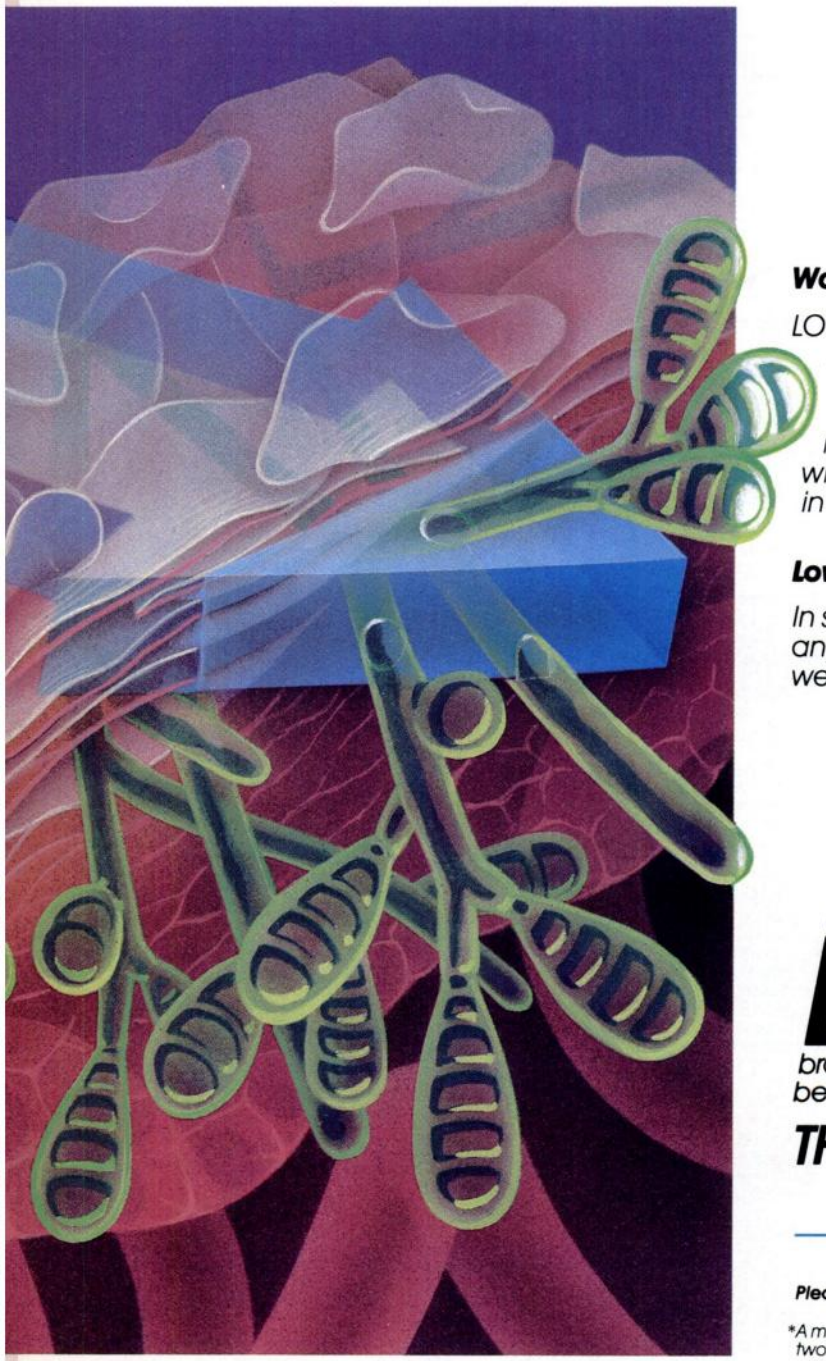
WYETH AYERST™



Schering

Artist's Representation

SPEEDS SYMPTOM RELIEF AS IT CURES* FUNGAL INFECTION.



Works on the surface and works on the source.

LOTRISONE quickly brings relief to irritating symptoms like redness, scaling and itching as it goes to work against invading dermatophytes. In clinical studies, this rapid response led to significantly more patients completing their course of therapy with LOTRISONE than with clotrimazole — resulting in greater treatment success.

Low incidence of adverse reactions.

In safety evaluations of 200 patients, only 6 had any adverse experience — usually mild. There were no reports of skin thinning or telangiectasia.

DUAL-ACTION

LOTRISONE®

brand of clotrimazole, USP and betamethasone dipropionate, USP CREAM

THE LOGICAL FIRST CHOICE FOR FUNGAL INFECTION.

Please see next page for brief summary of prescribing information.

*A mycologic cure consists of negative culture at the end of treatment and two weeks post-treatment.

DUAL-ACTION LOTRISONE® CREAM

brand of clotrimazole, USP and betamethasone dipropionate, USP

SPEEDS SYMPTOM RELIEF AS IT CURES* FUNGAL INFECTION.

For Dermatologic Use Only—
Not for Ophthalmic Use

DESCRIPTION *Each gram of LOTRISONE Cream contains 10.0 mg clotrimazole, USP, and 0.64 mg betamethasone dipropionate, USP (equivalent to 0.5 mg betamethasone), in a hydrophilic emollient cream consisting of purified water, mineral oil, white petrolatum, cetearyl alcohol, ceteareth-30, propylene glycol, sodium phosphate monobasic, and phosphoric acid; benzyl alcohol as preservative.*

LOTRISONE is a smooth, uniform, white to off-white cream.

INDICATIONS AND USAGE *LOTRISONE Cream is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum, and Microsporum canis.*

CONTRAINDICATIONS *LOTRISONE Cream is contraindicated in patients who are sensitive to clotrimazole, betamethasone dipropionate, other corticosteroids or imidazoles, or to any ingredient in this preparation.*

PRECAUTIONS ***General*** *Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.*

*Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. (See **DOSAGE AND ADMINISTRATION** section.)*

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

*Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See **PRECAUTIONS-Pediatric Use**.)*

If irritation or hypersensitivity develops with the use of LOTRISONE Cream, treatment should be discontinued and appropriate therapy instituted.

Information for Patients *Patients using LOTRISONE Cream should receive the following information and instructions:*

1. *This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.*
2. *The medication is to be used for the full prescribed treatment time, even though the symptoms may have improved. Notify the physician if there is no improvement after one week of treatment for tinea cruris or tinea corporis, or after two weeks for tinea pedis.*
3. *Patients should be advised not to use this medication for any disorder other than for which it was prescribed.*
4. *The treated skin areas should not be bandaged or otherwise covered or wrapped as to be occluded. (See **DOSAGE AND ADMINISTRATION** section.)*
5. *When using this medication in the groin area, patients should be advised to use the medication for two weeks only, and to apply the cream sparingly. The physician should be notified if the condition persists after two weeks. Patients should also be advised to wear loose fitting clothing. (See **DOSAGE AND ADMINISTRATION** section.)*
6. *Patients should report any signs of local adverse reactions.*
7. *Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressing. (See **DOSAGE AND ADMINISTRATION** section.)*
8. *Patients should avoid sources of infection or reinfection.*

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

The following tests may be helpful in evaluating HPA axis suppression due to the corticosteroid component:

Urinary free cortisol test
ACTH stimulation test

Carcinogenesis, Mutagenesis, Impairment of Fertility *There are no animal or laboratory studies with the combination clotrimazole and betamethasone dipropionate to evaluate carcinogenesis, mutagenesis or impairment of fertility.*

An 18-month oral dosing study with clotrimazole in rats has not revealed any carcinogenic effect.

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

Pregnancy Category C *There have been no teratogenic studies performed with the combination clotrimazole and betamethasone dipropionate.*

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

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

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

There are no adequate and well-controlled studies in pregnant women on teratogenic effects from a topically applied combination of clotrimazole and betamethasone dipropionate. Therefore, LOTRISONE Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Drugs containing corticosteroids should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers *It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised when LOTRISONE Cream is used by a nursing woman.*

Pediatric Use *Safety and effectiveness in children below the age of 12 have not been established with LOTRISONE Cream. However, dosage forms containing concentrations of clotrimazole and of betamethasone dipropionate found in LOTRISONE Cream have been demonstrated to be safe and effective when used as indicated and in the recommended dosages.*

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical dermatologics containing a corticosteroid to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS *The following adverse reactions have been reported in connection with the use of LOTRISONE Cream: paresthesia in 5 of 270 patients, maculopapular rash, edema, and secondary infection, each in 1 of 270 patients.*

Adverse reactions reported with the use of clotrimazole are as follows: erythema, stinging, blistering, peeling, edema, pruritus, urticaria, and general irritation of the skin.

