ARTICLES
681 Testosterone Treatment of Constitutional Delay of Growth—R. G. Rosenfeld et al
688 Psychopharmacology of Attention Deficit Disorder—S. E. Shaywitz et al
695 Conjunctivitis-OTitis Syndrome—F. F. Bodor
699 Relationship of Magnitude of Bacteremia and the Clinical Disease—T. D. Sullivan et al
703 Effects of Parent Training on Teenage Mothers—T. Field et al
708 Knowledge About Insulin-Dependent Diabetes—S. B. Johnson et al
714 Arachidonic Acid Metabolism in the Neonatal Platelet—M. J. Stuart and J. B. Allen
719 Creatinine Excretion in Preterm Infants—J. L. Sutphen
728 Congenital Complete Atroventricular Block—W. W. Pinsky et al
734 Hemoglobin F Levels—A. D. Metaxotou-Mavromati et al
739 School Absence—M. Weitzman et al
747 Marital Stability and Congenital Heart Disease—A. R. Silbert et al
751 Air Rifle Injuries—S. Blocker et al
755 Histochemical Diagnosis of Hirschsprung Disease—C. C. Huntley et al
762 Pediatric Plague—J. M. Mann et al
768 Effectiveness of Positioning Therapy for Gastroesophageal Reflux—W. F. Meyers and J. J. Herbst
773 Zinc Dependency as Cause of Chronic Diarrhea—I. Krieger et al
778 Abnormal Cerebral Hemodynamics and Patent Ductus Arteriosus—B. Lipman et al
782 Diaphragm Strength in Near-Miss Sudden Infant Death Syndrome—C. B. Scott et al
785 Respiratory Behavior in Near-Miss Sudden Infant Death Syndrome—J. E. Hodgman et al
793 Sleep-Wake Patterns and Non-rapid Eye Movement Sleep Stages during the First Six Months of Life—S. Coons and C. Guilleminault

EXPERIENCE AND REASON
799 Catheter Tip Localization During Umbilical Venous Exchange Transfusion and Necrotizing Enterocolitis—M. Thangavel et al
801 Zinc Deficiency Following Surgery in Zinc-Supplemented Infants—P. A. Palma et al
804 Factitious Hypoglycemia—J. H. Mayefsky et al
805 Immersion Accidents in Hot Tubs and Whirlpool Spas—B. Monroe

AMERICAN ACADEMY OF PEDIATRICS
808 Climatic Heat Stress and the Exercising Child—Committee on Sports Medicine

SPECIAL REPORT
810 Aspirin and Reye Syndrome—Committee on Infectious Diseases

COMMENTARIES
813 A General Journal, High Prices, and New Journals—J. F. Lucey
813 Prevention of Fetal Alcohol Effects—H. L. Rosett and L. Weiner
816 Help Wanted—L. H. Margolis
818 Pulsatility Index, Patent Ductus Arteriosus, and Brain Damage—R. Bejar et al
822 Reye Syndrome and Aspirin Use—J. T. Wilson and R. D. Brown

837 INDEX TO VOLUME 69

PEDIATRICS 69(6) 681-846 (1982)
**CORTISPORIN® OTIC SUSPENSION**
Sterile (Polymyxin B-Neomycin-Hydrocortisone)

**DESCRIPTION**
Each cc contains:
- Neomycin sulfate (Polymyxin B Sulfate) 10,000 units
- Neomycin sulfate (equivalent to 3.5 mg neomycin base) 5 mg
- Hydrocortisone 10 mg (1%)
- Each vehicle contains the inactive ingredients cetyl alcohol, propylene glycol, polysorbate 80, water for injection and thimerosal (preservative) 0.01%. 

**INDICATIONS:** For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotic.

**PRECAUTIONS:** This drug should be used with care in cases of perforated eardrum and in long-standing cases of chronic otitis media because of the possibility of ototoxicity caused by neomycin.

**CONTRAINDICATIONS:** These products are contraindicated in those individuals who have shown hypersensitivity to any of the components, and in herpes simplex, varicella.

**ADVERSE REACTIONS:** Stinging and burning have been reported when this drug has gained access to the middle ear.

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- Hydrocortisone 10 mg (1%) 
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**ADVERSE REACTIONS:** Stinging and burning have been reported when this drug has gained access to the middle ear.

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**CONTRAINDICATIONS:** These products are contraindicated in those individuals who have shown hypersensitivity to any of the components, and in herpes simplex, varicella.

**ADVERSE REACTIONS:** As with other antibiotic preparations, prolonged treatment may result in overgrowth of nonsusceptible organisms and 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 continued.

When using neomycin-containing products to control secondary infection in the chronic dermatoses, such as chronic otitis externa, 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. During long-term use of neomycin-containing products, 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 that patient thereafter.

**PRECAUTIONS:** If sensitization or irritation occurs, medication should be discontinued promptly. Patients who prefer to warm the medication before using should be cautioned against heating the solution above body temperature, in order to avoid loss of potency.

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 is a not uncommon cutaneous sensitizer. There are articles in the current literature that indicate an increase in the prevalence of persons sensitive to neomycin.
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Before prescribing, please consult 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, e.g., 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:** Neuropsychologic and sensory reactions reported during therapy with ethosuximide have included drowsiness, headache, dizziness, euphoria, hiccups, irritability, hyperactivity, lethargy, fatigue, and ataxia. Psychiatric or psychologic 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 case 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 urticana, 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.
MANUSCRIPT PREPARATION

Send all manuscripts to:

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Pediatrics Editorial Office
Mary Fletcher Hospital
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Burlington, VT 05401

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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.

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.

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Revised, March 1982

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CONTRAINDICATIONS: Not for use in the eyes or in the external ear canal if the ear drum is perforated. This product is contraindicated in those individuals who have shown hypersensitivity to any of its components.

WARNING: Because of the potential hazard of nephrotoxicity and ototoxicity due to neomycin, care should be exercised when using this product in treating extensive burns, trophic ulceration and other extensive conditions where absorption of neomycin is possible. In burns where more than 20 percent of the body surface is affected, especially if the patient has impaired renal function or is receiving other aminoglycoside antibiotics concurrently, not more than one application a day is recommended.

When using neomycin-containing products to control secondary infection in the chronic dermatitis, it should be borne in mind that the skin is more liable 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. During long-term use of neomycin-containing products, 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 preparations should be avoided for that patient thereafter.

