

# ACTIFED-C<sup>®</sup> EXPECTORANT C<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<br>(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 methyldopa, 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:** Guafenesin 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.

### Outcomes of Birthing Rooms To the Editor:

The paper by Petravage<sup>1</sup> is an important contribution to the literature on alternative birth. Our recently completed study<sup>2</sup> and survey<sup>3</sup> demonstrates that birthing rooms fall into two broad categories: those that allow all procedures except cesarean section (generally community hospitals with low transfer rates) and those that permit no major procedures (generally tertiary centers with high transfer rates). Presenting transfer rate by parity would help the reader understand the functioning of the birthing room, as would data on women excluded prior to birthing room use.

The use of mean Apgar score can be misleading. Since Apgar scores are always skewed toward the high end of the scale, important information on poor outcomes is easily buried. It is useful to have Apgar scores presented as above or below certain clinically significant levels, and this is generally reported as  $\leq 6$  or 7. The 5-minute Apgar score, coupled with data on admissions specifically because of asphyxia, is more to the point.

The author draws attention to the development of unforeseen complications that make proximity to a traditional obstetrical unit

necessary. This interpretation is dependent on the rules of operation of the birthing room, the quality of staff providing intrapartum care, and proximity of care to obstetrical backup. For example, while Table 5 lists fetal bradycardia, late decelerations, cesarean section, and meconium staining among the reasons for transfer, it is not necessarily true that even these indications can be used to justify the statement that birthing rooms should be in proximity to obstetrical suites. We are given no information about the relationship of these complications to interventions that may have been contributory, such as epidural anesthesia, oxytocin stimulation, the lithotomy position, and the absence of ambulation. No data were given on the time required for transfer or the real urgency of the conditions listed, without which it is not possible to judge the appropriateness of the author's observation about optimal location of birthing rooms. It is always possible that what might seem ideal from the point of view of proximity (and even given rare real emergencies like cord prolapse), perinatal gains through proximity to an operating room may be balanced by iatrogenic losses.<sup>4,5</sup>

Lest I seem too critical, let me assure the author that her survey in

fact represents the state of the art. It is likely that much of the information that I have requested will not have been available because of inadequate record-keeping.<sup>3</sup> If we are to improve the quality of the data, it will be necessary to keep separate birthing room logs that will list major and minor procedures—emphasizing that the birthing room is not just another delivery room.

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#### References

1. Petravage JB: Outcomes of three birthing rooms. *J Fam Pract* 16:929, 1983
2. Klein M, Papageorgiou AN, Westreich R, et al: A randomized controlled trial of medical/psychological outcomes in a birth room vs conventional labour and delivery. Presented at the meeting of the Society for Pediatric Research, Washington, DC, May 1982
3. Klein M, Westreich R: Birth room transfer and procedure rates—What do they tell about the setting? *Birth* 10:93, 1983
4. Klein M, Lloyd I, Redman C, et al: A comparison of low-risk pregnant women booked for delivery in two systems of care: Shared-care (consultant) and integrated general practice unit: 1. Obstetrical procedures and neonatal outcome. *Br J Obstet Gynaecol* 90:118, 1983
5. Klein M, Lloyd I, Redman C, et al: A comparison of low-risk pregnant women booked for delivery in two systems of care: Shared-care (consultant) and integrated general practice unit. 2. Labour and delivery management and neonatal outcome. *Br J Obstet Gynaecol* 90:123, 1983

### Use of Mini-Wright Peak Flow Meter

To the Editor:

Having used the Mini-Wright Peak Flow Meter for several years in England, I would like to reinforce its usefulness as described by Dr. David Katz (*Katz DN: The*

*Mini-Wright peak flow meter for evaluating airway obstruction in a family practice. J Fam Pract* 17:51, 1983).

I have found four other uses for the meter.

1. *Compliance.* One of the advantages of the Mini-Wright Peak Flow Meter is the rapidity of the test. I offer it to every asthmatic patient on each visit. Asthmatics, like patients with other chronic or relapsing conditions, often find difficulty in complying with preventive treatment such as sodium cromoglycate or beclomethasone, particularly teenagers. We have found that encouraging patients to buy their own mini peak flow meter or lending them one gives them a greater sense of control of their own asthma and greater autonomy, which seems to lead to better compliance and fewer relapses.

2. *Chronic obstructive airway disease.* The meter can also be used to assess the reversible aspects of COAD.

