ACTICOL SYRUP

COMPOSITION:

Each 5 ml contains: 1.25 mg Triprolidine Hydrochloride
30.00 mg Pseudoephedrine Hydrochloride

Preservative : Methylparaben 7.50 mg / 5 ml

DESCRIPTION:

A clear yellow colour syrup with raspberry odour.

INDICATIONS:

Acticol Syrup is indicated for the symptomatic relief of upper respiratory tract disorders which are benefited by a combination of a histamine H1-receptor antagonist and a decongestant of the mucous membranes of the upper respiratory tract, especially the nasal mucosa and sinuses, such as:

- Allergic rhinitis
- Vasomotor rhinitis
- The common cold and influenza

PHARMACODYNAMICS:

Pseudoephedrine is an orally effective upper respiratory tract decongestant. It acts on alpha-adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction. It shrinks swollen nasal mucous membrane; reduces tissue hyperemia, edema and nasal congestion; and increases nasal airway potency. Pseudoephedrine produces its decongestant effects within 30 minutes, persisting for at least 4 hours.
Triprolidine is an antihistamine (H_1-receptor). It acts by competing with histamine for H_1-receptor sites on effector cells. Triprolidine provides symptomatic relief in conditions believed to depend wholly, or partly, upon the triggered release of histamine. The onset of action after oral administration of a single dose of 2.5mg triprolidine to adults was within 1 to 2 hours, as determined by the ability to antagonize histamine-induced weals and flares in the skin. Peak effects occurred at about 3 hours, and although activity declined thereafter, significant inhibition of histamine-induced weals and flares still occurred 8 hours after a single dose.

PHARMACOKINETICS:

Following oral administration, pseudoephedrine and triprolidine are well absorbed from the gut.
After administration of 2.5mg triprolidine and 60mg pseudoephedrine, the following values were obtained:

Pharmacokinetic	Pseudoephedrine	Triprolidine
C_{max}	180 ng/ml	6.0 ng/ml
T_{max}	1.5 hours	1.5 hours

Apparent volume of distribution (Vol/F)	2.8 L/kg	7.5 L/kg
Plasma half life (t_{12})	5.5 hours	3.2 hours
Apparent total body clearance (Cl/F)	7.5 ml/min/kg	30-37 ml/min/kg
Elimination rate (K_{el})	0.13 hr^{-1}	0.26 hr^{-1}

Metabolism and elimination
Pseudoephedrine is partly metabolized in the liver by N-demethylation to norpseudoephedrine, an active metabolite which is excreted in the urine. 55% to 90% of a dose is excreted unchanged.
Triprolidine: Animal hepatic microsomal enzyme studies have revealed the presence of several triprolidine metabolites with an oxidized product of the toluene methyl group predominating. In man it is reported that only about 1% of an administered dose is eliminated as unchanged triprolidine.

CONTRAINDICATIONS:

Acticol Syrup is contraindicated in

- Individuals with known hypersensitivity to the product, any of the excipients, or acrivastine.
- Patients with severe hypertension or severe coronary artery disease.
- Individuals with severe hepatic impairment
- Patients who are taking or have taken monoamine oxidase inhibitors (including the antibacterial agent furazolidone) within the preceding two weeks. This concomitant use of pseudoephedrine and this type of product could occasionally cause a rise in blood pressure.

DRUG INTERACTIONS:

Concomitant use of Acticol Syrup 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.
Acticol syrup may partially reverse the hypotensive action of drugs which interfere with sympathetic activity including bretylium, bethanidine, guanethidine, debrisoquine, methyldopa, alpha- and beta-adrenergic blocking agents because of its pseudoephedrine content.
Concomitant use of alcohol or other centrally acting sedatives should also be avoided although there are no objective data.

WARNING:

Not suitable to be used in children below 2 years old.
For children between 2 to 6 years old – use with caution and follow the advice given by the doctor or pharmacist.

PRECAUTIONS:

Acticol Syrup 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.
A warning to users against the concomitant use of alcohol or other centrally acting sedatives and Acticol Syrup is prudent.
As with other sympathomimetic agents and decongestants Acticol Syrup should be used with caution in patients with heart disease, diabetes, hyperthyroidism, elevated intra-ocular pressure or prostatic enlargement.
Acticol Syrup should be used with caution in patients suffering mild to moderate hypertension, although pseudoephedrine has virtually no pressor effects in normotensive patients.
Caution should be exercised when using the product in the presence of mild to moderate hepatic impairment or moderate to severe renal impairment, particularly if accompanied by cardiovascular disease.

PREGNANCY AND LACTATION:

No data is available on the use of Acticol Syrup during human pregnancy. Caution should be exercised when prescribing to pregnant women.
Pseudoephedrine and triprolidine are excreted in breast-milk in small amounts but the effect of this on breast fed infants is not known. The use of Acticol Syrup in nursing mothers is not recommended unless the expected benefit to the mother is greater than any possible risk to the infant.

ADVERSE REACTIONS:

Pseudoephedrine may cause symptoms of central nervous system excitation, including sleep disturbance and rarely hallucinations. Skin rashes, with or without irritation, have occasionally have reported with pseudoephedrine. Urinary retention may occasionally occur in male subjects where prostatic enlargement is present.
Triprolidine may cause drowsiness. Skin rashes, with or without irritation, have occasionally been reported. Dryness of the mouth, nose and throat may occur. Tachycardia.

DOSAGE AND ADMINISTRATION:

Dosage for adults and children over 12 years:
10ml 3 times daily
Children under 12 years:
6 – 12 years : 5 ml 3 times daily.
2 – 5 years : 2.5 ml 3 times daily.

Acticol Syrup may be diluted with Syrup B.P.

The elderly
Normal adult dosage is appropriate

Hepatic impairment
Caution should be exercised when administering Acticol Syrup to patients with severe hepatic impairment.

Renal Impairment
Patients with moderate to severe renal impairment, particularly if accompanied by cardiovascular disease should exercise caution when administering Acticol Syrup.

ROUTE OF ADMINISTRATION:
Oral administration

OVERDOSAGE:

The effects of acute toxicity from Acticol Syrup may include lethargy, dizziness, ataxia, weakness, hypotonicity, respiratory depression, dryness of the skin and mucous membranes, hyperpyrexia, hyperactivity, tremor, irritability, convulsions, hypertension, palpitations and restlessness.
Necessary measures should be taken to maintain and support respiration and controlled 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 4 hours of hemodialysis removed approximately 20% of the total body load of pseudoephedrine in a combination product containing 60 mg pseudoephedrine + 8 mg acrivastine.

STORAGE CONDITIONS:
Store below 30°C
Keep container tightly closed.
Protect from light.
Keep out of reach of children.
Jauhi dari kanak-kanak.

PRESENTATION
Bottles of 120 ml and 60ml.

MANUFACTURED BY:
NORIPHARMA SDN. BHD. 200701034604 (792633-A)
Lot 5030, Jalan Teratai,
5 ½ Mile Off Jalan Meru,
41050 Klang,
Selangor Darul Ehsan.

Date of revision
May 2023