PRECAUTIONS: As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

ADVERSE REACTIONS: Neomycin is a not uncommon cutaneous sensitizer. Articles in the current literature indicate an increase in the prevalence of persons allergic to neomycin. Ototoxicity and nephrotoxicity have been reported (see Warning section). Complete literature available on request from Professional Services Dept. PML.
ARTICLES

681 A Prospective, Randomized Study of Testosterone of Constitutional Delay of Growth and Development in Male Adolescents—Ron G. Rosenfeld, Gregory B. Northcraft, and Raymond L. Hintz

688 Psychopharmacology of Attention Deficit Disorder: Pharmacokinetic, Neuroendocrine, and Behavioral Measures Following Acute and Chronic Treatment with Methylphenidate—Sally E. Shaywitz, Robert D. Hunt, Peter Jatlow, Donald J. Cohen, Jerald Young, Richard N. Pierce, George M. Anderson, and Bennett A. Shaywitz

695 Conjunctivitis-Otitis Syndrome—Frank Franjo Bodor

699 Relationship Between the Magnitude of Bacteremia in Children and the Clinical Disease—T. Dennis Sullivan, Leonard J. LaScolet, Jr, and Erwin Neter

703 Effects of Parent Training on Teenage Mothers and Their Infants—Tiffany Field, Susan Widmayer, Reena Greenberg, and Sherilyn Stoller

708 Cognitive and Behavioral Knowledge About Insulin-Dependent Diabetes Among Children and Parents—Suzanne Bennett Johnson, R. Timothy Pollak, Janet H. Silverstein, Arlan L. Rosenbloom, Rebecca Spiller, Martha Callum, and Jill Harkey

714 Arachidonic Acid Metabolism in the Neonatal Platelet—Marie J. Stuart and Judith B. Allen

719 Anthropometric Determinants of Creatinine Excretion in Preterm Infants—James L. Surphen


728 Diagnosis, Management, and Long-Term Results of Patients with Congenital Complete Atrophic Ventricular Block—William W. Pinsky, Paul C. Gillette, Arthur Garson, Jr, and Dan G. McNamara

734 Developmental Changes in Hemoglobin F Levels During the First Two Years of Life in Normal and Heterozygous Beta-Thalassemia Infants—Anna D. Metaxotou-Mavromati, Helene K. Antonopoulou, Sophie S. Laskari, Helene K. Tsiarta, Vasilis A. Ladis, and Christos A. Kattamis

739 School Absence: A Problem for the Pediatrician—Michael Weitzman, Lorraine V. Klerman, George Lamb, Jean Menary, and Joel J. Alpert

747 Marital Stability and Congenital Heart Disease—Annette R. Silbert, Jane W. Newburger, and Donald C. Fyler

751 Serious Air Rifle Injuries in Children—Sterling Blocker, Dale Coln, and Jack H. T. Chang

755 Histochemical Diagnosis of Hirschsprung Disease—Carolyn Coker Huntley, Louis deS. Shaffner, Venkata R. Challa, and Anne D. Lyerly
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762 Pediatric Plague—Jonathan M. Mann, Laurence Shandler, and Alice H. Cushing

768 Effectiveness of Positioning Therapy for Gastroesophageal Reflux—William F. Meyers and John J. Herbst

773 Zinc Dependency as a Cause of Chronic Diarrhea in Variant Acrodermatitis Enteropathica—Ingeborg Krieger, Gary W. Evans, and Patricia S. Zelkowitz

778 Abnormal Cerebral Hemodynamics in Preterm Infants with Patent Ductus Arteriosus—Brian Lipman, Gerald A. Serwer, and Jane E. Brazy

782 Diaphragm Strength in Near-Miss Sudden Infant Death Syndrome—Charles B. Scott, Bruce G. Nickerson, Charles W. Sargent, Paula C. Dennies, Arnold C. G. Platzker, and Thomas G. Keens

785 Respiratory Behavior in Near-Miss Sudden Infant Death Syndrome—Joan E. Hodgman, Toke Hoppenbrouwers, Susan Geidel, Anthony Hadeed, Maurice B. Sterman, Ronald Harper, and Dennis McGinty

793 Development of Sleep-Wake Patterns and Non-rapid Eye Movement Sleep Stages during the First Six Months of Life in Normal Infants—Susan Coons and Christian Guilleminault

801 Zinc Deficiency Following Surgery in Zinc-Supplemented Infants—Paul A. Palma, Susan B. Conley, Sharon S. Crandell, and Susan E. Denson

804 Factitious Hypoglycemia—Jay H. Mayefsky, Ashok P. Sarnaik, and Daniel C. Postellon

805 Immersion Accidents in Hot Tubs and Whirlpool Spas—Byron Monroe

810 Aspirin and Reye Syndrome—Committee on Infectious Diseases

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813 Prevention of Fetal Alcohol Effects—Henry L. Rosett and Lyn Weiner

816 Help Wanted—Lewis H. Margolis


LETTERS TO THE EDITOR

826 Value of Parental Documentation of Medical Events—Nancy H. Doub

826 Boob Tube Time—Marc Weisbluth; Reply by Deborah N. W. Guttenberg

827 Lactose Breath Hydrogen Test—Sam Sheps; Reply by Ronald G. Barr, John B. Watkins, and Jay A. Perman

829 Testing and Stuffing Cotton Balls in Your Ears—Larry W. Desch and Randy P. Laskowski; Reply by Jack L. Paradise

830 Response to Letters on Infant Botulism—Stephen S. Aron

831 Imipramine and Enuresis: Never Forget Its Dangers—Howard J. Bennett

832 Skinfold Thickness—P. R. Swyer, T. Heim, and B. Reichman; Reply by James Sumners and Ruth Heimler

833 Hyperalimentation Laboratory Support—Joe Rutledge and Larry Miller

834 Epileptics and School Personnel—Gary B. Beringer, Marcia Biel, Dewey K. Ziegler, and Chi-Wan Lai; Reply by Philip R. Nader and Susan G. Brink

