Pediazole

erythromycin ethylsuccinate and sulfisoxazole acetyl for oral suspension

BRIEF SUMMARY:

enclosure for full prescribing information.

Indication
For treatment of ACUTE OTITIS MEDIA in children caused by susceptible strains of Hemophilus influenzae.

Contraindications

Contraindications
Known hypersensitivity to either erythromycin or sulfonamides.
Infants less than 2 months of age.
Pregnancy at term and during the nursing period, because sulfonamides pass into the placental circulation and are excreted in human breast milk and may cause kernicterus in the infant. Warnings

Warnings
Usage in Pregnancy (SEE ALSO: CONTRAINDICATIONS): The
sale use of erythromycin or sulfonamides in pregnancy has not bee
stablished. The teratogenic potential of most sulfonamides has not
been thoroughly investigated in either animals or humans. However,
a significant increase in the incidence of cleft patate and other bony
abnormalities of offspring has been observed when certain sulform
indes of the short, intermediate and long-acting types were given to
pregnant rats and muce at high or and tobese (7 to 25 times the human
herapeutic doze).

pregnant rats and mice at high oral doses (7 to 25 times the human therapeutic doses). Reports of deaths have been associated with sulfonamide administration from hypersensitivity reactions, agranulocytosis, aplastic anemia and other blood dyscrasisa. The presence of clinical signs such as ore frontal, tever, pallor, burpura or jaundice may be early indications of senior, patients receiving sulfonamides. The frequency of renal complications is considerably lower in patients receiving sulfonamides such as sulfisoxazole. Urinalysis with careful microscopic examination should be obtained frequently in patients receiving sulfonamides.

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

Recent data from studies of erythromycin reveal that its use in patients who are receiving high doses of theophylline may be associated with an increase of serum theophylline levels and potential theophylline broughly included in the patient is receiving concomitant erythromycin therapy.

duced while the patient is storing.

Surgical procedures should be performed when indicated.

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

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

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

Blood dyscrasias: Agranulocytosis, aplastic anemia, thromboc topenia, leukopenia, hemolytic anemia, purpura, hypoprothron binemia and methemoglobinemia.

Allergic reactions: Erythema multiforme (Stevens-Johnson syndrome), generalized skin eruptions, epidermal necrolysis, urticaria, serum sickness, puritus, exfoliative dermattis, anaphylactioid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthrajla and allergic myocarditis.

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

C.N.S. reactions: Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia.

Miscellaneous reactions: Drug fever, chills and toxic nephrosis with oliguria or anuria. Periarteritis nodosa and L.E. phenomenon have occurred.

occurred.

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

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

Dosage and Administration

PEDIAZOLE SHOULD NOT BE ADMINISTERED TO INFANTS UNDER 2 MONTHS OF AGE BECAUSE OF CONTRAINDICA-TIONS OF SYSTEMIC SULFONAMIDES IN THIS AGE GROUP.

For Acute Othis Media in Children: The dose of Pediazole can be calculated based on the erythromycin component (50 mg/kg/day) or the sullisovazole component (150 mg/kg/day) to a maximum of 6 g/day). Pediazole should be administered in equally divided doses four times a day for 10 days. It may be administered without regard to four times a day for 10 days.

The following approximate dosage schedule is recommended for using Pediazole:

Children: Two months of age or older.

Weight	Dose—every 6 hours
Less than 8 kg (less than 18 lb) 8 kg (18 lb) 16 kg (35 lb) 24 kg (53 lb) Over 45 kg (over 100 lb)	Adjust dosage by body weight 1/2 teaspoonful (2.5 ml) 1 teaspoonful (5 ml) 11/2 teaspoonfuls (7.5 ml) 2 teaspoonfuls (10 ml)

now supplied Pediazole Suspension is available for teaspoon dosage in 100 ml (NDC 0074-8030-13) and 200-ml (NDC 0074-8030-53) bottles, in the form of granules to be reconstituted with water. The suspension provides erythromycin ethylsuccinate equivalent to 200 mg erythromycin activity and sulfisoxazole acetyl equivalent to 600 mg sulfisoxazole per teaspoonful (5 ml).

Letters to the Editor

The Journal welcomes Letters to the Editor: if found suitable, they will be published as space allows. Letters should be typed double-spaced, should not exceed 400 words, and are subject to abridgment and other editorial changes in accordance with journal style.

