

Broad-spectrum antifungal

Mycelex® (clotrimazole)

1% Cream
1% Solution

Indications: Mycelex Cream and Solution are indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, and *Microsporum canis*; candidiasis due to *Candida albicans*; and tinea versicolor due to *Malassezia furfur*.

Contraindications: Mycelex Cream and Solution are contraindicated in individuals who have shown hypersensitivity to any of their components.

Warnings: Mycelex Cream and Solution are not for ophthalmic use.

Precautions: In the first trimester of pregnancy, Mycelex should be used only when considered essential to the welfare of the patient.

If irritation or sensitivity develops with the use of Mycelex, treatment should be discontinued and appropriate therapy instituted.

Adverse Reactions: The following adverse reactions have been reported in connection with the use of this product: erythema, stinging, blistering, peeling, edema, pruritus, urticaria, and general irritation of the skin.

Dosage and Administration: Gently massage sufficient Mycelex Cream or Solution into the affected and surrounding skin areas twice a day, in the morning and evening.

Clinical improvement, with relief of pruritus, usually occurs within the first week of treatment. If a patient shows no clinical improvement after four weeks of treatment with Mycelex, the diagnosis should be reviewed.

How Supplied: Mycelex Cream 1% is supplied in 15 g and 30 g tubes, and 90 g package (2 x 45 g tube).

Mycelex Solution 1% is supplied in 10 ml and 30 ml plastic bottles.

Store between 35° and 86°F.

Manufactured by Schering Corporation, Kenilworth, NJ 07033, for Miles Pharmaceuticals, Division of Miles Laboratories, Inc.

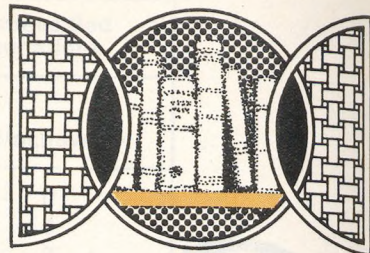
References: 1. Spiekermann PH, Young MD: Clinical evaluation of clotrimazole: A broad-spectrum antifungal agent. *Arch Dermatol* 112:350-352, 1976. 2. Duhm B, et al: The pharmacokinetics of clotrimazole ¹⁴C. *Postgrad Med J*, July suppl, 1974, pp 13-16.

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Miles Pharmaceuticals

Book Reviews



Medicine for Sport. David F. Apple, Jr, John D. Cantwell. Year Book Medical Publishers, Chicago, 1979, 241 pp., \$19.95.

Apple and Cantwell have attempted a sports medicine monograph for team physicians, trainees, health educators, and athletes. In trying to reach a diverse audience, the authors have failed to meet the needs of either health care professionals or participants in athletics.

Much of the language of the book is in medicalese that most athletes and many trainers would have difficulty comprehending; however, it is as a reference book for physicians that the monograph most clearly misses the mark. The material fails the reader in a number of categories such as: (1) the introduction of new information, (2) the organization of sports medicine data into a format that would be useful to the practicing physician, and (3) the treatment of a few subjects in depth so that the book might be considered a definitive reference for certain problems in sports medicine.

Furthermore, the authors must be criticized for producing a document that does not address important questions that are being raised by physicians concerned with the care of athletes. What is a thorough medical history and physical examination for the athlete? What are the absolute and relative contraindications to sports participation for

contact and endurance sports. What is the work-up required when evaluating a child with a heart murmur? Should all middle-aged or older individuals be stress tested if they wish to participate in endurance sports? What are the components of an exercise prescription; is it based on "target heart rate" alone? What evidence is there that warm-up before endurance exercise reduces frequency of musculo-tendon injury? Is there a place for standard blood test and urinalysis in the routine evaluation of a healthy young athlete? How does a diabetic prepare for sports events that will require major physical effort? How does a diabetic reestablish homeostasis after competition? What are the specific functional and laboratory tests that a physician should apply when evaluating an athlete for return to full participation in a sport? These and other questions remain unanswered after reading *Medicine for Sport*.