835 Opinion on a Computer—Michael R. Weir

835 Airplane Travel and Child Safety—Stephen H. Sheldon and Richard R. Wilson

837 INDEX TO VOLUME 69

A20 BOOKS RECEIVED

A5 MANUSCRIPT PREPARATION

A72 GENERAL INFORMATION

A82 CLASSIFIED ADS

A74 INDEX TO ADVERTISERS
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<table>
<thead>
<tr>
<th>Age Group</th>
<th>0-3 mos</th>
<th>4-11 mos</th>
<th>12-23 mos</th>
<th>2-3 yrs</th>
<th>4-5 yrs</th>
<th>6-8 yrs</th>
<th>9-10 yrs</th>
<th>11-12 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (lb)</td>
<td>6-11</td>
<td>12-17</td>
<td>18-23</td>
<td>24-35</td>
<td>36-47</td>
<td>48-59</td>
<td>60-71</td>
<td>72-95</td>
</tr>
<tr>
<td>Dose of TYLENOL in milligrams</td>
<td>40</td>
<td>80</td>
<td>120</td>
<td>160</td>
<td>240</td>
<td>320</td>
<td>400</td>
<td>480</td>
</tr>
<tr>
<td>DROPS (80 mg/0.8 ml) dropperfuls</td>
<td>½</td>
<td>1</td>
<td>1½</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>—</td>
</tr>
<tr>
<td>ELIXIR (160 mg/5 ml) teaspoonfuls</td>
<td>—</td>
<td>½</td>
<td>¼</td>
<td>1</td>
<td>1½</td>
<td>2</td>
<td>2½</td>
<td>3</td>
</tr>
<tr>
<td>CHEWABLE TABLETS (80 mg each)</td>
<td>—</td>
<td>—</td>
<td>1½</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

Doses should be administered 4 or 5 times daily—but not to exceed 5 doses in 24 hours.

**NOTE** Since TYLENOL pediatric products are available without a prescription, parents are warned on the package label to consult a physician for use by children under two or for use longer than ten days and to contact a physician immediately in case of accidental overdose.

---

There's nothing better!

McNeil Consumer Products Company
Fort Washington, PA 19034
Wide gram-negative spectrum
Gram-negative organisms commonly susceptible in vitro:
- Escherichia coli
- Proteus mirabilis
- Proteus vulgaris
- Proteus morganii
- Klebsiella-Enterobacter
- Shigella flexneri
- Shigella sonnei

*Pseudomonas aeruginosa* is commonly not susceptible.
In vitro data do not necessarily correlate with clinical results.

Proven efficacy in these serious infections:

**Pneumocystis carinii pneumonitis**—In this potentially fatal infection of immunosuppressed patients, Bactrim I.V. Infusion has proven effective in both children and adults.†

**Severe or complicated urinary tract infections**—
Bactrim I.V. Infusion is useful in both hospital-acquired and acute presenting cases of these gram-negative infections.‡

**Shigellosis**—Bactrim I.V. Infusion may also be used in cases of severe enteritis due to susceptible *Shigella* strains.†

*Due to susceptible strains of *E. coli*, *Klebsiella*-Enterobacter and *Proteus* species when oral administration of Bactrim is not feasible and the organism is not susceptible to single-agent antibacterials.
Low incidence of adverse reactions

The most frequent adverse reactions were rash in 2.2 percent (17 of 766), nausea and vomiting in 1.5 percent (11 of 766) and thrombocytopenia in 2.2 percent (17 of 766) of patients treated with Bactrim (trimethoprim and sulfamethoxazole/Roche) I.V. Infusion. For other adverse reactions which may occur, please see the summary of product information on the following page.

Guidelines for use

Dilution—Bactrim I.V. Infusion must be diluted. Each 5-ml ampul should be diluted in 125 ml of 5% dextrose in water and administered within 6 hours. When fluid restriction is desirable, each ampul may be added to 75 ml of solution if administered within 2 hours.

Administration—Administer ONLY by I.V. drip over a period of 60 to 90 minutes. RAPID INFUSION OR BOLUS INJECTION MUST BE AVOIDED. NOT FOR I.M. USE.

Dosage—For dosage in specific indications, see summary of product information on following page.

Contraindications—Hypersensitivity to either component; documented megaloblastic anemia due to folate deficiency; pregnancy at term and nursing mothers; infants less than two months of age.

from Roche, a world leader in antimicrobial therapy

Please see next page for summary of product information.

Bactrim™ IV
(trimethoprim and sulfamethoxazole/Roche)
Infusion

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

Indications: Bactrim I.V. Infusion is indicated in the treatment of Pneumocystis carinii pneumonitis and enteritis caused by susceptible strains of Shigella flexneri and S. dysenteriae Enterobacter and Proteus species when oral administration of Bactrim is not feasible and the organism is not susceptible to the single agent ampicillin. Bactrim I.V. Infusion has been used in the treatment of other urinary tract infections due to susceptible strains of E. coli, Proteus, Enterobacter, and Pseudomonas species. In addition, Bactrim I.V. Infusion has been used in the treatment of infants less than two months of age.

Contraindications: Hypersensitivity, documented megaloblastic anaemia due to folate deficiency, renal impairment and during the last trimester of pregnancy.

Dosage: Children and Adults. Pneumocystis carinii Pneumonitis. Total daily dose is 15 to 20 mg/kg (based on the trimethoprim component) given in three or four equally divided doses every 6 to 8 hours for up to 14 days.

Adverse Reactions: Most frequently reported are nausea, vomiting, anemia and rash.

Carcinogenesis, mutagenesis, impairment of fertility. Carcinogenesis. Long term animal studies evaluating carcinogenic potential have not been conducted with Bactrim I.V. Infusion. Mutagenesis. Bacterial mutagenic studies have not been performed with trimethoprim in combination. Trimethoprim was nonmutagenic in the Ames assay. No chromosomal damage was observed in human leukocytes cultured in vitro with the components alone or in combination. The concentrations used exceeded blood levels following Bactrim therapy. Leukocytes from patients treated with Bactrim showed no chromosomal abnormalities. Impairment of fertility. Bactrim I.V. Infusion has not been studied in animals for evidence of impairment of fertility, but studies in rats at oral doses as high as 70 mg/kg trimethoprim plus 350 mg/kg sulfamethoxazole daily showed no adverse effects on fertility or general reproductive performance.

Pregnancy. Teratogenic Effects. Pregnancy Category C. In rats, oral doses of 533 mg/kg sulfamethoxazole or 200 mg/kg trimethoprim produced teratological effects, mainly cleft palate. The highest dose causing cleft palate in rats was 512 mg/kg sulfamethoxazole or 192 mg/kg trimethoprim, administered separately. Ten rats showed no teratology with 512 mg/kg of sulfamethoxazole and 128 mg/kg of trimethoprim. In rabbit studies, an overall increase in fetal loss was associated with doses of trimethoprim six times the human therapeutic dose. While there are no large, well-controlled studies on the use of trimethoprim plus sulfamethoxazole in pregnant women, Brumfield and Purcell reported the outcome of 186 pregnancies during which the mother received trimethoprim or this combination orally. The incidence of congenital abnormalities was 4.5% (3 of 66) in those receiving placebo and 3.3% (4 of 120) with trimethoprim plus sulfamethoxazole. There were no abnormalities in the 10 children whose mothers received the drug during the first trimester in a separate survey conducted by Brumfield and Purcell also found no congenital abnormalities in 35 children whose mothers had received oral trimethoprim plus sulfamethoxazole. Can the concept be shorted or ignored? Because this combination may interfere with folic acid metabolism, Bactrim I.V. Infusion should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nonteratogenic Effects. See "CONTRA-INDICATIONS" section.