The following local adverse reactions are reported infrequently when topical corticosteroids are used as recommended. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

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

*Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. (See **PRECAUTIONS**.)*

HOW SUPPLIED *LOTRISONE Cream is supplied in 15-gram (NDC 0085-0924-01), and 45-gram tubes (NDC 0085-0924-02); boxes of one.*

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

13182310S

Schering

Schering Corporation
Kenilworth, NJ 07033

LS-A065/13630100

**A mycologic cure consists of negative culture at the end of treatment and two weeks post-treatment.*

MANUSCRIPT PREPARATION

Send all manuscripts to:
Jerold F. Lucey, MD, Editor
Pediatrics Editorial Office
Medical Center Hospital
Burlington, VT 05401

Manuscripts for *Pediatrics* will be accepted for review with the stipulation that they are being submitted only to the American Academy of Pediatrics and that the material has not been previously published. This should be confirmed by an accompanying written statement. Once a manuscript has been reviewed and accepted for publication, the author(s) will receive a standard Copyright Assignment which should be read, signed, and returned to the Editor as soon as possible to avoid delay in the publication process.

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Return of Manuscripts. Manuscripts will not be returned to authors. Reviewers are instructed to destroy manuscripts after review. Original illustrations will be returned only if requested by the author.

Three complete copies of the manuscript including tables and illustrations must be supplied. All material should be typed on white bond paper, 21.6 × 27.9 cm (8½ × 11 in). **Use double spacing throughout, including title page, abstract, text, acknowledgments, references, tables, and legends for illustrations.** If word processing is used, typewriter quality printing, rather than dot-matrix, is preferred.

The author's style will be respected; however, writing should conform to acceptable English usage and syntax, and American Medical Association style preferences will be observed. Titles should be concise and clear, subtitles avoided. Terminology should follow *Standard Nomenclature of Diseases and Operations*. Give authors' full names and professional degrees, principal author's address, and name of institution(s) where work was done; omit departmental appointments unless necessary for special reasons. Slang, medical jargon, obscure abbreviations, and abbreviated phrasing should be avoided. Mathematical terms, formulas, abbreviations, and units of measurement must conform to usage in PEDIATRICS, based on standards in *Science* 120:1078, 1954. The metric system will be used; equivalent measurement in the English system may be included in parentheses. Name of chemical compounds—not formulas—should be given. Proprietary names, if unavoidable, will be indicated by capitalization of the first letter. Conversions to accepted standards and terms should be made before the manuscript is submitted.

Authors are requested to furnish (in addition to the full title) a condensed title for the cover, not exceeding 60 spaces, and a running foot of not more than 35 spaces. Original articles should be accompanied by an abstract of 200 words or less, as well as up to five key words under which the paper should be indexed. Reviews, commentaries, and articles for "Experience and Reason" do not require abstracts. Authors should also supply an alphabetical list of any unusual abbreviations used and their definitions.

Manuscripts should include a clear introductory statement of purpose; a historical review when desirable; a description of the technique and the scope of the experiments or observations (previously published procedures require only references to the original); a full presentation of the *Results* obtained; a brief *Comment or Discussion* on the significance of the findings and any correlation with those of other workers; a paragraph headed *Speculation and Relevance*, or *Implications*; and a *Summary*, in brief, logical résumé which may include conclusions.

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.

Illustrations—Photographs of line drawings and any other figures that are not composed simply of letters, numerals, and routine symbols must be furnished. Do not send original artwork or printed forms. A reasonable number of black-and-white illustrations will be printed from black-and-white glossies or film without charge.

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Statistical Guidelines—Authors should consult Altman DG, et al: Statistical guidelines for contributors to medical journals. *Br Med J* 1983;286:1489–1493 for advice concerning the presentation of the statistical aspects of studies.

Revised, July 1985

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Cost-effective, proven, supported. No wonder Marion CULTURETTE STREP ID is preferred by professionals.

*Over 16 million patient tests have been performed since product introduction in 1984.

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Pediatrics

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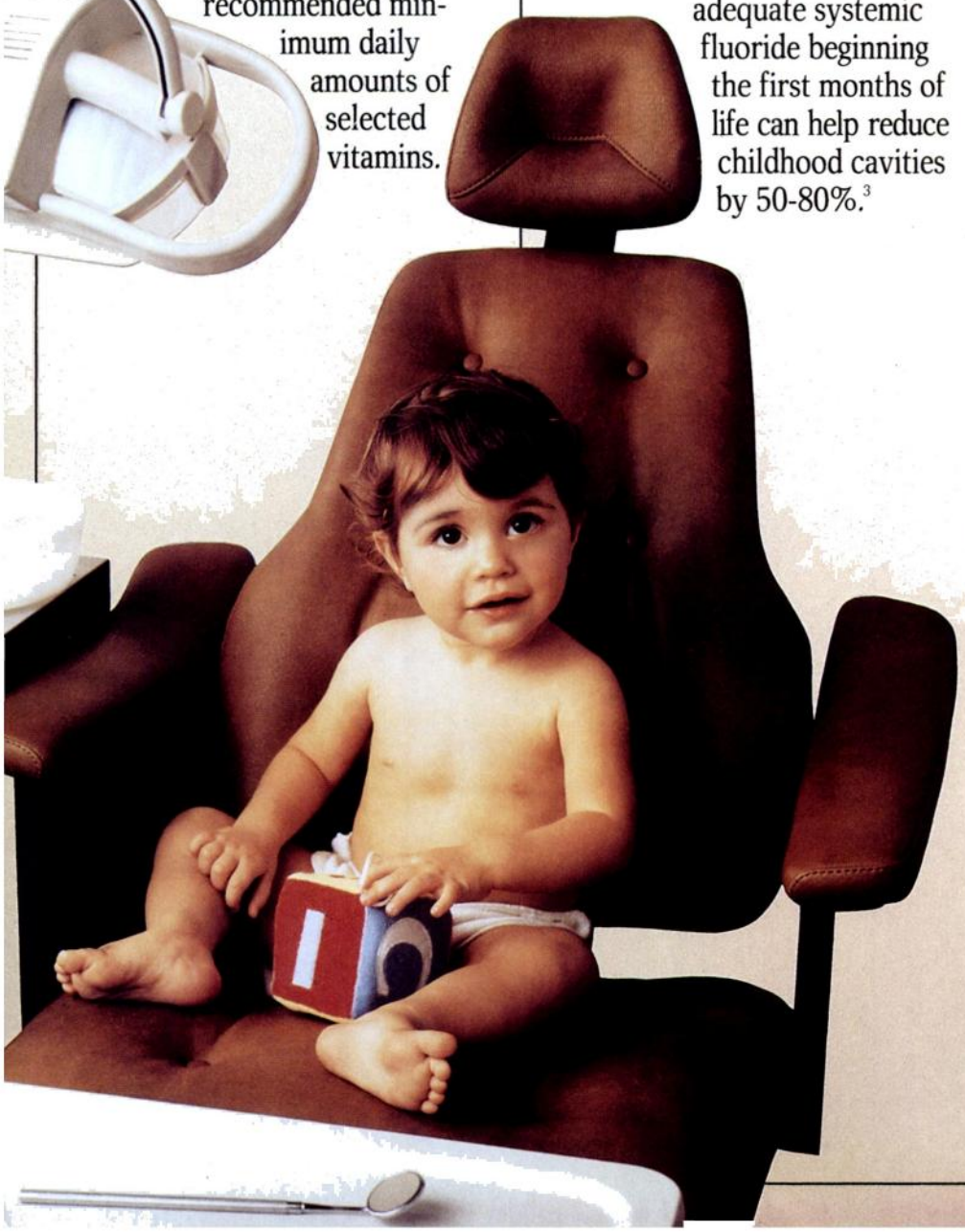
ARTICLES

Your prescription now...

for a lifetime of happy dental visits

During the first months of life, Vi-Flor® vitamin-fluoride supplements begin to enhance tooth morphology,[1] increase enamel hardness, and promote mineralization of unerupted teeth[2]—all while providing recommended minimum daily amounts of selected vitamins.

Fluoride supplementation is both prophylactic *and* therapeutic, especially with newborns who are already in the process of developing 20 primary and 32 permanent teeth. In fact, receiving adequate systemic fluoride beginning the first months of life can help reduce childhood cavities by 50-80%.[3]



And that *daily* use through age 16 results in optimal levels of fluoride supplementation, for a lifetime of stronger teeth and lower-cost dental care.

Prescribe
Vi-Flor® vitamin-fluoride supplements... now.
The essential first step begins with you, and...

