

# ACTIFED-C<sup>®</sup>

## EXPECTORANT <sup>Ⓢ</sup>

**INDICATIONS:** 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:

"Lacking substantial evidence of effectiveness as a fixed combination." For the symptomatic relief of cough in conditions such as: the common cold, acute bronchitis, allergic asthma, bronchitis, croup, emphysema, tracheobronchitis.  
Final classification of the less-than-effective indications requires further investigation.

### CONTRAINDICATIONS:

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

**Use in Nursing Mothers:** Because of the higher risk of antihistamines, codeine and sympathomimetic amines for infants generally and for newborn and premature in particular, Actifed-C Expectorant therapy is contraindicated in nursing mothers.

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

Actifed-C Expectorant is also contraindicated in the following conditions:

Hypersensitivity to: 1) triprolidine hydrochloride and other antihistamines of similar chemical structure; 2) sympathomimetic amines including pseudoephedrine; and/or 3) any of the other ingredients.

Monoamine oxidase inhibitor therapy (see Drug Interactions Section).

**WARNINGS:** Actifed-C Expectorant should be used with considerable caution in patients with:

Increased intraocular pressure (Narrow angle glaucoma)	Hypertension
Stenosing peptic ulcer	Diabetes mellitus
Pyloroduodenal obstruction	Ischemic heart disease
Symptomatic prostatic hypertrophy	Hyperthyroidism
Bladder neck obstruction	

Sympathomimetics may produce central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension.

Codeine can produce drug dependence of the morphine type, and therefore has the potential of being abused.

**Use in Children:** As in adults, the combination of an antihistamine and sympathomimetic amine can elicit either mild stimulation or mild sedation in children.

While it is difficult to predict the result of an *overdosage* of a combination of triprolidine, pseudoephedrine, and codeine the following is known about the individual components:

In infants and children especially, antihistamine in overdosage may cause hallucination, convulsion or death. Large doses of pseudoephedrine are known to cause weakness, lightheadedness, nausea and/or vomiting. An overdosage of codeine may cause CNS depression with muscular twitching and convulsion, weakness, disturbed vision, dyspnea, respiratory depression, collapse and coma.

**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:** Triprolidine and codeine phosphate have additive effects with alcohol and other CNS depressants (hypnotics, sedatives, 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 appliances, machinery, etc.

**Use in the Elderly (approximately 60 years or older):** Antihistamines are more likely to cause dizziness, sedation and hypotension in elderly patients. Overdosages of sympathomimetics in this age group may cause hallucinations, convulsions, CNS depression, and death.

**PRECAUTIONS:** Actifed-C Expectorant should be used with caution in patients with: history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease, hypertension.

**DRUG INTERACTIONS:** MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines and overall effects of sympathomimetics. Sympathomimetics may reduce the antihypertensive effects of methyl dopa, decamylamine, reserpine, and veratrum alkaloids.


The CNS depressant effect of triprolidine hydrochloride and codeine phosphate may be additive with that of other CNS depressants.

### ADVERSE REACTIONS:

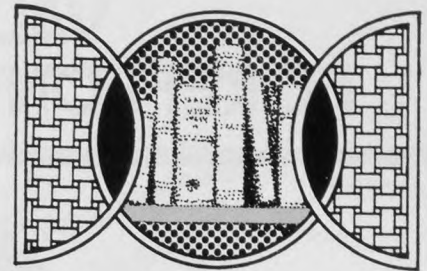
- 1. General:** Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and throat.
- 2. Cardiovascular System:** Hypotension, headache, palpitations, tachycardia, extrasystoles.
- 3. Hematologic System:** Hemolytic anemia, thrombocytopenia, agranulocytosis.
- 4. Nervous System:** Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesias, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions, CNS depression, hallucination.
- 5. G.I. System:** Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
- 6. G.U. System:** Urinary frequency, difficult urination, urinary retention, early menses.
- 7. Respiratory System:** Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

**NOTE:** Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

**HOW SUPPLIED:** Bottles of 1 pint, 1 gallon and 4 oz Unit of Use Bottle with Child Resistant Cap.

 **Burroughs Wellcome Co.**  
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## Book Reviews



**Medicine.** *Mark C. Fishman, Andrew R. Hoffman, Richard D. Klausner, Stanley G. Rockson, Malcolm S. Thaler. J. B. Lippincott, Philadelphia, 1981, 500 pp., \$19.75 (paper).*

I believe this book satisfies its objective of providing a condensed textbook on medicine, covering the diseases and problems commonly seen in family practice. I particularly like the reference to the underlying pathophysiology in many instances which helps the reader constructively think of his patient's problems. It amounts to a quick reference which would be used by both the resident and active family physician in practice.

