

ACTIHIST

VIACT09-var (MY)3

DESCRIPTION

Actihist Syrup

Yellow transparent liquid with plum flavour.

Actihist Tablet

Round, white uncoated tablet with shallow convex faces, scored and "HD" embossed on the same face.

COMPOSITION

Actihist Syrup: Each 5 ml contains:

Triprolidine Hydrochloride	1.25 mg
Pseudoephedrine Hydrochloride	30.00 mg

Actihist Tablet: Each tablet contains:

Triprolidine Hydrochloride	2.50 mg
Pseudoephedrine Hydrochloride	60.00 mg

PHARMACODYNAMICS

Pseudoephedrine is a sympathomimetic agent. It is used as a bronchodilator and peripheral vasoconstrictor in preparations for the relief of nasal and bronchial congestion. It has a stimulant action on the respiratory center. It acts on alpha-adrenergic receptors in the mucosa of the respiratory tract.

Triprolidine is an antihistamine. It is an antagonist of the H₁ receptor effects of histamine. It acts by competing with histamine for H₁ receptor sites on effector cells. It diminishes or abolishes most of the actions of histamine mediated by the H₁ receptors. The action of histamine most readily affected is that on the involuntary muscle of the intestines, bladder, uterus and bronchioles.

The antimuscarinic actions of Triprolidine provide a drying effects on the nasal mucosa.

PHARMACOKINETICS

Absorption: Well absorbed from the gastrointestinal tract.

Metabolic Reactions: Both Pseudoephedrine and Triprolidine are metabolized in the liver.

Excretion: Undergoes renal excretion. Pseudoephedrine is largely excreted unchanged in the urine together with small amounts of its hepatic metabolite while Triprolidine is mainly excreted as metabolites in the urine. Both Pseudoephedrine and Triprolidine are also excreted in breast milk.

INDICATIONS

This medication is used for the symptomatic relief of nasal and sinus congestion associated with common cold and allergic rhinitis.

CONTRAINDICATIONS

This medication should not be given to premature infants or neonates, patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics and patients with hyperthyroidism, cardiovascular disease or acute attacks of asthma. It should not be used concurrently with monoamine oxidase inhibitors.

WARNINGS AND PRECAUTIONS

- This medication should be used with caution in hypersensitive patients and in geriatrics. It should be carefully considered when the following medical problems exist: Diabetes mellitus, close-angle glaucoma, hypertension, peptic ulcer and renal function impairment.
- Not to be used in children less than 2 years of age.
- To be used with caution and doctor's / pharmacist's advice in children 2 to 6 years of age.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

Actihist 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.

PREGNANCY AND LACTATION

Safety for use in nursing mother has not been established.

DRUG INTERACTIONS

Concurrent use with the following drugs is not recommended: Beta-adrenergic blocking agents, digitalis glycosides, guanethidine, methyl dopa, alcohol, CNS depressants, tricyclic antidepressants, antimuscarinics and ototoxic medications.

MAIN SIDE/ADVERSE EFFECTS

Drowsiness, insomnia, urinary retention, nausea, vomiting and allergic reactions.

OVERDOSE AND TREATMENT

Clinical features: Headache, nausea, vomiting, dryness of the mouth, tachycardia, respiratory depression, coma.

Treatment for overdose: Emesis or gastric lavage, followed by activated charcoal, with supportive and symptomatic measure if necessary.

Adrenaline and physostigmine are contraindicated.

DOSAGE AND ADMINISTRATION

Actihist Syrup

Adults

Oral, 10 ml three times a day as needed.

Paediatrics

2 to 6 years of age: Oral, 2.5 ml three times a day as needed.
6 to 12 years of age: Oral, 5 ml three times a day as needed.

Note:

Geriatric patients may be more sensitive to the effects of the usual adult dose. This medication may be taken with food, water or milk to minimize stomach irritation.

Storage: Store below 30°C. Protect from light and freezing.
Presentation/Packing: Syrup x 60 ml, 100 ml, 120ml, 3.6 Litres
(*Not all presentation available locally*).

Actihist Tablet

Adults

Oral, 1 tablet three times a day as needed.

Paediatrics

Below 6 years of age: Not recommended.
6 - 12 years of age: Oral 1/2 tablet three times a day as needed.

Storage: Store below 30°C. Protect from light and moisture.

Presentation/Packing:
Tablet bottle of 100's, 250's, 1000's (for export only).
Tablet blisters of 10 x 10's.

Note: Geriatric patients may be more sensitive to the effects of the usual adult dose.

This medication may be taken with food, water or milk to minimize stomach irritation.

The information given here is limited. For further information, consult your doctor or pharmacist.

Actihist Syrup

Product Registration Holder / Manufactured by: HOVID Bhd.
121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.

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Lot 56442, 7 1/2 Miles, Jalan Ipoh / Chemor,
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