Patient Mobility and Consulting Rates

To the Editor:

Dr. D.J.G. Bain's paper on patient mobility and consulting rates (J Fam Pract 12:891, 1981) addresses a pertinent issue in family practice. A mobile population certainly challenges concepts of comprehensive and continuous care.

There appears to be some bias in the study, however. The Livingston, Scotland, sample consisted of "100 consecutive families registered for the first time in a family physician's practice," while the Gainesville, Florida, sample included "50 consecutive families who had recently moved to Gainesville and who had attended the family practice center." These are not, in fact, samples of families who had recently moved; they reflect families who had moved and soon thereafter consulted a family physician. There is a substantial difference.

In Scotland, families are required to register with a general practitioner. This is done immediately if there is an illness (real or perceived) but may not be done by other families until the need arises. In the United States, families are under no obligation to register, and many who have recently moved into a new area will similarly not visit a primary care practitioner until a problem exists.

It is not entirely accurate, then, to generalize from "families who



have recently moved and consulted a family physician" to "patients new in town." Dr. Bain notes that "there are probably personality differences in adults who move house frequently as opposed to those who remain in one area for a prolonged period of time." Likewise, some differences also exist between those who move and consult and those who simply move. The latter group represents a significant demand for health care, but this is unknown, especially in this country, until visits to family physicians are made. While there may be actual differences in consulting rates between mobile and stable families, the differences seem to be overstated in this paper.

and Family Practice Medical College of Virginia Richmond, Virginia The preceding letter was referred to Dr. Bain, who responds as follows:

Russell M. Boyle, Instructor

Departments of Biostatistics

Dr. Boyle's comments on my paper are welcomed. While accepting that the two groups of families studied are not strictly comparable, I still consider that there were many similarities which support my conclusions. If I were repeating this study, I would naturally prefer to attempt to control for the variables mentioned.

> D.J.G. Bain, MB, MD Aberdeen, Scotland Continued on page 228



Tenuate Dospan®

(diethylpropion hydrochloride USP)

controlled-release

AVAILABLE ONLY ON PRESCRIPTION

Brief Summary

INDICATION: Tenuate and Tenuate Dospan are indicated in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction. The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use such as those described

below.

CONTRAINDICATIONS: Advanced arteriosclerosis, hyperthyroidism, known hypersensitivity, or idiosyncrasy to the sympathomimetic amines, glaucoma. Agitated states. Patients with a history of drug abuse. During or within 14 days following the administration of monoamine oxidase inhibitors, (hypertensive crises may result).

WARNINGS: If tolerance develops, the recommended dose should not be exceeded in an attempt to increase the effect: rather, the drug should be discontinued. Tenuate may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle, the patient should therefore be cautioned accordingly. When central nervous system active agents are used, consideration must always be given to the possibility of adverse interactions with alcohol. Drug Dependence: Tenuate has some chemical and pharmacologic similarities to the amphetamines and other related stimulant drugs that have been extensively abused. There have been reports of subjects becoming psychologically dependent on diethylpropion. The possibility of including a drug as part of a weight reduction program. Abuse of amphetamines and related drugs may be associated with varying degrees of psychologic dependence and social dysfunction which, in the case of certain drugs, may be severe. There are reports of patients who have increased the dosage to many times that recommended. Abrugt cessation follow-CONTRAINDICATIONS: Advanced arteriosclerosis, hyperthyroidism. may be severe. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity, and personalty changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia. Use in Pregnancy: Although rat and human reproductive studies have not indicated adverse effects, the use of Tenuate by women who are pregnant or may become pregnant requires that the potential risks. Use in Children: Tenuate is not recommended for use in children under 12 years of ace. vears of age

PRECAUTIONS: Caution is to be exercised in prescribing Tenuate for

pears of age.

PRECAUTIONS: Caution is to be exercised in prescribing Tenuate for patients with hypertension or with symptomatic cardiovascular disease, including arrhythmias. Tenuate should not be administered to patients with severe hyperension. Insulin requirements in diabetes mellitus may be altered in association with the use of Tenuate and the concomitant dietary regimen. Tenuate may decrease the hypotensive effect of quanethidine. The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. Reports suggest that Tenuate may increase convulsions in some epileptics. Therefore, epileptics receiving Tenuate should be carefully monitored. Titration of dose or discontinuance of Tenuate may be necessary.