It is obvious that the authors have a large backlog of experience in sports medicine. This is most evident in their discussion of stress testing and orthopedic problems; however, I question their sensitivity to the problems that face the family physician who must facilitate a patient's decision to engage in sports activities. In a discussion on "Endurance," it is noted that "pa-

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tients with heart disease should confine rigorous activity to medically supervised classes. . . ." The family physician needs to know what is meant by "heart disease," and the patient needs a definition of "medically supervised" class.

In the section "Testing the Athlete," curiosity is piqued by a note that the Cybex isokinetic equipment can measure the ratio of the quadriceps to the hamstring. Yet, the reader is left wondering if there is a proper ratio between these two muscle groups.

In a monograph dedicated to highlighting "useful" sports medicine intervention, the section on general medical problems is an enigma. For example, an item on tracheo-bronchitis and pneumonia includes a comment that these problems ". . . are infrequently found in the athlete." Exercise induced asthma is discussed without describing the clinical manifestations for its diagnosis. Viral hepatitis, an interesting but infrequent invader of the locker room, is discussed; while the clinical management of one of the most common infectious problems of young adults, infectious mononucleosis, is barely mentioned. Renal failure due to an overdose of alcohol, heroin, or drugs finds a place in the text, but the authors do not indicate how to do a follow-up evaluation of an athlete with primary albuminuria.

The imbalance in the text is most poignant in the incomplete description of the discussion and management of head injuries. As one of the major causes of death in contact sports, this problem deserves careful treatment in any general sports medicine text. What is the natural history of an acute

subdural hemorrhage, a subarachnoid hemorrhage, or a cerebral contusion? What parameters must be tracked by the physician charged with the care of the athlete with an acute head injury?

Medicine for Sport is an effort to collate and share knowledge by two experienced physicians in sports medicine who have included in their text many useful references; however, *Medicine for Sport* appears to have some serious flaws in organization and content. It is not recommended for the student or practitioner of family medicine.

Gabriel Smilkstein, MD
University of Washington
Seattle, Washington

Pediatric Diagnosis: Interpretation of Symptoms and Signs in Different Age Periods (3rd Edition). Morris Green. W. B. Saunders Company, Philadelphia, 1980, 658 pp., \$25.00.

This text was written to fulfill a need not met by ". . . encyclopedic textbooks of pediatrics, synopses, handbooks, or the monographs on specific diseases, organ systems, and age periods." Since children present with problems characterized by signs or symptoms, or for health maintenance, this text can serve as a useful problem oriented guide to pediatrics. The author focuses on the differential diagnoses of problems by dividing the book into two parts. The first section deals with techniques useful for performing the pediatric history and examination, with problems for each organ system. Interviewing skills and examination techniques are presented with the

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V6Sol® Otic Solution

(acetic acid-nonaqueous 2%)

V6Sol® HC Otic Solution

(hydrocortisone 1%, acetic acid-nonaqueous 2%)

Description: V6Sol is a non-aqueous solution of acetic acid (2%), in a propylene glycol vehicle containing propylene glycol diacetate (3%), benzethonium chloride (0.02%), and sodium acetate (0.015%). V6Sol HC also contains hydrocortisone (1%) and citric acid (0.2%).

Action: V6Sol is antibacterial, antifungal, hydrophilic, has an acid pH and a low surface tension.

V6Sol HC is, in addition, anti-inflammatory and antipruritic.

Indications: (V6Sol only)

Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications as follows:

Effective: For the treatment of superficial infections of the external auditory canal caused by organisms susceptible to the action of the antimicrobial.

"Possibly" effective: For prophylaxis of otitis externa in swimmers and susceptible subjects.

Final classification of the less-than-effective indication requires further investigation.

