Actifed* Expectorant

Wellcome

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 H_1-receptor antagonist, a nasal decongestant and an expectorant.

Dosage and Administration
Adults and children over 12 years
10ml three times daily.

Children under 12 years

6 – 12 years:	5ml three times daily.
2 – 5 years:	2.5ml three times daily.
6 months – under 2 years:	1.25ml three times daily†.

†A physician's advice should be obtained before administering Actifed Expectorant to children aged less than 2 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, Warnings, etc
Contra-indications
Actifed Expectorant is contra-indicated in individuals who have previously exhibited intolerance to it or to any of its constituents.
Actifed Expectorant is contra-indicated in patients with severe hypertension or severe coronary artery disease.
Actifed Expectorant is contra-indicated in patients who are taking or have taken monoamine oxidase inhibitors within the preceding 2 weeks. The concomitant use of pseudoephedrine and this type of product may occasionally cause a rise in blood pressure.
The antibacterial agent furazolidone is known to cause a dose-related inhibition of monoamine oxidase. Although there are no reports of hypertensive crises caused by the concurrent administration of Actifed Expectorant and furazolidone, they should not be taken together.

Precautions
Actifed Expectorant may cause drowsiness and impair performance in tests of auditory vigilance. Patients should not drive or operate machinery until they have determined their own response.
Although there are no objective data, users of Actifed Expectorant should avoid the concomitant use of alcohol or other centrally acting sedatives.
Although pseudoephedrine has virtually no pressor effects in normotensive patients, Actifed Expectorant should be used with caution in patients taking antihypertensive agents, tricyclic antidepressants or other sympathomimetic agents such as decongestants, appetite suppressants and amphetamine-like psychostimulants. The effects of a single dose on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment.
As with other sympathomimetic agents, Actifed Expectorant should be used with caution in patients with hypertension, heart disease, diabetes, hyperthyroidism, elevated intra-ocular pressure and prostatic enlargement.
There have been no specific studies of Actifed Expectorant in patients with hepatic and/or renal dysfunction. Caution should be exercised in the presence of severe renal or hepatic impairment.
Actifed Expectorant should not be used for persistent or chronic cough such as occurs with smoking, asthma or emphysema or where cough is accompanied by excessive secretions, unless directed by a physician.

Mutagenicity and carcinogenicity
There is insufficient information available to determine whether triprolidine, pseudoephedrine or guaiphenesin have mutagenic or carcinogenic potential.

Teratogenicity
In rats and rabbits, systemic administration of triprolidine up to 75 times the human daily dosage did not produce teratogenic effects.
Systemic administration of pseudoephedrine, up to 50 times the human daily dosage in rats and up to 35 times the human daily dosage in rabbits, did not produce teratogenic effects.
There is no information available to determine whether or not guaiphenesin has teratogenic potential.

Fertility
No studies have been conducted in animals to determine whether triprolidine or guaiphenesin have potential to impair fertility. Systemic administration of pseudoephedrine in rats, up to 7 times the human daily dosage in females and 35 times the human daily dosage in males, did not impair fertility nor alter foetal morphological development and survival. There is no information on the effect of **Actifed Expectorant** on human fertility.

Drug interactions
Concomitant use of **Actifed Expectorant** with sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants, or with monoamine oxidase inhibitors which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure (see Contra-indications and Precautions).
Because of its pseudoephedrine content, **Actifed Expectorant** may partially reverse the hypotensive action of drugs which interfere with sympathetic activity, including bretylium, bethanidine, guanethidine, debrisoquine, methyldopa and alpha- and beta-adrenergic blocking agents (see Precautions).

Side and adverse effects
Central nervous system depression or excitation may occur, drowsiness being reported most frequently. Sleep disturbance and, rarely, hallucinations have been reported.
Skin rashes, with or without irritation, tachycardia and dryness of the mouth, nose and throat, have occasionally been reported. Urinary retention has been reported occasionally in men receiving pseudoephedrine; prostatic enlargement could have been an important predisposing factor.

Use in pregnancy and lactation
Although pseudoephedrine, triprolidine and guaiphenesin have been in widespread use for many years without apparent ill-consequence, there are no specific data on their use during pregnancy. Caution should therefore be exercised by balancing the potential benefit of treatment to the mother against any possible hazards to the developing foetus.
Pseudoephedrine and triprolidine are excreted in breast milk in small amounts but the effect of this on breast-fed infants is not known. It has been estimated that 0.5–0.7% of a single dose of pseudoephedrine ingested by a mother will be excreted in the breast milk over 24 hours.
Guaiphenesin is excreted in breast milk in small quantities wiith no effect expected on the infant.

Toxicity and treatment of overdosage
The effects of acute toxicity from **Actifed Expectorant** may include drowsiness, lethargy, dizziness, ataxia, weakness, hypotonicity, respiratory depression, dryness of the skin and mucous membranes, tachycardia, hypertension, hyperpyrexia, hyperactivity, irritability, convulsions, difficulty with micturition, gastro-intestinal discomfort, nausea and vomiting.
Necessary measures should be taken to maintain and support respiration and control convulsions. Gastric lavage should be performed up to 3 hours after ingestion if indicated. Catheterisation of the bladder may be necessary. If desired, the elimination of pseudoephedrine can be accelerated by acid diuresis or by dialysis.

Pharmaceutical Precautions
Store below 25°C, do not refrigerate and 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.

Further Information
Mode of action
Triprolidine provides symptomatic relief in conditions believed to depend wholly or partly upon the triggered release of histamine. It is a potent competitive histamine H_1-receptor antagonist of the pyrrolidine class with mild central nervous system depressant properties which may cause drowsiness.
Pseudoephedrine has a direct and indirect sympathomimetic activity and is an effective upper respiratory tract decongestant. Pseudoephedrine is substantially less potent than ephedrine in producing both tachycardia and elevation of systolic blood pressure, and considerably less potent in causing stimulation of the central nervous system.
Guaiphenesin has an expectorant action. It is thought to reduce sputum viscosity by increasing the volume and water content of the bronchial secretions, thereby facilitating the expectoration of sputum.