ADVERSE REACTIONS: Cardiovascular: Palpitation, tachycardia, elevation of blood pressure, precordial pain, arrhythmia. One published report described T-wave changes in the ECG of a healthy young male after ingestion of diethylpropion hydrochloride. Central Nervous System: Overstimulation, nervousness, restlessness, dizziness, jitteriness, insomnia, anxiety, euphoria, depression, dysphoria, tremor, dyskinesia, mydriasis, drowsiness, malaise, headache; rarely psychotic episodes at recommended doses. In a few epileptics an increase in convulsive episodes has been reported. Gastrointestimal: Dryness of the mouth unpleasant laste, nausea, vomiting, abdominal discomfort, diarrhea, constipation, other gastrointestimal disturbances. Allergic: Urlicaria, rash, ecchymosis, erythema. Endocrine: Impotence, changes in libido, gynecomastia, menstrual upset. Hematopoietic System. Bone marrow depression, agranulocytosis, leukopenia. Miscellaneous: A variety of miscellaneous adverse reactions has been reported by hysicians. These include complaints such as dyspnea, hair loss, muscle pain, dysuria, increased sweating, and polyuria.

DOSAGE AND ADMINISTRATION: Tenuate (diethylpropion hydro-

DOSAGE AND ADMINISTRATION: Tenuate (diethylpropion hydro-

DOSAGE AND ADMINISTRATION: Tenuate (diethylpropion hydrochloride): One 25 mg, tablet three times daily, one hour before meals, and in midevening if desired to overcome night hunger. Tenuate Dospan (diethylpropion hydrochloride) controlled-release: One 75 mg, tablet daily, swallowed whole, in midmorning, Tenuate is not recommended for use in children under 12 years of age.

OVERDOSAGE: Manifestations of acute overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nause, vomiting, diarrhea, and abdominal cramps. Overdose of pharmacologically similar compounds has resulted in fatal poisoning, usually terminating in convulsions and coma. Management of acute Tenuate intoxication is largely symptomatic and includes lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Intravenous phentolamine (Regitine*) has been suggested on pharmacologic grounds for possible acute, severe hypertension, if this complicates Tenuate overdosage.

Product Information as of June, 1980

Product Information as of June, 1980

Reference: 1. Abramson R, Garg M, Cioffari A, and Rotman PA; An Evaluation of Behavioral Techniques Reinforced with an Anorectic Drug in a Double-Blind Weight Loss Study. J Clin Psych 41:234-237, 1980.

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LETTERS TO THE EDITOR

Continued from page 225

Ambulatory Blood Pressure Monitoring

To the Editor:

In their paper, "Diagnostic Use of Ambulatory Blood Pressure Monitoring in Medical Practice" (J Fam Pract 13:25, 1981), McCall and McCall have demonstrated that a device which monitors blood pressure automatically at 7.5-minute intervals is functional and that blood pressure measurements made in the course of daily life are often lower than those obtained in a physician's office. We have climbed to the top of another mountain, and yet another uncharted valley lies before us.

Armed with this new technology, we can begin to address questions like these: Are the limits of "normal" the same when home readings are counted as when all readings are taken in a health care setting? Or must a new set of "normals" be determined? What are the long-term implications of labile hypertension? Does anxiety in other life situations raise blood pressure as much as the anxiety associated with visiting a physician? What correlations are there between personality types, reactions to stress, and transient blood pressure elevations? How often and in which patients should automatic blood pressure monitoring be used? For what purposes? Here is another area where family medicine research can play a major role.

Robert D. Gillette, MD Associate Professor Department of Family Medicine University of Cincinnati Medical Center Cincinnati, Ohio

Management of Fingertip **Injuries**

To the Editor:

We read with interest the article

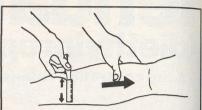


Figure 1. Cutting a graft with a knife. Note the adduction motion of the right hand

"Treatment of Fingertip Trauma" by Thomas W. Fawell (J Fam Pract 12:901, 1981). Unfortunately. a point which was not adequately emphasized is the possibility of fingertip replantation. Current reports demonstrate the experience in this

Although controversies still exist, there are many surgeons who feel that replantation may be tried when the tip is cleanly cut off, contains no bone, and is no more than 8 to 10 mm wide. 1-4

Regarding the split thickness skin grafting, the surgeon should operate from the more convenient side of the patient, cut down or up the limb, according to his position, in an adduction motion of his right hand,5,6 as shown in Figure 1, contrary to the position illustrated in the paper.