Indications: (V6Sol HC only) For the treatment of superficial infections of the external auditory canal caused by organisms susceptible to the action of the antimicrobial, complicated by inflammation.

Contraindications: These products are contraindicated in those individuals who have shown hypersensitivity to any of their components; perforated tympanic membranes are frequently considered a contraindication to the use of external ear canal medication. V6Sol HC is contraindicated in vaccinia and varicella.

Precautions: V6Sol HC: As safety of topical steroids during pregnancy has not been confirmed, they should not be used for an extended period during pregnancy. Systemic side effects may occur with extensive use of steroids.

V6Sol and V6Sol HC: If sensitization or irritation occurs, medication should be discontinued promptly.

Dosage and Administration: Carefully remove all cerumen and debris to allow V6Sol (or V6Sol HC) to contact infected surfaces immediately. To promote continuous contact, insert a V6Sol (or V6Sol HC) saturated cotton wick in the ear with instructions to the patient to keep wick moist for the next 24 hours by occasionally adding a few drops on the wick. Remove wick after first 24 hours and continue to instill 5 drops of V6Sol (or V6Sol HC) three or four times daily thereafter.

During treatment, to prevent infection of the other ear, use V6Sol in unaffected ear 3 times daily. To help prevent otitis externa in swimmers and susceptible subjects, instill two drops of V6Sol each morning and evening.

How Supplied: V6Sol Otic Solution, in 15 ml (NDC 0037-3611-10) and 30 ml (NDC 0037-3611-30) measured-drop, safety-tip plastic bottles.

V6Sol HC Otic Solution, in 10 ml measured-drop, safety-tip plastic bottle (NDC 0037-3811-12).
Rev. 8/78



WALLACE LABORATORIES
Division of Carter-Wallace, Inc.
Cranbury, New Jersey 08512

Valium® diazepam/Roche

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

Indications: Management of anxiety disorders, or short-term relief of symptoms of anxiety; symptomatic relief of acute agitation, tremor, delirium tremens and hallucinosis due to acute alcohol withdrawal; adjunctively in skeletal muscle spasm due to reflex spasm to local pathology; spasticity caused by upper motor neuron disorders; athetosis; stiff-man syndrome; convulsive disorders (not for sole therapy). The effectiveness of Valium (diazepam/Roche) in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.

Contraindicated: Known hypersensitivity to the drug. Children under 6 months of age. Acute narrow angle glaucoma; may be used in patients with open angle glaucoma who are receiving appropriate therapy.

Warnings: Not of value in psychotic patients. Caution against hazardous occupations requiring complete mental alertness. When used adjunctively in convulsive disorders, possibility of increase in frequency and/or severity of grand mal seizures may require increased dosage of standard anticonvulsant medication; abrupt withdrawal may be associated with temporary increase in frequency and/or severity of seizures. Advise against simultaneous ingestion of alcohol and other CNS depressants. Withdrawal symptoms similar to those with barbiturates and alcohol have been observed with abrupt discontinuation, usually limited to extended use and excessive doses. Infrequently, milder withdrawal symptoms have been reported following abrupt discontinuation of benzodiazepines after continuous use, generally at higher therapeutic levels, for at least several months. After extended therapy, gradually taper dosage. Keep addiction-prone individuals under careful surveillance because of their predisposition to habituation and dependence.

Usage in Pregnancy: Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Precautions: If combined with other psychotropics or anticonvulsants, consider carefully pharmacology of agents employed; drugs such as phenothiazines, narcotics, barbiturates, MAO inhibitors and other anti-depressants may potentiate its action. Usual precautions indicated in patients severely depressed, or with latent depression, or with suicidal tendencies. Observe usual precautions in impaired renal or hepatic function. Limit dosage to smallest effective amount in elderly and debilitated to preclude ataxia or oversedation.