It is very easily read and the organization is good. The illustrations and x-rays are appropriate and I believe that it would best serve the practicing physician as well as a resident. I am not sure if it is appropriate for a medical student because it assumes a certain amount of knowledge.

Since I have had the book in my possession I have personally referred to it and received some pertinent information, and it was helpful to me in patient care.

*G.S. Mitchell, Jr, MD*  
*Newport News, Virginia*

**Diagnosis and Management of Diabetes Mellitus: A Clinical Manual for Medical Students, Residents and Primary Care Physicians.** *O. Charles Olson. Lea & Febiger, Philadelphia, 1981, 294 pp, \$19.00 (paper).*

This is a solid medical text and one which is quite practical for the clinician. The strength of the book is the enthusiastic, personal, and humanitarian tone that seems to personify Olson's approach to medicine. While an abundance of "textbook knowledge" is certainly presented, an equal emphasis on the art of medicine is quite refreshing. Patient education, honesty, and the personal touch are repeatedly underscored.

The medical data are clearly presented for easy reading. Controversy is usually acknowledged as such, and various schools of thought are discussed. If there is a criticism of the text, it is the relatively few references cited, particularly when figures and percentages are used. While Olson makes it clear throughout the text that most of the information is founded on his 30 years of diabetology practice, occasionally the anecdotal style leaves some uncertainty in the reader's mind. Overall, this is a

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# VALIUM®

(diazepam/Roche)

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**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. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic. 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 as sole therapy).

The effectiveness of Valium 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 antidepressants 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.

The clearance of Valium and certain other benzodiazepines can be delayed in association with Tagamet (cimetidine) administration. The clinical significance of this is unclear.

**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).

**How Supplied:** For oral administration, Valium scored tablets—2 mg, white; 5 mg, yellow; 10 mg, blue—bottles of 100\* and 500;\* Prescription Paks of 50, available in trays of 10.\* Tel-E-Dose® packages of 100, available in trays of 4 reverse-numbered boxes of 25\* and in boxes containing 10 strips of 10.\*

\*Supplied by Roche Products Inc., Manati, Puerto Rico 00701

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

- References:** 1. Tallman JF et al: *Science* 207:274-281, Jan 18, 1980. 2. Bunney WE Jr: *Psychiatr Ann* 11:11-15, Jan 1981. 3. Davis JM et al: *J Clin Psychiatry* 42(11) Sec 2:4-14, Nov 1981. 4. Study RE, Barker JL: *JAMA* 247: 2147-2151, Apr 16, 1982. 5. Braestrup C, Nielsen M, Olsen CE: *Proc Natl Acad Sci USA* 77:2288-2292, Apr 1980. 6. Bosmann HB, Case KR, DiStefano P: *FEBS Lett* 82:368-372, Oct 1977. 7. Braestrup C, Albrechtsen R, Squires RF: *Nature* 269:702-704, Oct 20, 1977. 8. Snyder SH: *Psychosomatics* 22:986-989, Nov 1981. 9. Rickels K: *J Clin Psychiatry* 42(11) Sec 2:40-44, Nov 1981. 10. Haefely WE: *Br J Psychiatry* 133:231-238, Sep 1978.

minor problem easily compensated for by the information presented, the clarity of presentation, and the enthusiasm of the author.

The chapters "Management of the Older Diabetic Patient," "Exercise," "Surgery," and "Home Blood Glucose Monitoring" are particularly good, insightful, and probably worth the price of the text.

An excellent chapter on obesity and its myriad of therapeutic challenges is presented pragmatically as well as theoretically. The chapters entitled "Substitute Sweeteners," "Etiology and Genetics of Diabetes Mellitus," and the "University Group Diabetes Program (UGDP) Study" present a variety of information critical to the family physician not well synthesized elsewhere.

In summary this is a very fine text with a well-structured, clear format. The author's enthusiasm, caring, and touch of humor are bonuses. As an office manual on diabetes mellitus, it belongs in every family physician's library.