As for the donor site, it is recommended to take the skin graft from the forearm in men and, for aesthetic reasons, from the buttock in women.6 Our personal preference is to take the graft from the inner aspect of the arm, since a scar in this area is less noticeable and the skin there is thin and hairless.

A. M. Baruchin L. Rosenberg Department of Plastic Surgery Soroka University Hospital, and Faculty of Health Sciences Continued on page 230

BENADRYL® (Diphenhydramine Hydrochloride Capsules,

Before prescribing, please see full prescribing information.
A Brief Summary follows:
INDICATIONS. Benadryl in the oral form is effective for the fol-

lowing indications:
Antihistraminic: For perennial and seasonal (hay fever) allergic rhinitis; vasomotor rhinitis; allergic conjunctivitis due to inhalant allergens and foods; mild, uncomplicated allergic skin manifestations of urticaria and angioedema; amelioration of allergic reactions to blood or plasma; dermatographism; as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled.

Motion sickness: For active and prophylactic treatment of

Antiparkinsonism: For parkinsonism (including drug-induced extrapyramidal reactions) in the elderly unable to toler-ate more potent agents; mild cases of parkinsonism (including drug-induced) in other age groups; in other cases of parkin-sonism (including drug-induced) in combination with centrally

acting anticholinergic agents.

CONTRAINDICATIONS. Use in Newborn or Premature
Infants: This drug should not be used in newborn or premature

Use in Nursing Mothers: Because of the higher risk of anti-histamines for infants generally, and for newborns and prema-tures in particular, antihistamine therapy is contraindicated in

Use in Lower Respiratory Disease: Antihistamines should NOT be used to treat lower respiratory tract symptoms, including asthma.

Antihistamines are also contraindicated in the following con-

ditions: hypersensitivity to diphenhydramine hydrochloride and other antihistamines of similar chemical structure.

Monoamine oxidase inhibitor therapy (See Drug Interactions

WARNINGS. Antihistamines should be used with considerable caution in patients with narrow-angle glaucoma, stenosing pep-tic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, or bladder-neck obstruction.

Use in Children: In infants and children, especially, antihista-mines in overdosage may cause hallucinations, convulsions, or death

As in adults, antihistamines may diminish mental alertness in children. In the young child, particularly, they may produce

excitation.

Use in Pregnancy: Experience with this drug in pregnant women is inadequate to determine whether there exists a potential for harm to the developing fetus.

Use with CNS Depressants: Diphenhydramine hydrochloride has additive effects with alcohol and other CNS depressants (hypnotics; sedalives, tranquilizers, etc).

Use in Activities Requiring Mental Alertness: Patients should be warned about engaging in activities requiring mental alertness, such as driving a car or operating appliance

machinery, etc.

Use in the Elderly (approximately 60 years or older): Antihistamines are more likely to cause dizziness, sedation, and
hypotension in elderly patients.

PRECAUTIONS. Diphenhydramine hydrochloride has an
atropine-like action and, therefore, should be used with caution
in patients with a history of bronchial asthma; increased intraochistory and hypothyriddism participancy in patients. ular pressure, hyperthyroidism, cardiovascular disease, or

DRUG INTERACTIONS. MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

ADVERSE REACTIONS. The most frequent adverse reactions are underscored.

General: Urticaria, drug rash, anaphylactic shock, photo-sensitivity, excessive perspiration, chills, dryness of mouth, nose, and throat

nose, and throat

2. Cardiovascular System: Hypotension, headache, palpitations, tachycardia, extrasystoles

3. Hematologic System: Hemolytic anemia, thrombocytopenia, agranulocytosis

4. Nervous System: Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesia, blurred vision, diplopia, vertigo, tinnitus, acute labritabilis hysteria neurity sconvulsions paresthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions
5. GI System: Epigastric distress, anorexia, nausea, vomiting,
diarrhea, constipation
6. GU System: Urinary frequency, difficult urination, urinary
retention, early menses
7. Respiratory System: Thickening of bronchial secretions,
tightness of chest and wheezing, nasal stuffiness

OVERDOSAGE. Antihistamine overdosage reactions may vary

OVERDOSAGE. Antinistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Atropine-like signs and symptoms, dry mouth fixed. dilated pupils; flushing, and gastrointestinal symptoms may also occur. If vomiting has not occurred spontaneously the patient should be induced to vomit. This is best done by having him drink a glass of water or milk after which he should be made to gag. Precautions against aspiration must be taken, especially in infants and children.