TRI·VI·FLOR®
POLY·VI·FLOR®

References:

1. Moss SJ: The worldwide decline in caries prevention, in Mead Johnson Clinical Report Series, Clinical Importance of Fluoride Nutrition in Infants, Children, and Young Adults. Chicago, Pragmaton® 1985, Number 1, p. 2.

2. 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, Number 1, p. 5.

3. Aasenden R and Peebles T: Effects of fluoride supplementation from birth on human deciduous and permanent teeth. *Arch Oral Biol* 1974;19:321.

Mead Johnson
NUTRITIONAL DIVISION

L-K244-1-87

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 0.25 mg	Tablets	Bottle of 100	0.25
POLY-VI-FLOR 0.25 mg with Iron	Tablets	Bottle of 100	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.

VI-SOL®/VI-FLOR® products are the nation's most prescribed children's vitamin and vitamin-fluoride supplements.

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

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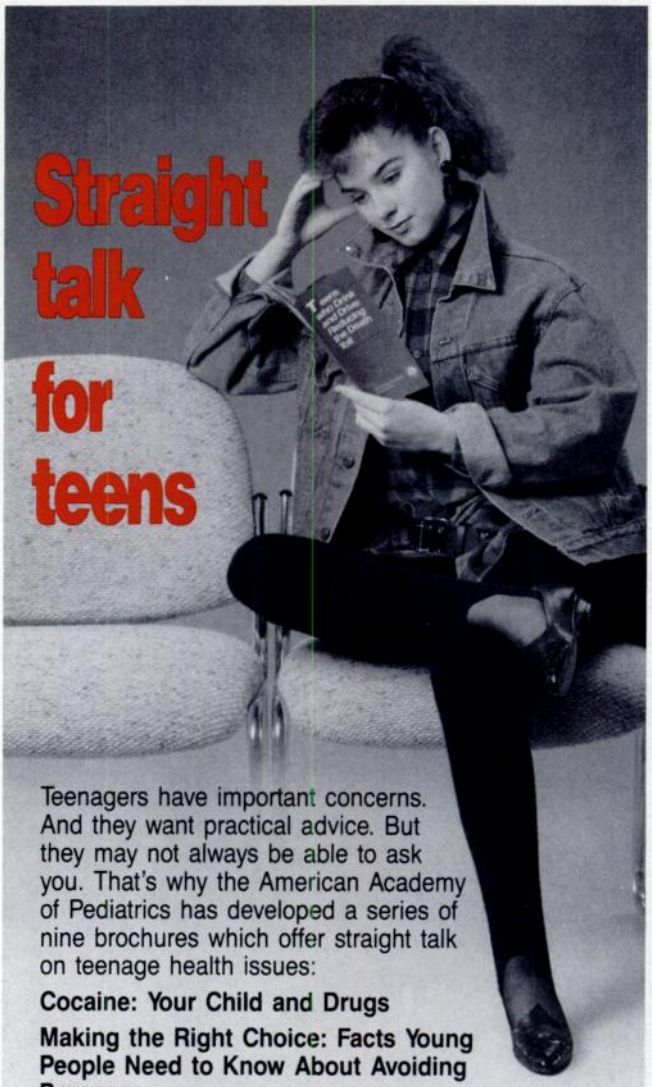

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SCHEDULE OF MEETINGS

ANNUAL MEETINGS

1988
San Francisco
October 15–20

1989
Chicago
October 21–26

1990
Boston
October 6–11

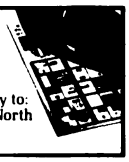
1991
New Orleans
October 26–31

1992
San Francisco
October 10–15

SPRING SESSIONS

1988
New York City
May 7–12

1989
Orlando, Florida
March 11–16



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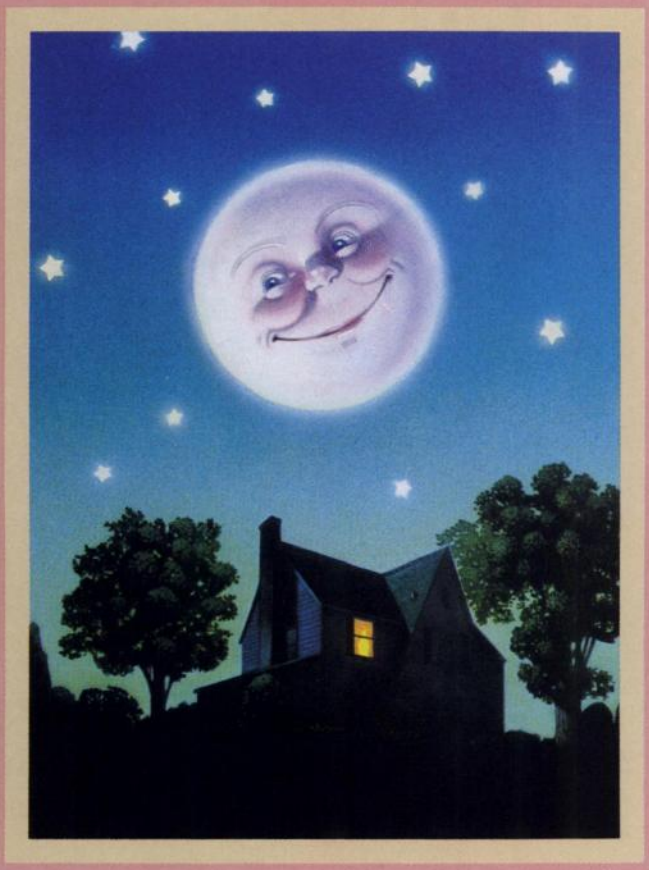

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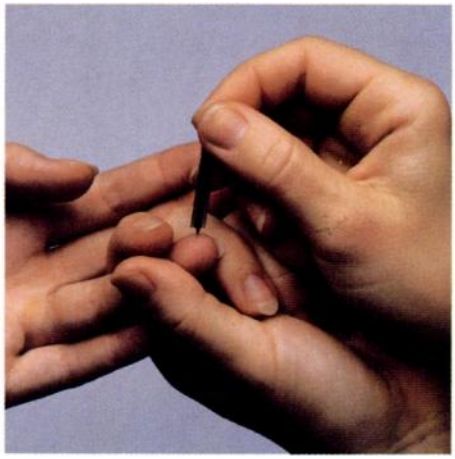
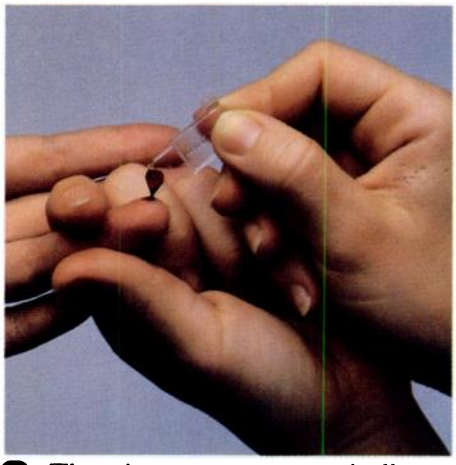
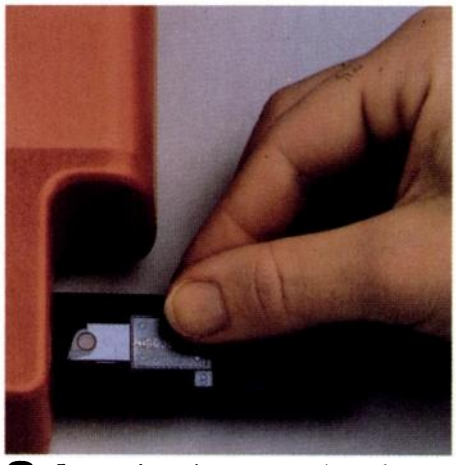


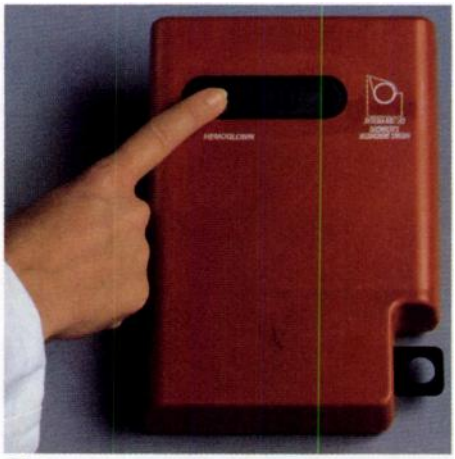
1. Obtain a blood sample by finger stick.