Adverse Reactions: Most frequently reported are nausea, vomiting, anemia and rash.

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Desitin—proven best in double-blind comparison study with A & D Ointment.

In a double-blind study of 50 infants with moderate or severe diaper rash, 25 infants were randomly assigned to be treated with Desitin, and the remaining 25 with A & D Ointment. Both products were applied at each diaper change, and results were evaluated at 4, 10 and 24 hours after start of therapy.

Desitin—unmatched in speed of action.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>4 hrs.</th>
<th>10 hrs.</th>
<th>24 hrs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desitin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A &amp; D Ointment</td>
<td>0</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Comparing the speed of action, it is evident that Desitin worked significantly faster—with 17 of 25 cases improving within 10 hours, and 3 cases in as little as 4 hours.

Desitin—unmatched in overall efficacy.

<table>
<thead>
<tr>
<th></th>
<th>24 hrs.</th>
<th>10 hrs.</th>
<th>4 hrs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desitin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A &amp; D Ointment</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Overall results showed 23 of 25 babies (92%) improved with Desitin within 24 hours. In contrast, only 4 of 25 babies (16%) improved with A & D Ointment within 24 hours.

In a previous study in which 45 infants with diaper rash were treated with Desitin, a significant degree of reduction in the severity of rash as well as in the size of the rash area was observed within 24 hours.

Desitin—unique, proven formula makes the difference.

Desitin Ointment is the only leading diaper rash formula with natural vitamins A and D (from Norwegian cod liver oil) to help promote granulation and the formation of epithelium... plus zinc oxide to dry and soothe. Two emollients—lanolin and petrolatum—combine with the zinc oxide to form a long-lasting protective barrier against wetness and ammonia compounds.

A comprehensive formula, rapid action, plus proven efficacy—three important reasons why pediatricians have made Desitin Ointment their number one OTC recommendation for diaper rash.

   Data on file, Leeming/Pacquin Division of Pfizer Inc.
   © 1981, Pfizer Inc.
BOOKS RECEIVED


TEACHERS REWARD MUDDY PROSE, STUDY FINDS

Two Chicago researchers have confirmed what high school and college students have known for years: Many English teachers are more impressed by purple prose than by the clear, concise language that they profess to teach.

In a series of experiments over a six-year period, Rosemary L. Hake of Chicago State University and Joseph M. Williams of the University of Chicago asked English teachers to rate pairs of student essays that were identical in everything except linguistic style. One of each pair was marked by simple language, active verbs and straightforward sentences, the other by flowery language, passive verbs and complex sentence structures.

The two professors found not only that the teachers consistently preferred verbosity to tight writing but also that the style of language affected their judgement about the kinds of errors they discovered.

"The teachers tended to find errors of logic and meaning in the verbose papers and mechanical errors in the others—even though the papers were identical in the errors they contained," Dr. Hake said in an interview. "The operating principle seemed to be that the higher the level of the language, the greater the importance of the errors."

In a report on their research in the September issue of the journal College English, the two scholars suggested that it pointed to a certain hypocrisy in a profession that is presumably committed to the teaching of clear writing. They said their findings indicated that many teachers were "encouraging precisely the stylistic values we claim we reject and discouraging precisely the stylistic values we claim we support."

Proven Clinical Accuracy
THE CRITICAL FACTOR IN TB SCREENING

Lederie Tuberculin, Old, TINE TEST®
95.8% agreement with Mantoux

ACCURACY* demonstrated in over 31,000 clinical comparisons
BENEFITS confirmed in over 150,000,000 office uses

*Data on file—Lederie Laboratories, Pearl River, N.Y.
© 1982 Lederie Laboratories

Please see following page for Brief Summary of Prescribing Information.
Proven Clinical Accuracy
THE CRITICAL FACTOR IN TB SCREENING

...and no easier method to confirm the results.
Lederle Tuberculin, Old, TINE TEST™

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

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

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

American Academy of Pediatrics
Continuing Medical Education

Plan now to attend CME course #12...

TODAY'S ADOLESCENT AND THE SCHOOL ENVIRONMENT: MEDICAL AND BEHAVIORAL ASPECTS

July 30, 31, August 1, 1982
Parker House Hotel
Boston, Massachusetts

Cosponsored with the Children's Service, Massachusetts General Hospital, Boston, Massachusetts

This course highlights major aspects of health care for the adolescent in secondary school and college considering his/her needs, both at and away from home. Commonly encountered medical problems such as diabetes, obesity, infectious mononucleosis and handicaps, venereal disease and gynecological disorders, as well as problems of the woman athlete and the management and prevention of sports injuries will be considered by a faculty selected for their practicing experience with the adolescent. Adjustment problems of adolescence including dealing with drugs, depression and suicide and evaluation of school failure will also be discussed. Physicians who have directed secondary school and college health programs will moderate the three hour sessions of didactic talks and open panel and seminar discussions to keep the focus on practical management of the whole adolescent as well as to contribute some new thoughts about methods of providing such care.

- A complete listing of guest faculty, along with detailed course information and a course registration form, will be forwarded to you upon request. PLEASE REMEMBER, course brochures will no longer be mailed to the entire membership prior to each course.

- For further information, contact:

Jean Dow
American Academy of Pediatrics
Department of Education
P.O. Box 1034
Evanston, Illinois 60204

Or phone toll-free: 800/323-0797
An important first:

NIZORAL®
(ketoconazole)

Safe and effective and offers a number of distinct advantages over nystatin in treating severe oral thrush

Saves time and trouble for patients and staff
- Simple one-tablet-a-day regimen fosters compliance, facilitates ambulatory and outpatient therapy
- No need for patients to suck on suppositories or swish around nystatin preparations several times a day
- Cost of therapy significantly less than nystatin treatment

Systemic action can reach remote Candida lesions
- In contrast to the topical action of nystatin, NIZORAL® (ketoconazole) can reach asymptomatic lesions in the esophagus or GI tract
- Excellent overall effectiveness...one week clinical cures seen in over 50 percent of patients
- SAFE: Can be administered for prolonged periods; well tolerated. Since possible idiosyncratic hepatocellular dysfunction has been reported, it is desirable to perform appropriate liver function tests before and during treatment, particularly in patients on long-term therapy.

Please see revised brief summary of Prescribing Information on next page.