Side Effects: Drowsiness, confusion, diplopia, hypotension, changes in libido, nausea, fatigue, depression, dysarthria, jaundice, skin rash, ataxia, constipation, headache, incontinence, changes in salivation, slurred speech, tremor, vertigo, urinary retention, blurred vision. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances, stimulation have been reported; should these occur, discontinue drug. Isolated reports of neutropenia, jaundice; periodic blood counts and liver function tests advisable during long-term therapy.

Dosage: Individualize for maximum beneficial effect. **Adults:** Anxiety disorders, symptoms of anxiety, 2 to 10 mg b.i.d. to q.i.d.; alcoholism, 10 mg t.i.d. or q.i.d. in first 24 hours, then 5 mg t.i.d. or q.i.d. as needed; adjunctively in skeletal muscle spasm, 2 to 10 mg t.i.d. or q.i.d.; adjunctively in convulsive disorders, 2 to 10 mg b.i.d. to q.i.d. **Geriatric or debilitated patients:** 2 to 2½ mg, 1 or 2 times daily initially, increasing as needed and tolerated. (See Precautions.) **Children:** 1 to 2½ mg t.i.d. or q.i.d. initially, increasing as needed and tolerated (not for use under 6 months).

Supplied: Valium® (diazepam/Roche) Tablets, 2 mg, 5 mg and 10 mg—bottles of 100 and 500; Tel-E-Dose® packages of 100, available in trays of 4 reverse-numbered boxes of 25, and in boxes containing 10 strips of 10; Prescription Paks of 50, available in trays of 10.



Roche Laboratories
Division of Hoffmann-La Roche Inc.
Nutley, New Jersey 07110

BOOK REVIEWS

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skill of an experienced clinician and seasoned with practical advice for the beginner.

Part 2 emphasizes general signs and symptoms that do not fit nicely into any organ system. The more common problems, such as fever and abdominal pain, are covered, along with some of the more unusual ones, such as dysphagia, sleep disorder, noisy breathing, and unusual body or urine odors.

Since the focus of the book is on the differential diagnosis of problems, little or no information on evaluation and therapy is presented. Although these limitations allow the author to cover a vast subject area within a minimum of space, each section seems incomplete, and needs to be coupled with a more traditional text for a full understanding. However, the differential diagnosis of each problem is so thoroughly covered that most health care providers will be hard-pressed to discover a significant omission. Whereas the first section of the book presents information valuable to the novice, the second part will stimulate the experienced clinician.

Important references are included in the body of the text under the appropriate problem; this system allows the reader to easily pursue a particular topic. Although the appendix contains a few growth charts that are readily available from other sources, the index more than makes up for this deficiency. It alone comprises 60 pages of key terms that allow immediate location of almost any problem in the text.

Given the limitations of a book that focuses on the differential diagnosis and excludes treatment,

Pediatric Diagnosis is a useful and extremely relevant text to add to a working library.

James E. Crutcher, MD
University of California, Davis
Sacramento, California

ICHPPC-2: International Classification of Health Problems in Primary Care (2nd Edition). World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONCA). Oxford University Press, New York, 1979, 146 pp., \$16.95 (cloth) \$7.95 (paper).

The publication of ICHPPC-2 is a landmark event since it establishes official World Health Organization recognition of a classification designed by and for primary care physicians. It has practical significance beyond its modest size of 362 rubrics since it is closely aligned with ICD-9. Its simplicity allows it to be readily mastered by relatively untrained staff in a physician's office, and the modest price makes it an offer that cannot be turned down.

In countries with a fee-for-service system where diagnostic coding is necessary for third party reimbursement it may be necessary to make some changes in the arbitrarily selected ICHPPC-2 codes for a given ICD-9 rubric.

For example, the ICHPPC-2 code selected for "Syphilis All Sites and Stages" is 090-. This particular code in ICD-9 refers to "Congenital Syphilis" and a better choice in ambulatory care would be "Early Syphilis, Symptomatic," which has been assigned code 091

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Indications: This is not an innocuous drug. Strict attention should be paid to the indications and contraindications.