2. The microcuvette automatically draws a precise volume of blood.



3. Insert the microcuvette into the HemoCue photometer.



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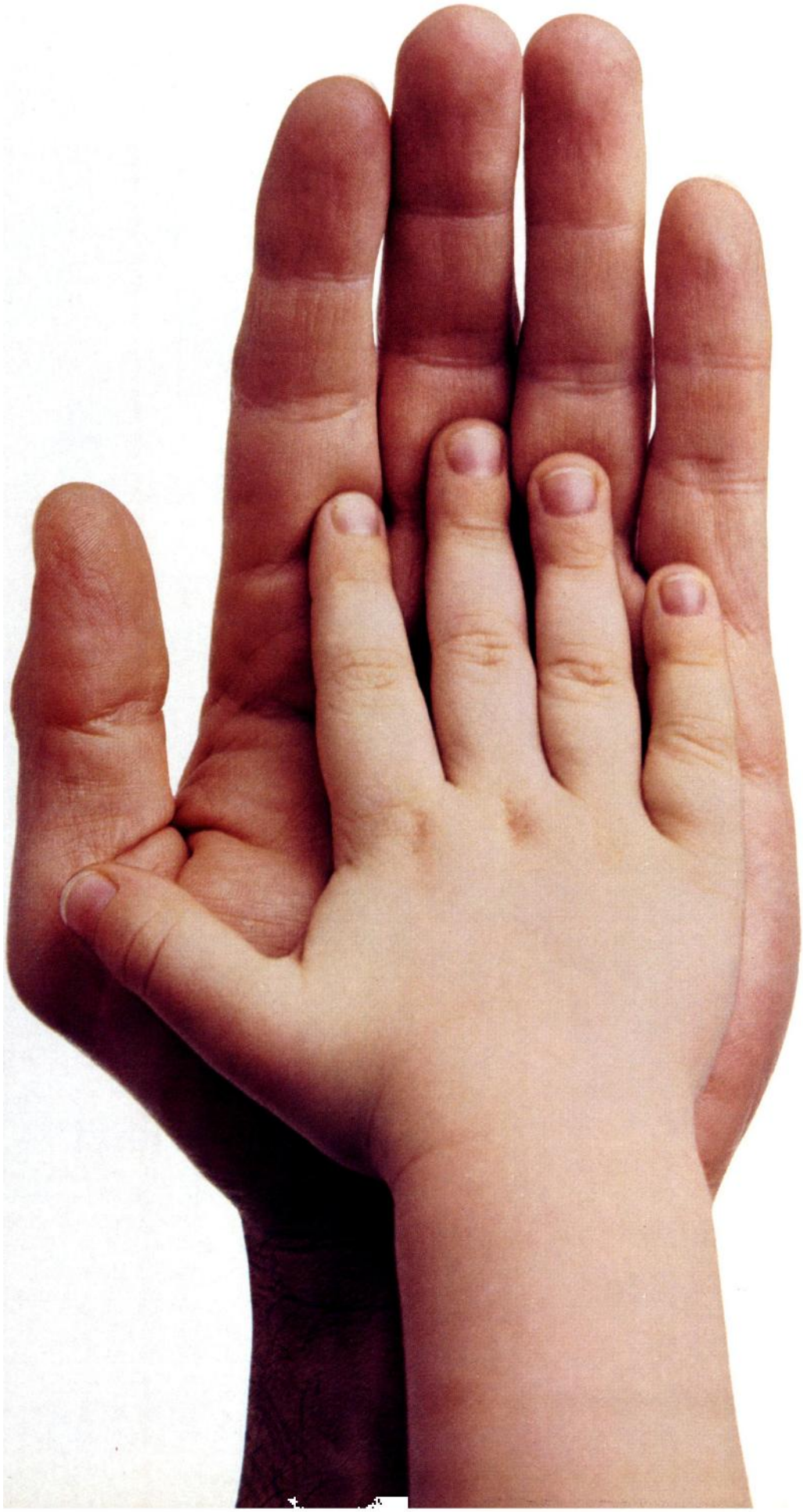

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In the past, the limited supply of pituitary-derived growth hormone meant that only the most profoundly growth hormone-deficient children were treated.[1,2]

Today, the recombinant DNA technology of Genentech ensures a virtually limitless supply of pure Protropin growth hormone for the treatment of all children lacking adequate endogenous growth hormone. Clinical studies of Protropin growth hormone, the most complete studies conducted for any growth hormone product, confirm its safety and efficacy in the treatment of this disorder.[3]

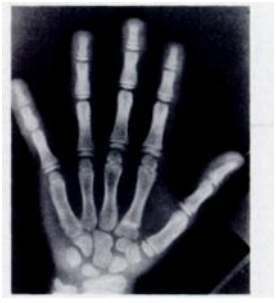
Some important clinical guidelines for patient identification

- Record height at all routine pediatric examinations.[4]
- Compare with cross-sectional data on a standard growth chart.[4]
- Careful, consistent technique for measuring children's height is critical.[4]
- Growth rates of less than 5 centimeters (2 inches) per year before age five, or less than 4.5 centimeters (1.8 inches) per year after age five, are cause for concern and may warrant further evaluation.[5]
- Progressive deviation from a normal growth curve may become apparent at any time during childhood.[5]
- Measurements made over four to six months, that show a decline in growth rate, may signal the need to refer the child for further evaluation.[6]

Early intervention: Time to grow

- Early diagnosis of children lacking adequate endogenous growth hormone is desirable because younger children typically demonstrate better responses to treatment and better long-term results than older children.[6]

For further information,
please call toll free 1-800-821-8590
or 1-800-551-2231



X-ray child aged 8

Protropin®
[somatrem for injection]

A Pure Product of Biotechnology

Genentech, Inc.

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

References: 1. Oberfield SE, Levine LS. The child with short stature. *NY State J Med*. Essays in pediatrics. Jan 1986; 15-21. **2.** Growth hormone in the treatment of children with short stature. Report of Ad Hoc Committee on Growth Hormone Usage, the Lawson Wilkins Pediatric Endocrine Society and Committee on Drugs AAP. *Pediatrics* 1983; 72 891-94. **3.** Glasbrenner K. Technology spurt resolves growth hormone problem, ends shortage. *JAMA*. 1986; 255 (5) 581-587. **4.** Rosenfeld RG, Hintz RL. Diagnosis and management of growth disorders. *Drug Therapy*. May 1983; 61-76. **5.** Growth and growth hormone. Disorders of the anterior pituitary, in Kaplan SA. *Clinical Pediatric and Adolescent Endocrinology*. WB Saunders Co. 1982. **6.** Underwood LE, Rosenfeld RG, Hintz RL. *Human Growth and Growth Disorders. An Update*. University of North Carolina School of Medicine and Stanford University School of Medicine. October 1985