Top: Severe oral thrush before therapy.
Bottom: After 7 days, 200 mg per day oral NIZORAL.
Before prescribing, please consult complete prescribing information, of which the following is a brief summary.

INDICATIONS AND USAGE
NIZORAL® is indicated for the treatment of the following systemic fungal infections: candidiasis, chronic mucocutaneous candidiasis, oral thrush, candidemia, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis. NIZORAL® should not be used for fungal meningitis because it penetrates poorly into the cerebral-spinal fluid.

For the initial diagnosis, the infective organism should be identified. However, therapy may be initiated prior to obtaining laboratory results.

CONTRAINDICATIONS
NIZORAL® is contraindicated in patients who have shown hypersensitivity to the drug.

WARNINGS
Several cases of possible idiosyncratic hepatocellular dysfunction have been reported during NIZORAL® treatment. It is important to recognize that liver disorders may occur with NIZORAL® therapy. The rare occurrences of liver disorders could be potentially fatal unless properly recognized and managed.

It is desirable to perform liver function tests, such as SGPT, alkaline phosphatase, SGOT, SGOT and bilirubin. before treatment and at periodic intervals during treatment (monthly or more frequently). particularly in patients who will be on prolonged therapy or who have a history of liver disease. Instances of minor elevations of liver enzyme levels in patients on NIZORAL® have been shown to normalize during therapy and may not necessitate discontinuation of treatment; however, if liver function tests are significantly elevated or other signs and symptoms are suggestive of hepatocellular dysfunction, NIZORAL® should be discontinued.

In female rats treated three to six months with ketoconazole at dose levels of 80 mg/kg and higher, increased fragility of long bones, in some cases leading to fracture, was seen. The maximum 'recommended' dose level in these studies was 20 mg/kg (2.5 times the maximum recommended human dose). The mechanism responsible for this phenomenon is obscure. Limited studies in dogs failed to demonstrate such an effect on the metacarpals and ribs.

PRECAUTIONS
General: In four subjects with drug-induced acalculous, a marked reduction in NIZORAL® absorption was observed. NIZORAL® requires acidity for dissolution of the tablets in the stomach.

In four subjects with drug-induced acalculous, NIZORAL® absorption was observed. NIZORAL® requires acidity for dissolution of the tablets in the stomach. Consequently, the patients should be instructed to dissolve each tablet in 4 ml aqueous solution of 0.2 N HCl. For ingestion the resulting mixture, they should use a glass or plastic straw so as to avoid contact with the teeth. This administration should be followed with a cup of tap water.

For safety in children under two years of age has been documented in a limited number of cases.

ADVERSE REACTIONS
NIZORAL® is usually well tolerated. Most adverse reactions reported have been mild and transient and have only rarely required withdrawal of therapy.

The most frequent adverse reactions were nausea and/or vomiting, which occurred in approximately 5% of patients. Abdominal pain was reported in approximately 12% of patients. Pruritus was reported in approximately 15% of patients. The following have been reported in less than 1% of patients: headache, dizziness, somnolence, fever and chills, photosensitivity, diarrhea, jaundice, and general malaise. Transient increases in serum liver enzymes have been observed. In the majority of cases, these increases have normalized during therapy or shortly after drug has been discontinued. However, several cases of idiosyncratic hepatocellular dysfunction have been reported (see WARNINGS).

OVERDOSAGE
In the event of accidental overdosage, supportive measures, including gastric lavage with sodium bicarbonate, should be employed.

DOSAGE AND ADMINISTRATION
Adults: The recommended starting dose of NIZORAL® is a single daily administration of 200 mg (one tablet). In very serious infections or if clinical responsiveness is insufficient within the expected time, the dose of NIZORAL® may be increased to 400 mg (two tablets) once daily.

Children:

- Children weighing 20 kg or less: 50 mg (½ tablet) once daily
- Children weighing 20-40 kg: 100 mg (1 tablet) once daily
- Children weighing over 40 kg: 200 mg (1 tablet) once daily

Generally, treatment should be continued until all clinical and laboratory tests indicate that active fungal infection has subsided. Inadequate periods of treatment may lead to early recurrence of clinical symptoms. Minimum treatment for candidiasis is one or two weeks. Patients with chronic mucocutaneous candidiasis usually require maintenance therapy. Minimum treatment for the other indicated systemic mycoses is six months.

HOW SUPPLIED
NIZORAL® is available as white, scored tablets containing 200 mg of ketoconazole debossed "JANSSEN" and on the reverse side debossed "K" and "200". They are supplied in bottles of 60 tablets and in blister packs of 10. 10 tablets.

Manufactured by Janssen Pharmaceutical N.V.
B-2340 Beerse, Belgium
For Janssen Pharmaceutical Inc.
New Brunswick, New Jersey 08903 USA

American Academy of Pediatrics
Section on Pediatric Nephrology

The Section Committee cordially invites all Fellows with an interest in the field of pediatric nephrology to apply for Section Membership.

APPLICATIONS for Section Membership may be obtained from the Section Secretary at the address below.
The new Radiometer non-invasive blood gas system is as flexible as your needs are.

Bedside, transport, operating room, emergency, intensive care; now there is a non-invasive oxygen and carbon dioxide system that can do it all. The new Radiometer TCM System with detachable TCM2, tcPO2, and TCM20 tcPCO2 Monitors and a recharger database that features a 2 pen, 2 speed recorder with 3 sensitivity ranges.

The rechargeable battery powered tcPO2 and tcPCO2 Monitors are microprocessor controlled and feature the convenience of automated push button calibration and built-in programs that monitor and control electrode temperature and performance characteristics. Other features include electrode temperature selectors, adjustable high and low visual and acoustic alarms, temperature out-of-range and low battery indicators and both analog and digital (RS232) outputs. Monitors may be used separately from the database for a typical six hours per charge or used in pairs in the database for two site or two patient monitoring.

The new small Radiometer electrodes for the TCM System feature new simple snap-on membranes and soft rimmed fixation rings that easily bend to the curvature of the body.

The Radiometer TCM transcutaneous blood gas system, flexible, convenient and easy to use. And, of traditional Radiometer quality. For a free descriptive brochure contact Radiometer America, Inc., 811 Sharon Drive, Westlake, Ohio 44145. Or call, toll free, (800) 321-9484. In Ohio, call (216) 871-8900.

