Tenuate® Ⓒ IV
(diethylpropion hydrochloride USP)
Tenuate Dospan® Ⓒ IV
(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 abuse should be kept in mind when evaluating the desirability 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. 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 benefits be weighed against the potential risks. *Use in Children:* Tenuate is not recommended for use in children under 12 years 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 hypertension. 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 guanethidine. 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. *Gastrointestinal:* Dryness of the mouth, unpleasant taste, nausea, vomiting, abdominal discomfort, diarrhea, constipation, other gastrointestinal disturbances. *Allergic:* Urticaria, 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 physicians. These include complaints such as dyspnea, hair loss, muscle pain, dysuria, increased sweating, and polyuria.
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 nausea, 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

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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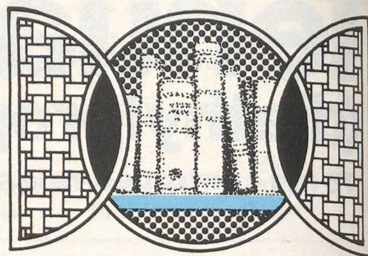
Book Reviews



Primary Care Medicine: Office Evaluation and Management of the Adult Patient. *Allan H. Goroll, Lawrence A. May, Albert G. Mulley (eds). J. B. Lippincott Company, Philadelphia, 1981, 856 pp., $37.50.*

Perusal of the introduction and table of contents of this book reveals a well organized, problem oriented approach to the adult patient and, if I had stopped reading at this point, would have produced strong advocacy for it. While one remains impressed, study of its 222 chapters does not produce the same feeling. Its favorable points may be summarized as (1) brief, pertinent consideration of discrete topics that may be read quickly for immediate application, (2) useful annotated bibliographies at the end of each chapter that cite usually available references, and (3) generally clear discussions of clinical and laboratory diagnosis. There are less favorable aspects. For example, the therapeutic recommendations reflect too many personal biases. All physicians develop bias based on experience, but when offering advice to colleagues, one must balance personal opinion with other knowledge. There is a certain unevenness to the entire text. While most chapters are arranged in a logical pattern of introduction, pathophysiologic-clinical presentation, management principles, patient education, referral, and a summation of therapy recommendations, the depth of topic consideration varies. Some may be used by the novice as nearly complete information for dealing with a specific patient problem, but many require preexistent knowledge to avoid diagnostic and management pitfalls. Several items reflect the author's local practice setting (eg, the approach and cost of screening for specific types of hypertension).

Several chapters are valuable and should be expanded. Chapter 2, concerning diagnostic tests, explains predicting usefulness and reliability of tests. Though well written, the novice would be forced to seek more information from the bibliography and from standard statistics books. Chapter 4 should be expanded and be required reading for all primary physicians. Chapter 101 on glucocorticoids should be studied and its references expanded.

In general, this book may be recommended for residents and practicing physicians in primary care. Students may find it useful as a general orientation for more detailed

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Keflex®
cephalexin

Brief Summary. Consult the package literature for prescribing information.

Indications: Keflex is indicated for the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Respiratory tract infections caused by *Streptococcus (Diplococcus) pneumoniae* and group A beta-hemolytic streptococci (Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Keflex is generally effective in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of Keflex in the subsequent prevention of rheumatic fever are not available at present.)

Note—Culture and susceptibility tests should be initiated prior to and during therapy. Renal function studies should be performed when indicated.

Contraindication: Keflex is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: BEFORE CEPHALEXIN THERAPY IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS AND PENICILLIN. CEPHALOSPORIN C DERIVATIVES SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS.

SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE EPINEPHRINE AND OTHER EMERGENCY MEASURES.

There is some clinical and laboratory evidence of partial cross-allergenicity of the penicillins and the cephalosporins. Patients have been reported to have had severe reactions (including anaphylaxis) to both drugs.

Any patient who has demonstrated some form of allergy, particularly to drugs, should receive antibiotics cautiously. No exception should be made with regard to Keflex.