Brief summary of prescribing information

PROTROPIN® (somatrem for injection)
INDICATIONS AND USAGE Protropin (somatrem for injection) is indicated only for the long term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion. Other etiologies of short stature should be excluded.
CONTRAINDICATIONS Protropin (somatrem for injection) should not be used in subjects with closed epiphyses. Protropin growth hormone should not be used when there is evidence of any progression of underlying intracranial lesion. Intracranial lesions must be inactive and antitumor therapy complete prior to instituting therapy. Protropin growth hormone should be discontinued if there is evidence of recurrent tumor growth. Protropin growth hormone, when reconstituted with Bacteriostatic Water for Injection, USP (Benzyl Alcohol Preserved) should not be used in patients with a known sensitivity to benzyl alcohol.
WARNINGS Benzyl alcohol as a preservative in Bacteriostatic Water for Injection has been associated with toxicity in newborns. When administering Protropin to newborns, reconstitute with Water for Injection, USP. USE ONLY ONE DOSE PER VIAL AND DISCARD THE UNUSED PORTION.
PRECAUTIONS Protropin (somatrem for injection) should be used only by physicians experienced in the diagnosis and management of patients with pituitary growth hormone deficiency. Patients with growth hormone deficiency secondary to an intracranial lesion should be examined frequently for progression or recurrence of the underlying disease process. Because Protropin growth hormone may induce a state of insulin resistance, patients should be observed for evidence of glucose intolerance. Concomitant glucocorticoid therapy may inhibit the growth promoting effect of Protropin growth hormone. Patients with coexisting ACTH deficiency should have their glucocorticoid replacement dose carefully adjusted to avoid an inhibitory effect on growth. Hypothyroidism may develop during Protropin treatment. Untreated hypothyroidism prevents optimal response to Protropin growth hormone. Therefore, patients should have periodic thyroid function tests and should be treated with thyroid hormone when indicated. See WARNINGS for use of Bacteriostatic Water for Injection, USP (Benzyl Alcohol Preserved) in newborns.
ADVERSE REACTIONS
A. Protropin (somatrem for injection) Approximately 30 percent of all Protropin treated patients developed persistent antibodies to growth hormone. In patients who had been previously treated with pituitary-derived growth hormone, one of twenty-two subjects developed persistent antibodies to growth hormone in response to Protropin therapy. In children not previously treated with any exogenous growth hormone approximately 40 percent developed persistent antibodies to growth hormone. In general, the growth hormone antibodies are not neutralizing and do not interfere with the growth response to Protropin growth hormone. One of eighty-four subjects treated with Protropin growth hormone for 6 to 36 months developed antibodies associated with high binding capacities and failed to respond to treatment with Protropin growth hormone. In addition to an evaluation of compliance with treatment program and thyroid status, testing for antibodies to human growth hormone should be carried out in any patient who fails to respond to therapy. Additional short term immunologic and renal function studies were carried out in a group of patients after approximately two years of treatment to detect other potential adverse effects of antibodies to growth hormone. The antibody was determined to be of the IgG class, no antibodies to growth hormone of the IgE class were detected. Testing included immune complex determination, measurement of total hemolytic complement and specific complement components, and immunochemical analyses. No adverse effects of growth hormone antibody formation were observed. These findings are supported by a toxicity study conducted in a primate model in which a similar antibody response to growth hormone was observed. Protropin (somatrem for injection), administered to monkeys by intramuscular injection at doses of 125 and 625 µg/kg t i w., was compared to pituitary-human growth hormone at the same doses and with placebo over a period of 90 days. Most monkeys treated with high-dose Protropin growth hormone developed persistent antibodies at week four. There were no biologically significant drug related changes in standard laboratory variables. Histopathologic examination of the kidney and other selected organs (pituitary, lungs, liver and pancreas) showed no treatment related toxicity. There was no evidence of immune complexes or immune complex toxicity when the kidney was also examined for the presence of immune complexes and possible toxic effects of immune complexes by immunohistochemistry and electron microscopy.
B. Bacteriostatic Water for Injection, USP (Benzyl Alcohol Preserved) Toxicity in newborns has been associated with benzyl alcohol as a preservative (see WARNINGS).
OVERDOSAGE The recommended dosage of up to 0.1 mg (0.2 IU) per kg body weight three times per week should not be exceeded due to the potential risk of side effects.
DOSAGE AND ADMINISTRATION The Protropin (somatrem for injection) dosage must be individualized for each patient. A dosage and schedule of up to 0.1 mg/kg (0.2 IU/kg) body weight administered three times per week (t i w.) by intramuscular injection is recommended. After the dose has been determined, reconstitute each 5 mg vial with 1-5 mL of Bacteriostatic Water for Injection, USP (Benzyl Alcohol Preserved) only. For use in newborns see WARNINGS. The pH of Protropin after reconstitution is approximately 7.8. To prepare the Protropin solution, inject the Bacteriostatic Water for Injection, USP (Benzyl Alcohol Preserved) into the vial of Protropin growth hormone, aiming the stream of liquid against the glass wall. Then swirl the product vial with a GENTLE rotary motion until the contents are completely dissolved. DO NOT SHAKE. It is recommended that Protropin growth hormone be administered using sterile, disposable syringes and needles. After reconstitution, vial contents should be clear, without particulate matter. If solution is cloudy or contains particulate matter the contents MUST NOT be injected. Before and after injections the septum of the vial should be wiped with an antiseptic solution to prevent contamination of the contents after repeated needle insertions. The syringes should be of small enough volume that the prescribed dose can be drawn from the vial with reasonable accuracy. The needle should be of sufficient length (usually 1 inch or more) to ensure that the injection reaches the muscular layer.

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BOOKS RECEIVED

Adolescent Growth and Motor Performance: A Longitudinal Study of Belgian Boys. G. P. Beunen, R. M. Malina, M. A. Van't Hof, et al. Champaign, IL, Human Kinetics Books, 1988, $16, 102 pp.

Assessment and Diagnosis in Child Psychopathology. M. Rutter, A Hussain Tuma, and I. S. Lann (eds). New York, The Guilford Press, 1988, $35, 477 pp.

Child Language: A Reader. M. B. Franklin and S. S. Barten (eds). New York, Oxford University Press, 1987, $17.95 paper, $29.95 cloth, 398 pp.

Current Therapy in Pediatric Infectious Disease-2. J. D. Nelson. Philadelphia, B. C. Decker, Inc, 1988, $48, 386 pp.

Le développement du cerveau foetal humain: Atlas anatomique. (Development of the Human Foetal Brain: An Anatomical Atlas). A. Feess-Higgins and J.-C. Larroche. Paris, Masson editeur, 1988, 350 F, 200 pp.

Early Vascular Complications in Children with Diabetes mellitus: Pediatric and Adolescent Endocrinology, 17. B. Weber (ed) and Z. Laron (series ed). Basel, Switzerland, S. Karger AG, 1988, $142.75 (subject to change), 284 pp.

Human Growth Hormone: Progress and Challenges. L. E. Underwood (ed). New York: Marcel Dekker, Inc, 1988, no price, 277 pp.

Legal Medicine: Legal Dynamics of Medical Encounters. American College of Legal Medicine. St Louis, C. V. Mosby, 1988, $80, 633 pp.

Nocturnal Enuresis: Psychological Perspectives. R. J. Butler. Littleton, MA, PSG Publishing Co, Inc, 1987, $27.50, 200 pp.

On Becoming a Special Parent: A Mini-Support Group in a Book. M. Routburg. Chicago, Parent/Professional Publications, c1986, $7 + $1 postage, 131 pp.

Otolaryngology—Head and Neck Surgery, ed 7. D. D. DeWeese, W. H. Saunders, D. E. Schuller, et al. St Louis, C. V. Mosby Co, 1988, $44.95, 627 pp.

Parent-Child Attachment: A Guide to Research. K. P. Watkins. New York, Garland Publishing, Inc, 1988, $27, 190 pp.

Pediatric Dermatology, vol 1 and 2. L. A. Schachner and R. C. Hansen (eds). New York, Churchill Livingstone, Inc, 1988, $295, 1631 pp.

The Psychiatry of Handicapped Children and Adolescents: Managing Emotional and Behavioral Problems. J. P. Gerring and L. P. McCarthy. San Diego, College-Hill Press/Little, Brown & Co, 1988, $24.50, 270 pp.

Taming Monsters, Slaying Dragons: The Revolutionary Family Approach to Overcoming Childhood Fears and Anxieties. J. Feiner and G. Yost. New York, William Morrow & Co, 1988, $16.95, 296 pp.

Tough Decisions: A Casebook in Medical Ethics. J. M. Freeman and K. McDonnell. New York, Oxford University Press, 1987, $12.95 paper, $24.95 cloth, 181 pp.

PEDIATRICS IN REVIEW: SEPTEMBER 1988 CONTENTS

BEST KEPT SECRET ABOUT SCIENTIFIC WORK

In an age when "scientific prose" is a virtual synonym for "literary Novocain," it seems hard to believe that American scientific journals once contained the most exciting writing of their era. Two hundred years ago, American scientists publishing their research offered not only sound empirical data but small jokes and vast vistas, the fear of God and the hope of an American paradise. But early scientific papers offered more than stylistic beauties; they included something essential about the nature of a scientific endeavor—its difficulties, the prospects for failure and the flexibility necessary to do scientific work.

Submitted by Student

From Coleman B: Science writing: Too good to be true. *The New York Times*, Sept 27, 1987.

ON MEANING

Language is not the garment but the incarnation of our thoughts.

Submitted by Student

From Wordsworth.