CAUTION
The TCM20 tcPCO2 Monitor is limited to use with neonates and infants.
Cyclapen · W (cyclocillin)

Indications
Cyclocillin has less in vitro activity than other drugs in the ampicillin class and its use should be confined to these indications: Treatment of the following infections:

- Respiratory Tract
  - Tonsillitis and pharyngitis caused by Group A beta-hemolytic streptococci:
  - Bronchitis and pneumonia caused by S. pneumoniae (formerly D. pneumoniae):
  - Otitis media caused by S. pneumoniae (formerly D. pneumoniae):
  - H. influenzae, and Group A beta-hemolytic streptococci:
  - Acute exacerbation of chronic bronchitis caused by H. influenzae*

*Though clinical improvement has been shown, bacteriologic cure cannot be expected in all patients with chronic respiratory disease due to H. influenzae.

- Skin and Skin Structures (penememegry) infections caused by Group A beta-hemolytic streptococci and staphylococci, non-penicillinase producing:

- Urinary Tract infections caused by E. coli and P. mirabilis.

(This drug should not be used in any E. coli and P. mirabilis infections other than urinary tract infections.)

NOTE: Perform cultures and susceptibility tests initially and during treatment to monitor effectiveness of therapy and susceptibility of bacteria. Therapy may be instituted promptly after initial sensitivity testing.

Contraindications: Contraindicated in individuals with history of an allergic reaction to penicillin.

Warning: This drug should only be prescribed for the indications listed herein.

Cyclocillin has less in vitro activity than other drugs of the ampicillin class. However, clinical trials demonstrated it is efficacious for recommended indications.

Serious and occasional fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin. Although anaphylactic reactions are less frequent following parental use, it has occurred in patients on oral penicillin. These reactions are more apt to occur in individuals with history of sensitivity to multiple allergens. There are reports of patients with history of penicillin hypersensitivity reactions who experienced severe hypersensitivity reactions when treated with a cephalosporin. Before penicillin therapy, carefully inquire about previous hypersensitivity reactions to penicillins, cephalosporins and other antibiotics. If allergic reaction occurs, discontinue drug and institute appropriate therapy. Serious and anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, I.V. steroids, airway management, including intubation, should also be administered as indicated.

Precautions: Prolonged use of antibiotics may promote overgrowth of nonsusceptible organisms. If superinfections occur, take appropriate measures.

Pregnancy: Category B: Reproduction studies performed in mice and rats at doses up to 10 times the human dose revealed no evidence of impaired fertility or harm to the fetus due to cyclocillin. However, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, use this drug 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 the nursing woman when cyclocillin is given to a nursing woman, it is recommended that infants of nursing mothers be treated with a different antibiotic.

Adverse Reactions: Oral cyclocillin is generally well tolerated. As with other penicillins, untoward sensitivity reactions are likely, particularly in those who have previously demonstrated penicillin hypersensitivity or have history of allergy, asthma, hay fever, or urticaria. Adverse reactions reported with cyclocillin include: rashes (in approximately 1 in 20 patients treated), urticaria, pain of injection, pruritus, diarrhea, cough, nausea, vomiting, and urticaria have been reported. (See WARNINGS) Other less frequent adverse reactions which may occur are: flushed face, sweating, dizziness, nausea, vomiting, anorexia, anemia, cutaneous eruptions, headache, anaphylaxis, and allergic reactions. These reactions are usually reversible on discontinuation of therapy.

As with other semisynthetic penicillins, SGOT elevations have been reported.

Respiratory Therapy generally, continuous treatment of at least 48 to 72 hours after patient becomes asymptomatic and until bacterial eradication is evidenced. In Group A beta-hemolytic streptococcal infections, at least 10 days, therapy is recommended to guard against risk of rheumatic fever or glomerulonephritis. In chronic urinary tract infection, frequent bacteriologic and clinical appraisal is necessary during therapy and possibly for several months after. Persistent infection may require treatment for several weeks.

Cyclocillin is not indicated in children under 2 months of age.

Patients with Renal Failure: Cyclocillin may be safely administered to patients with reduced renal function. Due to prolonged serum half-life, patients with various degrees of renal impairment may require change in dosage level (see DOSAGE AND ADMINISTRATION package insert).

Dosage (see equally spaced doses):

Infections: Adults: Children*:

<table>
<thead>
<tr>
<th>Infection</th>
<th>Dosage (in mg q d)</th>
<th>Dosage (in mg q d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Tract</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tonsillitis &amp; Pharyngitis</td>
<td>250-500</td>
<td>250-500</td>
</tr>
<tr>
<td>Bronchitis &amp; Pneumonia</td>
<td>250-500</td>
<td>250-500</td>
</tr>
<tr>
<td>Mild or Moderate Infections</td>
<td>500-1000</td>
<td>500-1000</td>
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<tr>
<td>Chronic Infections</td>
<td>250-500</td>
<td>250-500</td>
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<tr>
<td>Otis Media</td>
<td>250-500</td>
<td>250-500</td>
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<tr>
<td>Skin &amp; Skin Structures</td>
<td>500-1000</td>
<td>500-1000</td>
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<tr>
<td>Urinary Tract</td>
<td>500-1000</td>
<td>500-1000</td>
</tr>
</tbody>
</table>

*Dosage should not result in a dose higher than that for adults, depending on severity.

How Supplied: Tablets: 250 mg and 500 mg in bottles of 100.

Oral Suspension: 125 mg and 250 mg per 5 mL in bottles to make 100 mL and 200 mL of Suspension.
Compared to amoxicillin

Faster peak. Fewer problems.

... in infants and children

Cyclacen®-W (cyclacillin) produces twice the peak serum concentration* (15.6 mcg/ml versus 7.3 mcg/ml) in half the time (30 minutes versus 60 minutes).*1

Cyclacen®-W is just as effective in otitis media and streptococcal tonsillopharyngitis*1,2

Cyclacen®-W produces a significantly lower incidence of the most common side effect, diarrhea.*2

CYCLAPEN®-W
(cyclacillin) Tablets/Suspension

Rapid onset of action with fewer side effects.

New t.i.d. dosage for otitis media* and strep pharyngitis* in children

*Rapidly excreted unchanged in urine. Clinical efficacy may not always correlate with blood levels.
*Due to susceptible organisms.
2. Multicenter trials. Data to be published
Copyright © 1982, Wyeth Laboratories. All rights reserved.
See important information on adjoining column.
Leukemia. It's no longer a death sentence.

When you were young, no form of cancer terrified your parents more than leukemia did.

Just fifteen years ago, a child with leukemia could expect to live only months.

But, thanks to research, things have changed.

Children who once lived months are now living years. Many of them are growing up. Some are already adults, living normal lives.

Did you ever wonder what the American Cancer Society did with the money you gave us? Well, some of it went to leukemia research. And, if we had more, we could do more.

Give to the American Cancer Society.

To further encourage patient compliance, there's only one chewable theophylline.