Usage in Pregnancy—Safety of this product for use during pregnancy has not been established.

Precautions: Patients should be followed carefully so that any side effects or unusual manifestations of drug idiosyncrasy may be detected. If an allergic reaction to Keflex occurs, the drug should be discontinued and the patient treated with the usual agents (e.g., epinephrine or other pressor amines, antihistamines, or corticosteroids).

Prolonged use of Keflex may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs test may be due to the drug.

Keflex should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

As a result of administration of Keflex, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Adverse Reactions: *Gastrointestinal*—The most frequent side effect has been diarrhea. It was very rarely severe enough to warrant cessation of therapy. Nausea, vomiting, dyspepsia, and abdominal pain have also occurred.

As with other broad-spectrum antibiotics, colitis, including rare instances of pseudomembranous colitis, has been reported in conjunction with therapy with Keflex.

Hypersensitivity—Allergies (in the form of rash, urticaria, and angioedema) have been observed. These reactions usually subsided upon discontinuation of the drug. Anaphylaxis has also been reported.

Other reactions have included genital and anal pruritus, genital moniliasis, vaginitis and vaginal discharge, dizziness, fatigue, and headache. Eosinophilia, neutropenia, and slight elevations in SGOT and SGPT have been reported.

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Additional information available to the profession on request from Dista Products Company, Division of Eli Lilly and Company, Indianapolis, Indiana 46285.

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study of patients. It will not challenge established general textbooks but may penetrate the market for several of the nonencyclopedic texts. It reminds one of an expanded version of several well-known clinical manuals. It is bound and printed well and has been edited carefully with few misspelled words. The chapter sections on patient education are useful reminders to us to teach our patients.

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Teaching Bioethics: Strategies, Problems, and Resources. *K. Danner Clouser. The Hastings Center, Hastings-on-Hudson, New York, 1980, 77 pp., $5.00 (paper).*

Decision Making in Medicine: The Practice of Its Ethics. *Gordon Scorer, Anthony Wing (eds). Edward Arnold, London, 1979, 211 pp., price not available.*

At present there seem to be two broad approaches to the teaching of medical ethics. They can be broadly summarized as the *case oriented* approach and the *conceptual* approach. The case oriented approach seems to fit the natural pragmatic style of most physicians, focusing on the particular details of one or two cases and analyzing these to find the general ethical principles that lie behind the day-to-day problems presented by the case. The conceptual approach is one in which an attempt is made to systematically cover the ethical dimensions of day-to-day practice, focusing on such principles such as informed consent, euthanasia, or paternalism. The later approach is often presented in a general liberal arts style, being more conceptual than practical. It is more common among those who are not in day-to-day practice.

The two books reviewed here are broadly conceptual in nature. The *first* is written by a philosopher who is a professional medical ethicist and emphasizes teaching strategies, whereas the second is written and edited by and for physicians. Professor Clauser is one of the most experienced teachers in ethics in the United States, and he covers specific teaching approaches to many of the important ethical issues in medicine. His personal preference is for a Socratic style of seminar teaching. He is realistic about what can be achieved with medical students and gives a lot of sensible advice on handling issues and avoiding blind alleys in seminar management. He includes an extremely useful reference section as well as providing a bibliography that directs the reader to many sources of teaching materials, organizations, and journals specializing in bioethics. This book is highly recommended for anyone planning to teach ethics in a medical context. The style is informal, and the quality of the writing is excellent.

The *second volume* provides a very distinctive overview of modern medicine's ethical dilemmas from the viewpoint of the Judeo-Christian traditions of Western Europe. As with much medical writing from the United Kingdom, the style is pithy, terse, and clearly written. A wide variety of topics are covered, including problems arising from genetic advances, sex education, death and dying, the use and misuse of drugs, and problems in clinical psychiatry and in the physician himself. It includes excellent appendices on various codes of medical ethics, including the Hippocratic

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