TINEA KNOWS NO AGE BARRIERS.
NEITHER DOES
GRIFULVIN V
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(griseofulvin microsize)
• The only griseofulvin available in an oral suspension
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Please see next page for brief summary of Prescribing Information.
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Grifulvin V
(griseofulvin microsize)
Suspension

GRIFULVIN V
TRADEMARK

(griseofulvin microsize)
Tablets/Suspension

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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Lederle Biologicals Protecting Families Through Immunization®

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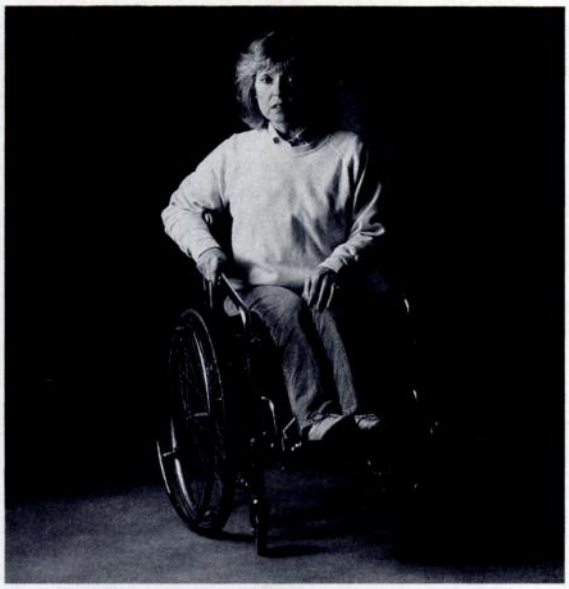

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ORIMUNE was the first live, oral, trivalent polio vaccine. No other oral polio vaccine has done more to help eradicate wild poliovirus in the US. Approximately 500 million doses have been distributed to date.

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Lederle has consistently met the nation's needs for oral polio vaccine for about 25 years. In fact, when all other US manufacturers discontinued the production of oral polio vaccine, Lederle has remained committed to this essential product and to the health of America's children.

Available in Single-Doses

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

*See adverse reactions section of brief summary

Orimune®
Poliovirus Vaccine Live, Oral Trivalent

Poliovirus Vaccine
Live Oral Trivalent
ORIMUNE*

A Brief Summary

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

INDICATIONS: *For prevention of poliomyelitis caused by Poliovirus Types 1, 2, and 3.*
CONTRAINDICATIONS: *Under no circumstances should this vaccine be administered parenterally.*

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

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

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

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

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

PRECAUTIONS: It would seem prudent not to administer trivalent oral poliovaccine (OPV) shortly after Immune Globulin (IG) unless such a procedure is unavoidable, for example, with unexpected travel to or contact with epidemic areas or endemic areas. If OPV is given with or shortly after IG, the dose probably should be repeated after three months if immunization is still indicated.

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

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

ADVERSE REACTIONS: Paralytic disease following the ingestion of live poliovirus vaccines has been, on rare occasion, reported in individuals receiving the vaccine (see, for example, CONTRAINDICATIONS), and in persons who were in close contact with vaccinees. The vaccine viruses are shed in the vaccinee's stools for at least six to eight weeks as well as via the pharyngeal route. Most reports of paralytic disease following ingestion of the vaccine or contact with a recent vaccinee are based on epidemiological analysis and temporal association between vaccination or contact and the onset of symptoms. Most authorities believe that a causal relationship exists. Prior to administration of the vaccine, the attending physician should warn or specifically direct personnel acting under his authority to convey the warnings to the vaccinee, parent, guardian, or other responsible person of the possibility of vaccine-associated paralysis, particularly to susceptible family members and other close personal contacts. The Centers for Disease Control report that during 1972 to 1983, approximately 278.8 million OPV doses were distributed in the United States. During this same period, 87 vaccine-associated cases in apparently immunologically normal individuals were reported. Thirty-two occurred among vaccine recipients (one case per 8.7 million OPV doses distributed), and 55 cases occurred among household and nonhousehold contacts of vaccinees (1 case per 5.1 million doses distributed). Sixteen other vaccine-associated cases have been reported in persons (recipients or contacts) with immune deficiency conditions.

Because the number of susceptible vaccine recipients or contacts of recipients is not known, the true risk of vaccine-associated poliomyelitis is impossible to determine precisely.

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

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

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

Rev. 8/86

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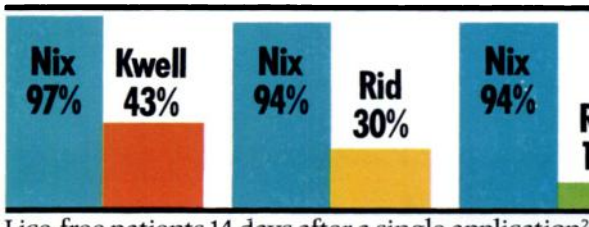

Lice-free patients 14 days after a single application.[2,3]
(Rid labelling requires a second application at 7-10 days.)

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Jan Smith, MD

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

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

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

WARNING: If hypersensitivity to Nix occurs, discontinue use.

PRECAUTIONS:

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

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

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

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

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

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

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

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

DOSAGE AND ADMINISTRATION:

Adults and Children: Nix is intended for use after the hair has been washed with shampoo, rinsed with water and towel dried. Apply a sufficient volume of Nix to saturate the hair and scalp. Nix should remain on the hair for 10 minutes before being rinsed off with water. A single treatment is sufficient to eliminate head lice infestation. Combing of nits is not required for therapeutic efficacy, but may be done for cosmetic or other reasons.

SHAKE WELL BEFORE USING.

HOW SUPPLIED: Nix (Permethrin) 1% (wt./wt.) Creme Rinse is supplied in plastic squeeze bottles that contain 2 fl. oz. weighing 56 g. (NDC-0081-0780-81)
Store at 15°-25°C (59°-77°F).

1. Davies J, Dedhia H, Morgade C, et al: Lindane poisonings, *Arch Dermatol* 1983;119:142-144.
2. Taplin D, Meinking T, Castillero P, et al: Permethrin 1% creme rinse for the treatment of *pediculus humanus* var *capitis* infestation. *Pediatr Dermatol* 1986;3:344-348.
3. Taplin D, Meinking T: Pyrethrins and pyrethroids for the treatment of scabies and pediculosis. *Semin Dermatol* 1987;6:125-135.

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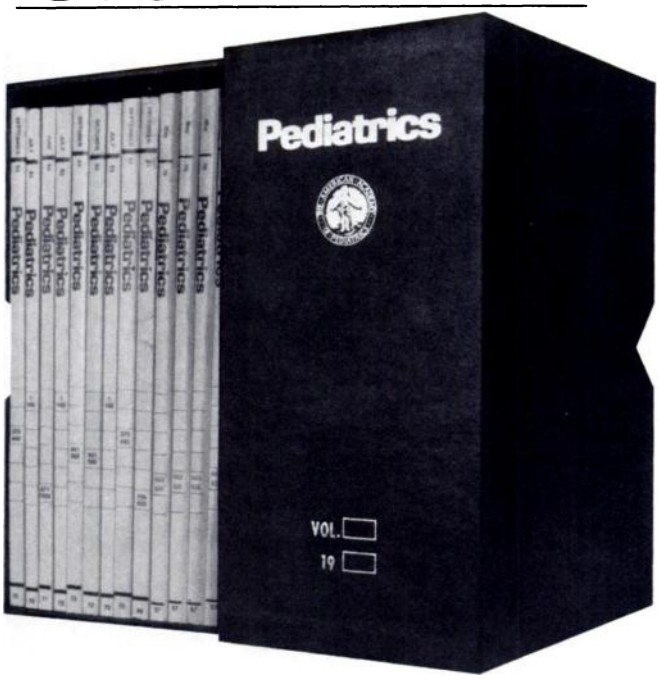

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These recommendations turn into purchases. And profits. Eucerin will continue to be a brand on the move, because the extensive professional sampling program gets bigger every year. Besides dermatologists and family practitioners, Eucerin is now being sampled and detailed to specialists in many other fields, all of whom see patients suffering from dry skin.

Eucerin Cleansing Bar adds even more luster to the brand, because this bar has been clinically demonstrated to be among the mildest available. In today's skin conscious marketplace, that's crucial.

The potential market for Eucerin products remains vast. Dry skin affects virtually everyone at one time or another. The Eucerin line is gaining wide acceptance in hospitals, nursing homes, and OTC. You'll find Eucerin a very profitable discovery.

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

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Now everyone can tell the twins apart. But they're still alike to their pediatrician, who finds that one treatment is very effective for minor injuries in juniors (children ages 6-14): a regimen of local therapy* for the inflammation,[1] and Junior Strength TYLENOL® acetaminophen for the pain.

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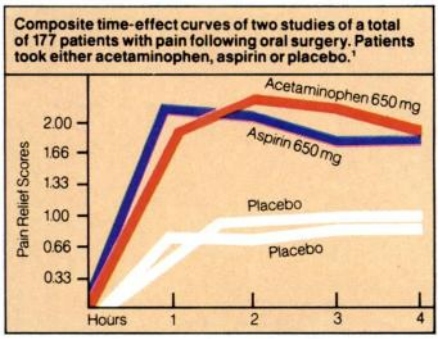

And there are few side effects such as GI irritation or allergic reactions—side effects associated with aspirin use.[3]

TYLENOL® products also offer a dosage form that's right for every patient. For children between the ages of 6 and 14,[4] 160 mg Junior Strength TYLENOL® coated caplets are often recommended. Children need only half as many Junior Strength TYLENOL® caplets as chewables, and they're coated for easier swallowing.