**Theophyl® Chewable**

100 mg TABLET (ANHYDROUS THEOPHYLLINE USP)

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

**CONTRAINDICATIONS:** Avoid using THEOPHYL® Chewable Tablets in individuals who have shown hypersensitivity to any of their components.

**WARNINGS:** Excessive theophylline doses may be associated with toxicity. Determination of serum theophylline levels is recommended to assure maximal benefit without excessive risk. Incidence of toxicity increases at serum levels greater than 20 mcg/ml.

Morphine, curare, and stilbamidine should be used with caution in patients with airflow obstruction since they stimulate histamine release and can induce asthmatic attacks. They may also suppress respiration leading to respiratory failure. Alternative drugs should be chosen whenever possible.

There is an excellent correlation between clinical manifestations of toxicity and high blood levels of theophylline resulting from conventional doses in patients with lowered body plasma clearances (due to transient cardiac decompensation), patients with liver dysfunction or chronic obstructive lung disease, and patients who are older than 55 years of age, particularly males. In about 50% of patients, nausea and restlessness precede more severe manifestations of toxicity. In other patients, ventricular arrhythmias or seizures may be the first signs of toxicity. These more serious side effects are likely to occur after intravenous administration of theophylline. Many patients who have high theophylline serum levels exhibit a tachycardia, and theophylline may worsen pre-existing arrhythmias.

**USAGE IN PREGNANCY:** Safe use in pregnancy has not been established relative to possible adverse effects on fetal development. The use of non-smokers. Therefore, theophylline in pregnant women should be balanced against the risk of uncontrolled asthma.

**PRECAUTIONS:** Mean half-life in smokers is shorter than in non-smokers. Therefore, smokers may require larger doses of theophylline.

**THEOPHYL® Chewable Tablets** are thought to be administered concurrently with other xanthine medications.

Use with caution in patients with severe cardiac disease, severe hypoxemia, hypertension, hyperthyroidism, acute myocardial injury, cor pulmonale, congestive heart failure, liver disease, peptic ulcer and in the elderly (especially males) and in neonates. Great caution should be used especially in giving theophylline to patients in congestive heart failure, such patients have shown markedly prolonged theophylline blood levels with theophylline persisting in serum for long periods following discontinuation of the drug.

Theophylline may occasionally act as a local irritant to the GI tract although gastrointestinal symptoms are more common central in origin and associated with serum concentrations over 20 mcg/ml.

**ADVERSE REACTIONS:** The most frequent adverse reactions to theophylline are usually due to over-dose (serum levels in excess of 20 mcg/ml) and are nausea, vomiting, epigastric pain, hematemesis, diarrhea, headaches, irritability, restlessness, insomnia, reflex hyperexcitability, muscle twitching, clonic and tonic generalized convulsions, palpitations, tachycardia, extra systoles, flushing, hypotension, circulatory failure, ventricular arrhythmias, tachypnea, albuminuria, increased excretion of renal tubular cells and red blood cells, potentiation of diuretics, hyperglycemia, and inappropriate ADH syndrome.

**DRUG INTERACTIONS:** Toxic synergism with epinephrine has been documented and may occur with some other sympathomimetic bronchodilators.

**DRUG**

Aminophylline with lithium carbonate

Aminophylline with propranolol

Theophylline with furosemide

Theophylline with hexamethonium

Theophylline with reserpine

Theophylline with chloralazine

Theophylline with troleandomycin

**EFFECT**

Increased excretion of lithium carbonate

Antagonism of propranolol effect

Increased diuresis

Decreased hexamethonium-induced hypertensive effect

Reserpine-induced tachycardia

Chloralazine-induced fatty acid mobilization

Increased theophylline plasma levels

**American Cancer Society**

This space contributed by the publisher in a public service.
For the child with Asthma:

To further encourage patient compliance, there's only one chewable theophylline.

Theophyl Chewable Tablets are microencapsulated for improved palatability and greater patient acceptance. They are scored for easy titration. With Theophyl Chewable Tablets, there is no mixing, no spilling. They are easy to take, convenient to carry, and economical to use. For the child who has difficulty with liquids, they are ideal. And the onset of action with Theophyl Chewable Tablets has been demonstrated to be equivalent to that of liquids.

Effective Theophylline Plasma Levels

Average of serum theophylline concentrations from 17 pediatric patients diagnosed as having chronic bronchial asthma (average age 8.6 years) after multiple dose administration of Theophyl Chewable Tablets (average dose of 4.5 \( \equiv 0.28 \) mg/kg).

Data on file, Johnson & Johnson.

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For full prescribing information, see other page.
The 19th edition of the Academy’s quick reference guide to more than 100 communicable diseases is now available for purchase. Officially known as the “Report of the Committee on Infectious Diseases,” this authoritative handbook gives the etiology, epidemiology, incubation period, period of communicability, clinical forms and differential diagnosis, diagnostic procedures, treatment and control measures for diseases ranging from actinomycosis to yersinia infections.

The “Red Book” has been a “must” for child health professionals since the first edition in 1938. Part one discusses active and passive immunization, including informed consent; part two is a summary of infectious diseases; and part three is composed of a number of tables and information on services of the Center for Disease Control.

New sections in this edition include recently described diseases caused by Chlamydia trachomatis, corona viruses, Legionella pneumophila, hepatitis B and non A and non B hepatitis, Kawasaki disease and yersinia species, and use of new vaccines and specific immune globulin preparations for hepatitis, rabies and varicella-zoster. Also new are sections on diagnostic virology, information sheets for immunization, 32 tables on etiologic agents of common pediatric diseases, and information used for isolation techniques in hospitals. The tables for use of antimicrobial agents have been revised to include new drugs and changes in dosage schedules for old drugs. 1982 indexed: 379 pages.

Note: All Fellows and Junior Fellows will be mailed one complimentary copy in June.

The new “Red Book” is here...

Please send me:  
[ ] copies,  
"Infectious Diseases"  
@ $15.00

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Publications Department  
P.O. Box 1034  
Evanston, Illinois 60204

[ ] Check for $__________ is enclosed.  
Personal order must be prepaid. Make check payable to: American Academy of Pediatrics.

[ ] Bill the institution. Formal purchase order required. Quantity discounts available. Special discounts for school nurses, administrators.

Name ________________________________
Address ________________________________
City __________ State ________ Zip ________
Dealing with the problems of school children

A new (1981) edition of School Health: A Guide for Health Professionals is now available. Revised by the AAP Committee on School Health, this manual gives practical information on how school health programs function and how these programs fit into the school structure. It discusses the problems of pre-school age children, elementary school children and adolescents, and has a section on children with special educational needs. In addition, it reports on screening tests needed as well as the essentials of history and physical examination, follow-up procedures and record keeping.

