

ACTIFED-C[®] EXPECTORANT C[®]

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.

Monamine 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 hypertension.

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 *overdose* of a combination of triprolidine, pseudoephedrine, and codeine the following is known about the individual components:

In infants and children especially, antihistamine in overdose may cause hallucination, convulsion or death. Large doses of pseudoephedrine are known to cause weakness, lightheadedness, nausea and/or vomiting. An overdose 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. Overdoses 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.

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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.

Content of Family Practice

To the Editor:

I began to read the study, "The Structure and Content of Family Practice: Current Status and Future Trends" (Rosenblatt RA, Cherkin DC, Schneeweiss R, et al. *J Fam Pract* 15:681, 1982), with enthusiasm, but was shocked when I read the list of diagnostic categories used. It was a long string of predominantly medical complaints. Categories such as situational stress reactions were absent, as was any mention of family or psychosocial problems, except for the single cluster "depression/anxiety."

Where was the feel and texture of what I do every day? I wondered. Where was the flavor of family practice, the sense of the constantly shifting communication between patient and physician, the drama of "treating the whole person," or even (forgive the expression) "the family in family medicine"? Why did the study seem so neat and well organized, when my own daily practice felt so chaotic?

My consternation peaked when I re-examined the diagnostic cluster of "depression/anxiety." Its incidence was 2.9 percent. Of course, the figure was somewhat higher for residency-trained physicians, but still . . .

Epidemiologists have reported the prevalence of psychiatric disorder as anywhere from 50 to 80 percent among medical outpatients¹; and Goldstein et al² report that 64 percent of patients in three

family practice settings perceive one or more areas of psychosocial concern in their families, while close to 50 percent had concerns about themselves. Carmichael and Carmichael³ have written that perhaps 80 percent of family practice falls into the "relational model," which is concerned not with the "cure or control of disease, but rather with the attention, support, and comfort the patient receives."

My own experience suggests that many patients' medical problems have a psychosocial core, which strongly affects their meaning and presentation. The presenting problem often screens a pressing psychosocial concern ("Why have you come to the physician now, at this point in your life?"), a notion that has been understood for generations and to which Balint referred in discussing the "deeper" diagnosis.⁴

Why is this missing from the "landmark" University of Washington study?

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References

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3. Carmichael LP, Carmichael JS: The relational model in family practice. *Marr Fam Rev* 4:123, 1981
4. Balint M: *The Doctor, His Patient and the Illness*. New York, International Universities Press, 1957