So patients get effective pain relief without aspirin side effects, in a dosage form that is just right. Next time juniors in your practice are in pain, recommend Junior Strength TYLENOL® acetaminophen.

*Local therapy often encompasses rest, ice, compression and elevation.[1]

References: **1.** Goldberg B: *Pediatr Ann* 13:596-600, 1984. **2.** Cooper SA: *Arch Intern Med* 141:282-285, 1981. **3.** Aspirin or paracetamol? *Lancet* II:287-289, 1981. **4.** Data on file, McNeil Consumer Products Company.

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1. de Sola Pool N, Loehle K, Radzik AJ, et al: A comparison of nonsystemic and systemic antidiarrheal agents in the treatment of acute nonspecific diarrhea in adults. *The Journal of New Developments in Clinical Medicine* 1987;5(2):31-38.

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

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

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

PARKE-DAVIS

Please see next page for brief summary of prescribing information.

ZARONTIN® (ethosuximide capsules, USP)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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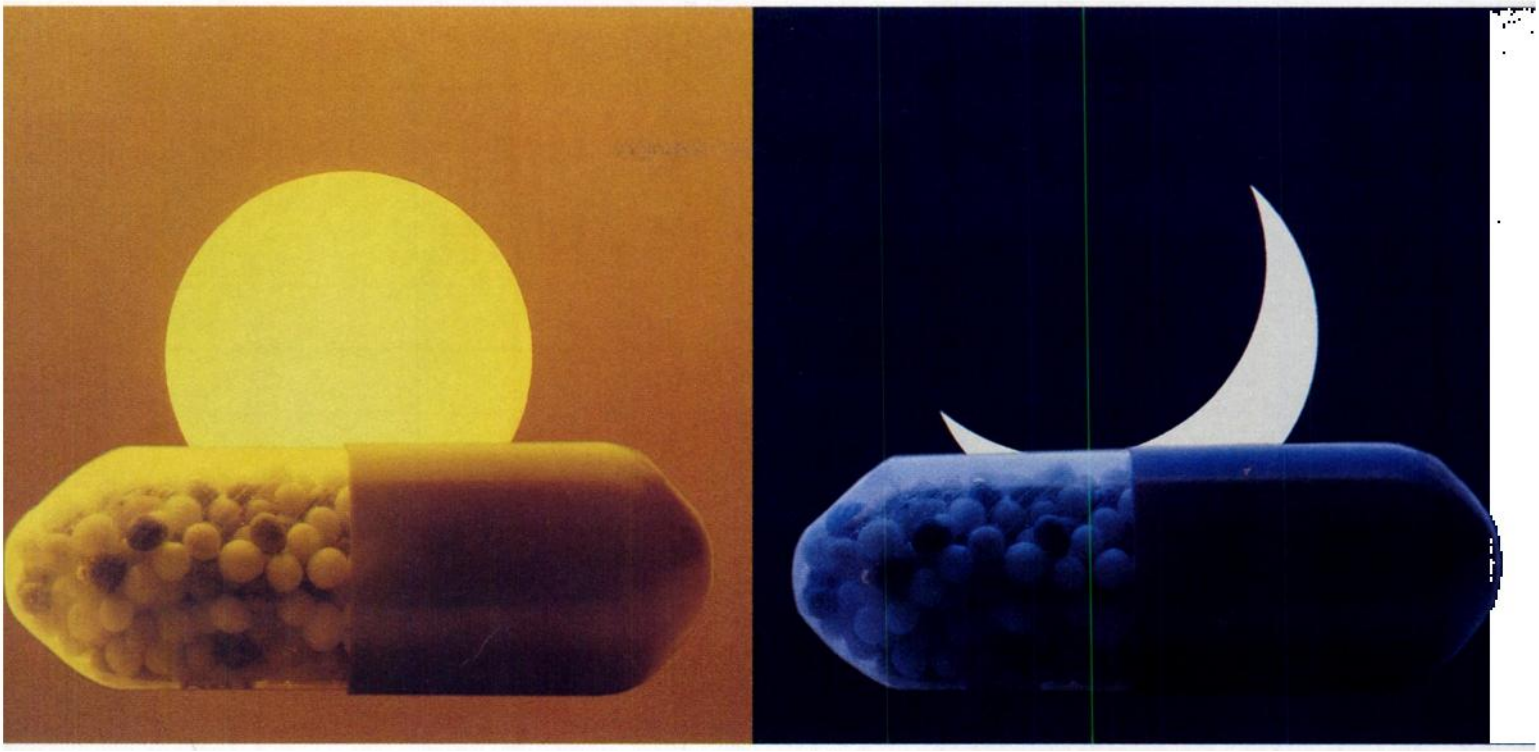

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Sustained release for sustained pruritus relief with

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Temaril is the only antipruritic available in a 12-hour, sustained release capsule. Children over six years old can get the benefit of once-a-day dosing with this 5 mg Spansule.

And for children from six months to six years old, Temaril also comes in a pleasant-tasting, raspberry-flavored 2.5 mg/5 mL syrup and easy-to-swallow 2.5 mg tablets.

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Temaril®
(trimeprazine tartrate)

INDICATIONS Treatment of pruritic symptoms in urticaria. Relief of pruritic symptoms in a variety of allergic and non-allergic conditions including atopic dermatitis, neurodermatitis, contact dermatitis, pityriasis rosea, poison ivy dermatitis, eczematous dermatitis, pruritus ani and vulvae, and drug rash.

CONTRAINDICATIONS Temaril (trimeprazine tartrate) is contraindicated in comatose patients, in patients who have received large amounts of central nervous system depressants (alcohol, barbituates, narcotics, etc.), in patients with bone marrow depression, in patients who have demonstrated an idiosyncrasy or hypersensitivity to 'Temaril' or other phenothiazines, in newborn or premature children, and in nursing mothers. It should not be used in children who are acutely ill and/or dehydrated, as there is an increased susceptibility to dystonias in such patients.

WARNINGS Temaril (trimeprazine tartrate) may impair the mental and/or physical ability required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery. Similarly, it may impair mental alertness in children. The concomitant use of alcohol or other central nervous system depressants may have an additive effect. Patients should be warned accordingly.

'Temaril' should be used with extreme caution in patients with:

- Asthmatic attack
- Narrow-agle glaucoma
- Prostatic hypertrophy
- Stenosing peptic ulcer
- Pyloroduodenal obstruction
- Bladder neck obstruction
- Patients receiving monoamine oxidase inhibitors

Usage in Pregnancy: The safe use of 'Temaril' has not been established with respect to the possible adverse effects upon fetal development. Therefore, it should not be used in women of childbearing potential. Jaundice and prolonged extrapyramidal symptoms have been reported in infants whose mothers received phenothiazines during pregnancy.

Usage in Children: 'Temaril' should be used with caution in children who have a history of sleep apnea or a family history of sudden infant death syndrome (SIDS). It should also be used with caution in young children, in whom it may cause excitation.

Overdosage may produce hallucinations, convulsions and sudden death.

Usage in Elderly Patients (60 years or older): Elderly patients are more prone to develop the following side effects from phenothiazines:

- Hypotension
- Syncope
- Toxic confusional states
- Extrapyramidal symptoms, especially parkinsonism
- Excessive sedation

PRECAUTIONS Temaril (trimeprazine tartrate) may significantly affect the actions of other drugs. It may increase, prolong or intensify the sedative action of central nervous system depressants such as anesthetics, barbiturates or alcohol. When 'Temaril' is administered concomitantly the dose of a narcotic or barbiturate should be reduced to 1/4 or 1/2 the usual amount. In the patient with pain, receiving treatment with narcotics, excessive amounts of 'Temaril' may lead to restlessness and motor hyperactivity. 'Temaril' can block and even reverse the usual pressor effect of epinephrine.

'Temaril' should be used cautiously in persons with acute or chronic respiratory impairment, particularly children, as it may suppress the cough reflex.

This drug should be used cautiously in persons with cardiovascular disease, impairment of liver function, or those with a history of ulcer disease.

Since 'Temaril' has a slight antiemetic action, it may obscure signs of intestinal obstruction, brain tumor, or overdosage of toxic drugs.