James B. Tucker, MD  
Upstate Medical Center  
Syracuse, New York

**Family Medicine and Supportive Interventions: An Epidemiological Approach.** Berton H. Kaplan, Michel A. Ibrahim (eds). *Institute for Research in Social Science, University of North Carolina, Chapel Hill, North Carolina, 1981, 71 pp, \$4.00 (paper).*

This book contains four papers delivered at a 1977 symposium, "Family and Health." The purpose of the symposium was to address "the relationship of family process

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**Keflex®**  
cephalexin

**Brief Summary. Consult the package literature for prescribing information.**

**Indications and Usage:** 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.)

Otitis media due to *S. pneumoniae*, *Haemophilus influenzae*, staphylococci, streptococci, and *Neisseria catarrhalis*

Skin and skin-structure infections caused by staphylococci and/or streptococci

Bone infections caused by staphylococci and/or *Proteus mirabilis*

Genitourinary tract infections, including acute prostatitis, caused by

*Escherichia coli*, *P. mirabilis*, and *Klebsiella* sp.

**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.

SEVERE 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.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

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

**Precautions: General 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 Rehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

**Usage in Pregnancy—Pregnancy Category B**—The daily oral administration of cephalexin to rats in doses of 250 or 500 mg/kg prior to and during pregnancy, or to rats and mice during the period of organogenesis only had no adverse effect on fertility, fetal viability, fetal weight, or litter size. Note that the safety of cephalexin during pregnancy in humans has not been established.

Cephalexin showed no enhanced toxicity in weanling and newborn rats as compared with adult animals. Nevertheless, because the studies in humans cannot rule out the possibility of harm, Keflex should be used during pregnancy only if clearly needed.

**Nursing Mothers**—The excretion of cephalexin in the milk increased up to four hours after a 500-mg dose; the drug reached a maximum level of 4 mcg/ml, then decreased gradually, and had disappeared eight hours after administration. Caution should be exercised when Keflex is administered to a nursing woman.

**Adverse Reactions: Gastrointestinal**—Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. The most frequent side effect has been diarrhea. It was very rarely severe enough to warrant cessation of therapy. Dyspepsia and abdominal pain have also occurred.

**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. Coenophilia, neutropenia, and slight elevations in SGOT and SGPT have been reported.

Additional information available to the profession on request from [060882]

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to health and social support and coping." Two contributors, Ian McWhinney and Jack Medalie, hold impressive family medicine credentials, but neither their writings nor those of the other symposium members seem to address the purpose of the symposium in a cohesive manner.

It was a joy to read McWhinney's scholarly treatment of how physicians accrue knowledge ("objective information and subjective understanding") that pertains to a family's social and behavioral history. McWhinney's honesty is refreshing: "Our (family physician's) information about patients and their families is at best fragmentary. In perhaps 10 percent of families it approaches what we might call completeness." In addition McWhinney notes, "treating the family as the patient—like many ideas transferred from other disciplines—has limited application to family practice."

Of the book's authors, Medalie comes closest to revealing the issues that must be addressed to clarify family health. Not only does he list presenting problems that may be considered cues for family study, but he also outlines strategies for assessment and intervention. Medalie's schema is not, however, utilitarian, but should serve as a springboard for future studies.

The chapter "Adaptation and Health: A Life-Span Perspective" by David and Beatrix Hamburg offers a general model for coping that is worth examining. There is, however, little explanation of how the practitioner can use general coping theory in dealing with problems of family dysfunction seen in the clinic or office. The reader will

nevertheless gain an improved understanding of coping strategies by reviewing the ways in which the Hamburgs examine how adolescents and middle-year adults deal with crises.

The final chapter on assertiveness training for adolescents seems to be a "filler." It lacks a sense of belonging to the book's theme. Granted, adolescents do have families, but the role of families in assertiveness training is never made clear.

This book may be of interest to a limited number of researchers in family studies. The lack of cohesiveness in the chapters leads this reader to the impression that not all symposia should be edited into books.

Gabriel Smilkstein, MD  
University of Washington  
Seattle

**Pediatric Drug Handbook.** William E. Benitz, David S. Tatro. Year Book Medical Publishers, Chicago, 1981, 475 pp, price not available.

This is an excellent book for quick reference on pediatric drug dosages, indications, availability, administration, and toxic side effects. It is well-indexed and divided into chapters based on organ system as well as according to therapeutic indication. The index contains generic as well as brand name drugs for easy cross-referencing. There is also a very good review at the beginning of the book on antidotes for particular problems. The book would have been enhanced by adding treatments for drug overdoses with each drug that is discussed. Despite that oversight, it is an extremely handy book for office practice as well as for residency programs or students.

Linda Stewart, MD  
Baton Rouge, Louisiana