1/5168 (E/F)

Actifed* Tablets and Syrup

Wellcome

To the Medical and Pharmaceutical Professions

Presentation

Tablets: Each white, round, biconvex, scored tablet (coded WELLCOME and M2A) contains 2.5mg Triprolidine Hydrochloride BP and 60mg Pseudoephedrine Hydrochloride BP.
Syrup: Each 5ml contains 1.25mg Triprolidine Hydrochloride BP and 30mg Pseudoephedrine Hydrochloride BP in a clear yellow, pleasantly-flavoured oral solution.

Indications

Actifed* is indicated for the symptomatic relief of upper respiratory tract disorders which are benefited by a combination of a histamine H_1-receptor antagonist and a nasal decongestant. These include allergic rhinitis, vasomoter rhinitis, the common cold and influenza.

Dosage and Administration

Adults and children over 12 years
One tablet or 10ml syrup three times daily.

Children under 12 years

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

†A physician's advice should be obtained before administering **Actifed** to children aged less than 2 years.

The elderly

There have been no specific studies of **Actifed** 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 is contra-indicated in individuals who have previously exhibited intolerance to it or to any of its constituents.
Actifed is contra-indicated in patients with severe hypertension or severe coronary artery disease.
Actifed 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** and furazolidone, they should not be taken together.

Precautions

Actifed 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** should avoid the concomitant use of alcohol or other centrally acting sedatives.
Although pseudoephedrine has virtually no pressor effects in normotensive patients, **Actifed** 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** 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** in patients with hepatic and/or renal dysfunction. Caution should be exercised in the presence of severe renal or hepatic impairment.

Mutagenicity and carcinogenicity

There is insufficient information available to determine whether triprolidine or pseudoephedrine 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.

Fertility

No studies have been conducted in animals to determine if triprolidine has 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** on human fertility.

Drug interactions

Concomitant use of **Actifed** with other 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 contents, **Actifed** 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 and triprolidine have been in widespread use for many years without apparent ill-consequence, there are no specific data on their use du pregnancy. Caution should therefore be exercised by balancing the potential bene treatment to the mother against any possible hazards to the developing foetus.
Pseudoephedrine and triprolidine are excreted in breast milk in small amounts but effect of this on breast-fed infants is not known. It has been estimated that approximately 0.5–0.7% of a single dose of pseudoephedrine ingested by a moth will be excreted in the breast milk over 24 hours.

Toxicity and treatment of overdosage

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

Pharmaceutical Precautions

Tablets: Store below 25°C in a dry place and protect from light.
Syrup: Store below 25°C and protect from light.

Dilution

Actifed Syrup may be diluted to half-strength or quarter-strength with unpreserv 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 partly upon the triggered release of histamine. It is a potent competitive histami H_1-receptor antagonist of the pyrrolidine class with mild central nervous system depressant properties which may cause drowsiness.
Pseudoephedrine has direct and indirect sympathomimetic activity and is an effe upper respiratory tract decongestant. Pseudoephedrine is substantially less pote than ephedrine in producing both tachycardia and elevation of systolic blood pre and considerably less potent in causing stimulation of the central nervous syste