CHOLOXIN (dextrothyroxine sodium) is used for the reduction of elevated serum cholesterol (low density lipoproteins) in euthyroid patients with no known evidence of organic heart disease.

It has not been established whether the drug-induced lowering of serum cholesterol or lipid levels has a detrimental, beneficial, or no effect on the mortality or mortality due to atherosclerosis or coronary heart disease. Several years will be required before current investigations will yield an answer to this question.

Contraindications: The administration of CHOLOXIN (dextrothyroxine sodium) to euthyroid patients with one or more of the following conditions is contraindicated:

1. Known organic heart disease, including angina pectoris; history of myocardial infarction; cardiac arrhythmia or tachycardia, either active or in patients with demonstrated propensity for arrhythmias; rheumatic heart disease; history of congestive heart failure; and decompensated or borderline compensated cardiac status.
2. Hypertensive states (other than mild, labile systolic hypertension)
3. Advanced liver or kidney disease
4. Pregnancy
5. Nursing mothers
6. History of iodism

Warnings

Drugs with thyroid hormone activity, alone or together with other therapeutic agents, have been used for the treatment of obesity. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

CHOLOXIN (dextrothyroxine sodium) may potentiate the effects of anticoagulants on prothrombin time; the dosage of anticoagulants should be reduced up to one-third upon initiation of CHOLOXIN (dextrothyroxine sodium) therapy and readjusted on the basis of prothrombin time. The prothrombin time should be observed at least weekly during the first few weeks of treatment, thereafter as frequently as necessary.

Consider withdrawal of the drug two weeks prior to surgery if the use of anticoagulants during surgery is contemplated. Withdrawal prior to surgery is also advisable since the possibility of precipitating cardiac arrhythmias during surgery is greatest in patients treated with thyroid hormones.

CHOLOXIN (dextrothyroxine sodium) may increase blood sugar levels in diabetic patients, requiring an upward adjustment of antidiabetic drug dosage and subsequent readjustment if the drug is later withdrawn.

Precautions: If signs or symptoms of iodism develop during CHOLOXIN (dextrothyroxine sodium) therapy, the drug should be discontinued.

A few children with familial hypercholesterolemia have been treated with CHOLOXIN (dextrothyroxine sodium) for periods of one year or longer with no adverse effects on growth; it is recommended that the drug be continued only if a significant serum cholesterol-lowering effect is observed.

The 2 mg and 6 mg tablets of CHOLOXIN (dextrothyroxine sodium) contain FD & C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD & C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

Adverse Reactions: The side effects attributed to dextrothyroxine sodium therapy are, for the most part, due to increased metabolism, and may be minimized by following the recommended dosage schedule.

In the absence of known organic heart disease, some cardiac changes may be precipitated during dextrothyroxine sodium therapy. In addition to angina pectoris, arrhythmia consisting of extrasystoles, ectopic beats, or supraventricular tachycardia, ECG evidence of ischemic myocardial changes and increase in heart size have been observed. Myocardial infarctions, both fatal and non-fatal, have occurred, but these are not unexpected in untreated patients in the age groups studied. It is not known whether any of these infarcts were drug related.

Changes in clinical status that may be related to the metabolic action of the drug include the development of headache, dizziness, peripheral edema, malaise, tiredness, visual disturbances, psychic changes, paresis, muscle pain, and various bizarre subjective complaints. Skin rashes, including a few which appeared to be due to iodism, and itching have been attributed to dextrothyroxine sodium by some investigators. Gallstones have been discovered in occasional dextrothyroxine-treated patients and cholestatic jaundice has occurred in one patient, although its relationship to CHOLOXIN (dextrothyroxine sodium) therapy was not established.

In several instances, the previously existing conditions of the patient appeared to continue or progress during the administration of CHOLOXIN (dextrothyroxine sodium); a worsening of peripheral vascular disease, sensorium, exophthalmos and retinopathy have been reported.