Other points of interest are: health education, physical education, physical activities for children with handicaps, dental care, school sports programs, communicable disease, emergency care in schools, school personnel problems and school safety.

The book also includes 16 appendices and 3 tables. Indexed: 297 pages.

Coly-Mycin® S Otic
with Neomycin and Hydrocortisone
(colistin sulfate—neomycin sulfate—thoronzum bromide—hydrocortisone acetate 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 mastoid cavity 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.

WARNINGS
As with other antibiotic preparations, prolonged treatment may result in overgrowth of nonsusceptible organisms and 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.

Patients who prefer to warm the medication before using should be cautioned against heating the solution above body temperature, in order to avoid loss of potency.

PRECAUTIONS
General
If sensitization or irritation occurs, medication should be discontinued promptly.

This drug should be used with care in cases of perforated ear drum and in longstanding cases of chronic otitis media because of the possibility of ototoxicity caused by neomycin.

Treatment should not be continued for longer than 10 days.

Allergic cross-reactions may occur which could prevent the use of any one of the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin.

ADVERSE REACTIONS
Neomycin is not an uncommon cutaneous sensitizer. There are articles in the current literature that indicate an increase in the prevalence of persons sensitive to neomycin.

DOSEAGE AND ADMINISTRATION
The external auditory canal should be thoroughly cleansed and dried with a sterile cotton applicator.

For adults: 4 drops of the suspension should be instilled into the affected ear 3 or 4 times daily. For infants and children: 3 drops are suggested because of the smaller capacity of the ear canal.

The patient should lie with the affected ear upward and then the drops should be instilled. This position should be maintained for 5 minutes to facilitate penetration of the drops into the ear canal. Repeat, if necessary, for the opposite ear.

If preferred, a cotton wick may be inserted into the canal and then the cotton may be saturated with the solution. The wick should be kept moist by adding further solution every 4 hours. The wick should be replaced at least once every 24 hours.

HOW SUPPLIED
Coly-Mycin® S Otic is supplied as:
N 0071-3141-08—5 ml bottle
N 0071-3141-10—10 ml bottle

Each ml contains: Colistin sulfate equivalent to 3 mg of colistin base. Neomycin sulfate equivalent to 3.3 mg neomycin base. Hydrocortisone acetate 10 mg (1%). Thoronzum bromide 0.5 mg (0.05%). And Polysorbate 80 in an aqueous vehicle buffered with acetic acid and sodiumacetate. Thimerosal (mercury derivative) 0.002% added as a preservative.

Shake well before instilling.

Store at controlled room temperature 59-86°F (15-30°C).

Stable for 18 months at room temperature. Prolonged exposure to higher temperatures should be avoided.

3141C031

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"School Health"
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American Academy of Pediatrics
Publications Department
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Evanston, Illinois 60204

☐ Check for $_________ is enclosed.
☐ Personal order must be prepaid. Make check payable to: American Academy of Pediatrics.
☐ Bill the institution. Formal purchase order required.
☐ Quantity discounts available. Special discounts for school nurses, administrators.

Name
Address
City State Zip
This season, when patients complain of pain and inflammation of "swimmer's ear" (or other summertime external ear disorders due to susceptible bacterial organisms) prescribe the comprehensive symptomatic relief of Coly-Mycin S Otic.

Each drop delivers:
- Hydrocortisone Acetate—for fast reduction of inflammation and symptomatic pain relief
- Colistin Sulfate/Neomycin Sulfate—for broad antibacterial coverage with emphasis on gram-negative Ps aeruginosa
- Thonzonium Bromide—for enhanced efficiency by allowing penetration and dispersion of active ingredients through debris and exudate

Recommended Dosage: Adults—4 drops in each affected ear, 3-4 times daily.
Infants & Children: 3 drops in each affected ear, 3-4 times daily.

Available in 2 convenient sizes—each in a convenient, dropperless, breakproof, plastic bottle.
- 5 ml* for unilateral otic involvement
- 10 ml for bilateral otic involvement

*5-ml size supplies sufficient medication for an average course of therapy in one affected ear.

Before prescribing, please see full prescribing information. A brief summary appears on the opposite page.
A Prospective, Randomized Study of Testosterone Treatment of Constitutional Delay of Growth and Development in Male Adolescents

Ron G. Rosenfeld, MD, Gregory B. Northcraft, BA, and Raymond L. Hintz, MD

From the Departments of Pediatrics and Psychology, Stanford University, Stanford, California

ABSTRACT. The physiologic and psychological responses to androgen treatment of constitutional delay of growth and development were prospectively evaluated in 16 male adolescents, aged 14 to 17 years. Subjects were randomly assigned to a course of testosterone enanthate, 200 mg administered intramuscularly four times at three-week intervals or to observation. At one-year follow-up all subjects in the testosterone group exhibited excellent growth: 7.2 to 11.6 cm/yr (mean 9.2 cm/yr). Growth in control subjects was highly variable: 2.6 to 10.6 cm/yr (mean 6.0 cm/yr), significantly lower than that of the testosterone group (P < .02). The mean annual increment in bone age was 1.1 years for both groups. The Δ height age/Δ bone age ratio was slightly higher in the testosterone group (1.3 vs 1.1), and the treated subjects had a 1.7-cm increase in predicted adult height. Both groups showed improved self-image, and treated subjects also exhibited dramatic increases in both school-related and extraschool social activity. A brief course of testosterone enanthate appears to be an effective, safe means of promoting growth in select male adolescents. Pediatrics 69:681-687, 1982; testosterone, growth, puberty, short stature.

Although constitutional delay of growth and development is considered to be a normal growth variant, it remains the most common form of short stature observed in pediatric endocrine clinics. These cases can often be successfully managed by detailed explanation, reassurance, and observation. On occasion, however, significant growth retardation in male adolescents, especially when accompanied by delayed sexual maturation, may be associated with a sense of incompetence and vulnerability, impaired self-esteem, reluctance to participate in athletic activities, social isolation, decline in academic performance, and progressive anxiety and depression.2-4

Androgen therapy has been used in the treatment of such patients in an attempt to improve ultimate adult height, or at least induce a rapid growth spurt. Multiple reports have been published on the use of various androgenic and anabolic steroids, but generally suffer from being retrospective reviews.2-4

The following prospective, randomized investigation was undertaken in an attempt to investigate both the physiologic and psychological responses to androgen treatment of constitutional delay in male adolescents.

METHODS

Subjects

All subjects were teenaged boys referred to the Stanford University Pediatric Endocrinology Clinic.