Phenothiazines have been shown to elevate prolactin levels; the elevation persists during chronic administration. Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin-dependent in vitro, a factor of potential importance if the prescribing of these drugs is contemplated in a patient with a previously detected breast cancer. Although disturbances such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported, the clinical significance of elevated serum prolactin levels is unknown for most patients. An increase in mammary neoplasms has been found in rodents after chronic administration of neuroleptic drugs. Neither clinical nor epidemiologic studies conducted to date, however, have shown an association between chronic administration of these drugs and mammary tumorigenesis; the available evidence is considered too limited to be conclusive at this time.

Drugs which lower the seizure threshold, including phenothiazine derivatives, should not be used with 'Amipaque'*. As with other phenothiazine derivatives, 'Temaril' should be discontinued at least 48 hours before myelography, should not be resumed for at least 24 hours postprocedure, and should not be used for the control of nausea and vomiting occurring either prior to myelography or postprocedure.

ADVERSE REACTIONS Temaril (trimeprazine tartrate) may produce adverse reactions attributable to both phenothiazines and antihistamines.

Note: Not all of the following adverse reactions have been reported with Temaril (trimeprazine tartrate), however, pharmacological similarities among the phenothiazine derivatives require that each be considered when Temaril is administered. There have been occasional reports of sudden death in patients receiving phenothiazine derivatives chronically.

C.N.S. Effects: Drowsiness is the most common C.N.S. effect of this drug. Extrapyramidal reactions (opisthotonos, dystonia, akathisia, dyskinesia, parkinsonism) occur, particularly with high doses (See Overdosage section for management of extrapyramidal symptoms). Hyperreflexia has been reported in the newborn when a phenothiazine was used during pregnancy. Other reported reactions include dizziness, headache, lassitude, tinnitus, incoordination, fatigue, blurred vision, euphoria, diplopia, nervousness, insomnia, tremors and grand mal seizures, excitation, cataconic-like states, neuritis and hysteria, oculogyric crises, disturbing dreams/nightmares, pseudoschizophrenia, and intensification and prolongation of C.N.S. depressants (opiates, analgesics, antihistamines, barbiturates, alcohol), atropine, heat, organophosphorus insecticides.

Cardiovascular Effects: Postural hypotension is the most common cardiovascular effect of phenothiazines. Reflex tachycardia may be seen. Bradycardia, faintness, dizziness and cardiac arrest have been reported. ECG changes, including blunting of T waves and prolongation of the Q-T interval, may be seen.

Gastrointestinal: Anorexia, nausea, vomiting, epigastric distress, diarrhea, constipation, and dry mouth may occur. Increased appetite and weight gain have also been reported.

Genitourinary: Urinary frequency and dysuria, urinary retention, early menses, induced lactation, gynecomastia, decreased libido, inhibition of ejaculation and false positive pregnancy tests have been reported.

Respiratory: Thickening of bronchial secretions, tightness of the chest, wheezing and nasal stuffiness may occur.

Allergic Reactions: These include urticaria, dermatitis, asthma, laryngeal edema, angioneurotic edema, photosensitivity, lupus erythematosus-like syndrome and anaphylactoid reactions.

Other Reported Reaction: Leukopenia, agranulocytosis, pancytopenia, hemolytic anemia, elevation of plasma cholesterol levels and thrombocytopenic purpura have been reported. Jaundice of the obstructive type has also been reported; it is usually reversible but chronic jaundice has been reported. Erythema, peripheral edema, and stomatitis have been reported. High or prolonged glucose tolerance curves, glycosuria, elevated spinal fluid proteins and reversed epinephrine effects may also occur.

Rare occurrences of neuroleptic malignant syndrome (NMS) have been reported in patients receiving phenothiazines. This syndrome is comprised of the symptom complex of hyperthermia, altered consciousness, muscular rigidity and autonomic dysfunction and is potentially fatal.

Long-Term Therapy Considerations: After prolonged phenothiazine administration at high dosage, pigmentation of the skin has occurred, chiefly in the exposed areas. Ocular changes consist of the appearance of lenticular and corneal opacities, epithelial keratopathies and pigmentary retinopathy. Vision may be impaired.

*Trademark Reg. U.S. Pat. Off. 'Amipaque' for metrizamide, distributed by Winthrop-Breon Laboratories.

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References

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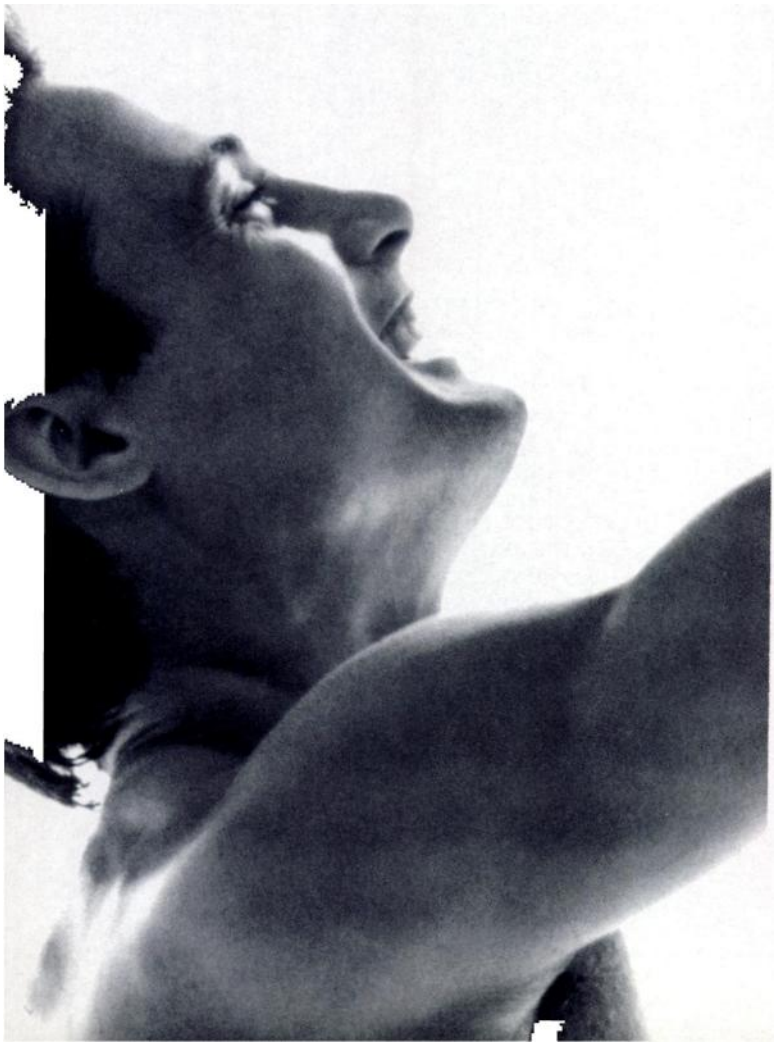

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1. de Sola Pool N, Loehle K, Radzik AJ, et al: A comparison of non-systemic and systemic antidiarrheal agents in the treatment of acute nonspecific diarrhea in adults. *The Journal of New Developments in Clinical Medicine* 1987;5(2):31-38.

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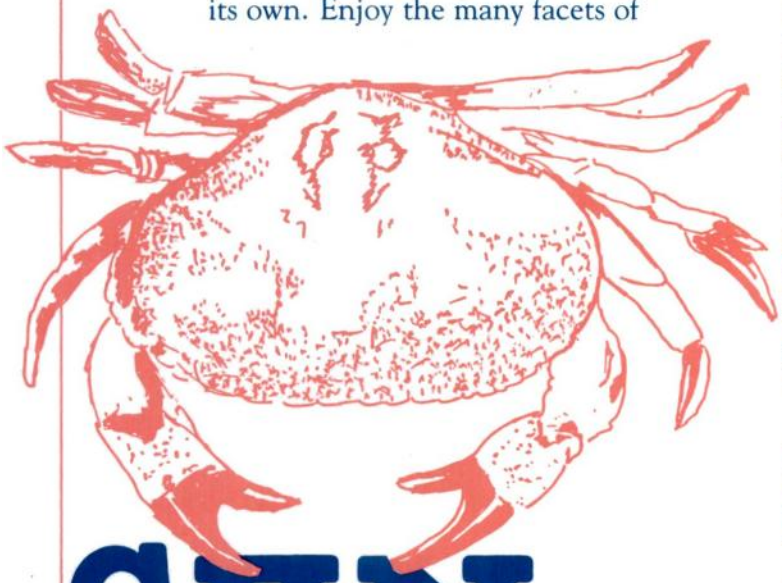

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