If vomiting is unsuccessful gastric lavage is indicated within 3 hours after ingestion and even later if large amounts of milk or cream were given beforehand. Isotonic or 1/2 isotonic saline is

the lavage solution of choice.

Saline cathartics, as milk of magnesia, by osmosis draw water into the bowel and, therefore, are valuable for their action in rapid dilution of bowel content. Stimulants should not be used.

Vasopressors may be used to treat hypotension.

HOW SUPPLIED. Supplied in (as) 50- and 25-mg capsules, and Elixir, 12.5 mg/5 ml with 14% alcohol.

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LETTERS TO THE EDITOR

Continued from page 228

Ben Gurion University of the Negev Beer Sheba, Israel

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Stress in Family Practice

To the Editor:

Presentations such as "The Family Physician's Family" by William M. Clements and Randy Paine (J Fam Pract 13:105, 1981) deserve to be made in every family practice residency program. The importance of this topic is underlined by the statistics presented by Dr. Clements; however, several points deserve additional comment.

Divorce is an unfortunate sequel to behavioral patterns developed as a result of excessive stress. It was noted that the peak incidence of physician divorce was between the ages 35 and 45 years, with the implication being that this might be the result of stresses accompanying the "establishment of a practice." This could be multifactoral, however, with the period of residency training (and its 88-hour work week) being a significant contributor in establishing the behavior patterns in question.

Secondly, the idea of creating and effectively using free time is certainly critical, though I share the reservations of Dr. Patten and Dr. Rakel regarding the ethical and legal implications of simply making oneself unavailable. There are probably as many ways of dealing with this aspect of practice as there are practitioners. It is usually possible to arrange for some form of coverage so that "off-call" time can be enjoyed while knowing that emergencies are being competently handled.

Finally, it has not been my experience that message taking by family members or weekends "off call" have been areas of difficulty. If the day following a vacation, long weekened, or holiday is typically busy, creative scheduling (such as that explored by Dr. B. W. Spears in the same issue of this journal) may relieve the problem. Thank you for providing a forum for these ideas to be explored.

Henry R. Ivey, MD Vinton, Virginia

Alcoholism and Drug Treatment Services

To the Editor:

The recent article by Cassata and Kirkman-Liff entitled "Mental Health Activities of Family Physicians" (J Fam Pract 12:683, 1981) struck a particular nerve. As a medical librarian, I appreciate physicians' needs for "access to alcoholism and drug treatment services" because, as cited, there is "limited access to inpatient facilities."

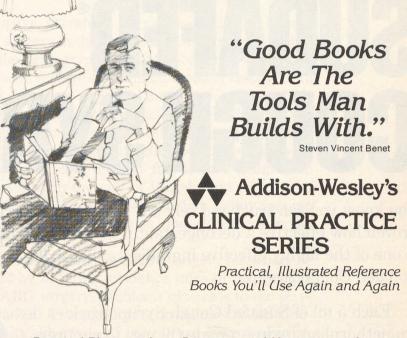
As a librarian, it was my futile search for information on such facilities that led to the establishment of Alcoholism Treatment Directories (ATD). Surveys were sent to hundreds of facilities across the country, and the responses supplied the material contained in our directories; Eastern, Western, and Central/Southern editions are now available.

Sold at cost, they give factual information on the location, admis-

sions director, insurance eligibility, patient census, and duration of program as well as a narrative description of the program offered at each listed facility. We are a shoestring enterprise; we can compile the directories, but we are limited in our efforts to get them into the hands of those who need the information they contain. We believe that the availability of such directories would be of interest to your readers. They can be

obtained on request from ATD Publications, Alcoholism Treatment Directories, West Woods Road, Sharon, CT 06069: Directory of Residential Alcoholism Treatment Centers, Eastern Edition (58 centers) \$8.00, Western Edition (49 centers) \$8.00, Central/Southern Edition (120 centers) \$12.00.

Jean Moore, Editor ATD Publications Sharon, Connecticut



- Practical Rheumatology: Diagnosis and Management, by Rodney Bluestone, M.D. \$23.95
- Diagnosis and Management of Stroke and TIA's, edited by John Stirling Meyer, M.D. and Terry Shaw, PhD. \$24.95
- Diagnosis and Management of Pulmonary Disease, by George T. Kiss, M.D. \$24.95
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