Dosage and Administration: For adult euthyroid hypercholesterolemic patients, the recommended maintenance dose of CHOLOXIN (dextrothyroxine sodium) is 4 to 8 mg per day. The initial daily dose should be 1 to 2 mg and be increased in 1 to 2 mg increments at intervals of not less than one month to a maximal level of 4 to 8 mg daily, if that dosage level is indicated to effect the desired lowering of serum cholesterol.

For pediatric hypercholesterolemic patients, the recommended maintenance dose of CHOLOXIN (dextrothyroxine sodium) is approximately 0.1 mg (100 mcg) per kilogram. The initial daily dosage should be approximately 0.05 mg (50 mcg) per kilogram to be increased in up to 0.05 mg (50 mcg) per kilogram increments at monthly intervals. The recommended maximal dose is 4 mg daily, if that dosage is indicated to effect the desired lowering of serum cholesterol.

If new signs or symptoms of cardiac disease develop during the treatment period, the drug should be withdrawn.

How Supplied: CHOLOXIN (dextrothyroxine sodium) is supplied in prescription packages of scored 1, 2, 4 and 6 mg tablets.

References:

1. Data on file at Flint Laboratories.

 **FLINT LABORATORIES**
DIVISION OF TRAVENOL LABORATORIES, INC.
Deerfield, Illinois 60015

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in ICD-9. In the majority of cases however, the ICHPPC-2 code will be acceptable uncritically to third party payers.

The text is well laid out but a slightly larger typesetting would be appreciated by this reviewer. Anyone involved in ambulatory medical care will find this classification a welcome, useful, and appropriate tool for practice management and research.

Ronald Schneeweiss, MD
University of Washington
Seattle, Washington

Basic Biostatistics in Medicine and Epidemiology. *Alfred A. Rimm, Arthur J. Hartz, John H. Kalbfleisch, Alfred J. Anderson, Raymond G. Hoffman. Appleton-Century-Crofts, New York, 1980, 353 pp., \$16.50 (paper).*

The family physician must critically evaluate new medical information and integrate it into the everyday care of patients. A fundamental understanding of biostatistics is essential to this intelligent translation of the results of medical and epidemiologic research into practice. This book helps the physician gain that understanding and acquire the maturity of judgment that is as important in evaluating the research paper as it is in evaluating the acutely ill patient.

The authors develop concepts keyed to the design, reading, and evaluation of scientific studies: sampling methods, descriptive statistics, the normal distribution, and hypothesis testing. Statistical techniques—both parametric and non-parametric—that are commonly

used in medical studies are clearly described, mathematically summarized, and illustrated by relevant examples. For each topic discussed, actual examples of published studies are cited. The appendix provides a helpful collection of tables, including all the material needed to use each of the techniques presented in the text. The authors show skill in using figures and tables and in avoiding mathematical notation. The emphasis is on the clear and concrete understanding of a few central concepts rather than upon the derivation of statistical formulae.

Ample discussion is devoted to experimental design, preparation of study protocols, questionnaire design, and sources of routinely collected statistical data. The cornerstones of epidemiologic methods are covered with discussion of rates, ratios, standardization techniques, and measures of strength of association. Correlation, regression, and survival curve methods are described in brief but helpful terms.

The book is designed to be used as a course text in concert with lectures and discussions. In this setting the instructor can fill in the gaps in content and the unevenness of style that result from the book's multi-author approach to such an expansive topic. This book reads well enough to satisfy the solitary student and summarizes the statistical methods clearly enough to serve later as a reference cookbook. In-depth study of statistics, experimental design, or epidemiology would require supplemental texts, but this basic presentation can serve as a core in mastering the fundamentals of the critical, quantitative study of medical research.

William R. Phillips, MD, MPH
University of Washington
Seattle, Washington