

# Actifed\* Expectorant

To the Medical and Pharmaceutical Professions

## Presentation

Each 5ml contains 1.25mg Triprolidine Hydrochloride BP, 30mg Pseudoephedrine Hydrochloride BP and 100mg Guaiphenesin BP in a clear orange-coloured, spicy, lemon-flavoured oral solution.

## Indications

**Actifed\* Expectorant** is indicated for the symptomatic relief of upper respiratory tract disorders accompanied by productive cough which are benefited by a combination of a histamine H1-receptor antagonist, a nasal decongestant and an expectorant.

## Dosage and Administration

**Adults and children over 12 years:** 10ml three times daily.

**Children from 6-12 years:** 5ml three times daily.

A physician's advice should be obtained before administering **Actifed\* Expectorant** to children aged less than 6 years.

## The elderly

There have been no specific studies of **Actifed\* Expectorant** in the elderly.

Experience has indicated that normal adult dosage is appropriate, although it may be advisable to monitor renal and/or hepatic function; if there is serious impairment then caution should be exercised.

## Contra-indications

**Actifed\* Expectorant** is contra-indicated in individuals with known hypersensitivity to the product, any of its excipients, or acrivastine.

**Actifed\* Expectorant** is contra-indicated in individuals with severe hypertension or severe coronary artery disease. **Actifed\* Expectorant** is contra-indicated in individuals with severe hepatic impairment.

**Actifed\* Expectorant** is contra-indicated in patients who are taking, or have taken, monoamine oxidase inhibitors (including the antibacterial agent furazolidone) within the preceding two weeks.

The concomitant use of pseudoephedrine and this type of product may occasionally cause a rise in blood pressure.

**Actifed\* Expectorant** must not be used for persistent or chronic cough, such as occurs with smoking, asthma or emphysema, or where cough is accompanied by excessive secretions.

## Precautions/Warnings

Although pseudoephedrine has virtually no pressor effects in normotensive patients, **Actifed\* Expectorant** should be used with caution in patients suffering mild to moderate hypertension. As with other sympathomimetic agents, **Actifed\* Expectorant** should be used with caution in patients with heart disease, diabetes, hyperthyroidism, elevated intra-ocular pressure or prostatic enlargement.

Caution should be exercised when using the product in the presence of mild to moderate hepatic insufficiency or moderate to severe renal insufficiency, particularly if accompanied by cardiovascular disease.

Although there are no objective data, users of **Actifed\* Expectorant** should avoid the concomitant use of alcohol and other centrally acting sedatives.

**Actifed\* Expectorant** may cause drowsiness.

## Effects on Ability to Drive and Use Machines

**Actifed\* Expectorant** may cause drowsiness and impair performance in tests of auditory vigilance. There is individual variation in response to antihistamines.

Since adverse events such as drowsiness have been reported in patients taking triprolidine

hydrochloride, patients should exercise caution before driving, using machinery or participating in dangerous activities until they are reasonably certain that **Actifed\* Expectorant** does not adversely affect performance.

## Use in Pregnancy and Lactation

### Pregnancy

For **Actifed\* Expectorant** no clinical data on exposed pregnancies are available. Animal studies with pseudoephedrine and triprolidine do not indicate direct or indirect harmful effects on embryofetal development. There is insufficient information available to determine the effects of guaiphenesin.

Caution should be exercised when prescribing to pregnant women.

### Lactation

Pseudoephedrine and triprolidine are excreted in breast milk in small amounts but the effect of this on breast-fed infants is not known. Guaiphenesin is excreted in breast milk in small amounts with no effect expected on the infant.

The use of **Actifed\* Expectorant** in nursing mothers is not recommended unless the expected benefit to the mother is greater than any possible risk to the infant.

### Fertility

There is no information on the effect of **Actifed\* Expectorant** on human fertility.

Studies in rats have shown no effects of pseudoephedrine on fertility. Extensive clinical usage has not identified any risks to fertility associated with the use of triprolidine under the recommended therapeutic dosage regimens. There is insufficient information available to determine whether guaiphenesin has the potential to impair fertility.

### Mutagenicity

Pseudoephedrine is not genotoxic in a battery of in vivo and in vitro tests in bacterial and mammalian assay systems.

There is insufficient information available to determine whether triprolidine or guaiphenesin have genotoxic potential.

### Carcinogenicity

Triprolidine was not carcinogenic in assays performed in mice and rats.

There is insufficient information available to determine whether pseudoephedrine or guaiphenesin have carcinogenic potential.

### Teratogenicity

Pseudoephedrine did not produce teratogenic effects at oral doses of up to 432 mg/kg/day in the rat, or 200 mg/kg/day in the rabbit.

Triprolidine did not produce teratogenic effects at oral doses of up to 125 mg/kg/day in the rat, or 100 mg/kg/day in the rabbit.

### Drug interactions

Although there are no objective data, users of **Actifed\* Expectorant** should avoid the concomitant use of alcohol or other centrally acting sedatives.

Concomitant use of **Actifed\* Expectorant** with tricyclic antidepressants, sympathomimetic agents (such as decongestants, appetite suppressants and amphetamine-like psychostimulants), or with monoamine oxidase inhibitors (including furazolidone), which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure.

Because of its pseudoephedrine content, **Actifed\* Expectorant** may partially reverse the hypotensive action of drugs which interfere with sympathetic activity including bethyridine, guanethidine, debrisoquine, methyldopa, alpha- and beta-adrenergic blocking agents. If urine is collected within 24 hours of a dose of **Actifed\* Expectorant**, a metabolite of guaiphenesin may cause a colour interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

## Adverse effects

### Pseudoephedrine

Symptoms of central nervous system excitation may occur, including sleep disturbance and rarely, hallucinations. Skin rashes, with or without irritation, have occasionally been reported with pseudoephedrine. Urinary retention has been reported occasionally in men receiving pseudoephedrine; prostatic enlargement could have been an important predisposing factor.

### Triprolidine

Triprolidine may cause drowsiness. Skin rashes, with or without irritation, have occasionally been reported. Dryness of the mouth, nose and throat may occur & tachycardia.

### Guaiphenesin

Gastrointestinal discomfort has occasionally been reported with guaiphenesin.

## Toxicity and treatment of over dosage

### Symptoms and signs

In addition to the undesirable effects seen with recommended doses, lethargy, dizziness, ataxia, weakness, hypotonicity, respiratory depression, dryness of the skin and mucous membranes, hyperpyrexia, hyperactivity, tremor, convulsions, irritability, restlessness, nausea, vomiting, palpitations and hypertension, may be seen following acute overdosage with **Actifed\* Expectorant**.

### Treatment

Necessary measures should be taken to maintain and support respiration and control convulsions. Gastric lavage may be performed if indicated. Catheterisation of the bladder may be necessary. Acid diuresis can accelerate the elimination of pseudoephedrine, although the potential therapeutic gain of this procedure is now in dispute. The value of dialysis in overdose is not known, although four hours of haemodialysis removed approximately 20% of the total body load pseudoephedrine in a combination product containing 60 mg pseudoephedrine + 8 mg acrivastine.

## Pharmaceutic Precautions

Store below 25°C, (do not refrigerate). Protect from light.

## Dilution

**Actifed\* Expectorant** may be diluted to half-strength or quarter-strength with unpreserved Syrup BP. The dilution should be stored at 25°C and used within 28 days.

## THIS IS A MEDICAMENT


- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

### Keep medicament out of reach of children

Council of Arab Health Ministers  
Union of Arab Pharmacists

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