3. *Beta-blockers.* Even cardioselective beta-blockers can precipitate asthma in a susceptible person. The history is our most useful screening test before prescribing these drugs, but a quick measurement of the peak expiratory flow rate (PEFR) is an added safeguard.

4. *Smoking and health education.* The PEFR is lowered in most smokers and the Mini-Wright Peak Flow Meter can be used to demonstrate this and thus help in health education. We know that fear is a poor motivator and cancer by the age of 50 years seems a long way off to most young people. A demonstration that they are not fit and healthy now can be a powerful incentive to stop smoking.

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(Continued from adjacent page)

**Nursing Mothers:** Captopril is secreted in human milk. Exercise caution when administering captopril to a nursing woman, and, in general, nursing should be interrupted.

**Pediatric Use:** Safety and effectiveness in children have not been established although there is limited experience with use of captopril in children from 2 months to 15 years of age. Dosage, on a weight basis, was comparable to that used in adults. Captopril should be used in children only if other measures for controlling blood pressure have not been effective.

**ADVERSE REACTIONS:** Reported incidences are based on clinical trials involving about 4000 patients.

**Renal—**One to 2 of 100 patients developed proteinuria (see WARNINGS). Renal insufficiency, renal failure, polyuria, oliguria, and urinary frequency in 1 to 2 of 1000 patients.

**Hematologic—**Neutropenia/agranulocytosis occurred in about 0.3% of captopril treated patients (see WARNINGS). Two of these patients developed sepsis and died.

**Dermatologic—**Rash (usually mild, maculopapular, rarely urticarial), often with pruritus and sometimes with fever and eosinophilia, in about 10 of 100 patients, usually during the 1st 4 weeks of therapy. Pruritus, without rash, in about 2 of 100 patients. A reversible associated pemphigoid-like lesion, and photosensitivity have also been reported. Angioedema of the face, mucous membranes of the mouth, or of the extremities in about 1 of 100 patients—reversible on discontinuance of captopril therapy. One case of laryngeal edema reported. Flushing or pallor in 2 to 5 of 1000 patients.

**Cardiovascular—**Hypotension in about 2 of 100 patients. See WARNINGS (Hypotension) and PRECAUTIONS (Drug Interactions) for discussion of hypotension on initiation of captopril therapy. Tachycardia, chest pain, and palpitations each in about 1 of 100 patients. Angina pectoris, myocardial infarction, Raynaud's syndrome, and congestive heart failure each in 2 to 3 of 1000 patients.

**Dysgeusia—**About 7 of 100 patients developed a diminution or loss of taste perception; taste impairment is reversible and usually self-limited even with continued drug use (2 to 3 months). Gastric irritation, abdominal pain, nausea, vomiting, diarrhea, anorexia, constipation, aphthous ulcers, peptic ulcer, dizziness, headache, malaise, fatigue, insomnia, dry mouth, dyspnea, and paresthesias reported in about 0.5 to 2% of patients but did not appear at increased frequency compared to placebo or other treatments used in controlled trials.

**Altered Laboratory Findings:** Elevations of liver enzymes in a few patients although no causal relationship has been established. Rarely cholestatic jaundice and hepatocellular injury with secondary cholestasis have been reported. A transient elevation of BUN and serum creatinine may occur, especially in volume-depleted or renovascular hypertensive patients. In instances of rapid reduction of longstanding or severely elevated blood pressure, the glomerular filtration rate may decrease transiently, also resulting in transient rises in serum creatinine and BUN. Small increases in serum potassium concentration frequently occur, especially in patients with renal impairment (see PRECAUTIONS).

**OVERDOSAGE:** Primary concern in correction of hypotension. Volume expansion with an I.V. infusion of normal saline is the treatment of choice for restoration of blood pressure. Captopril may be removed from the general circulation by hemodialysis.

**DOSAGE AND ADMINISTRATION:** CAPOTEN should be taken one hour before meals. Dosage must be individualized; see DOSAGE AND ADMINISTRATION section of package insert for detailed information regarding dosage in hypertension and in heart failure. Because CAPOTEN (captopril) is excreted primarily by the kidneys, dosage adjustments are recommended for patients with impaired renal function. **Consult package insert before prescribing CAPOTEN (captopril).**

**HOW SUPPLIED:** Available in tablets of 25, 50, and 100 mg in bottles of 100, and in UNIMATIC® unit-dose packs of 100 tablets.



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