

Olopatadine Hydrochloride USP

COMPOSITION

Alercon™ : Each ml contains Olopatadine Hydrochloride USP equivalent to Olopatadine 1 mg.

Alercon™ DS : Each ml contains Olopatadine Hydrochloride USP equivalent to Olopatadine 2 mg.

PHARMACOLOGY

Alercon™ (Olopatadine Hydrochloride) is a sterile eye drops, a relatively selective H₁-receptor antagonist.

INDICATIONS

Alercon™ (Olopatadine Hydrochloride) Eye Drops is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

DOSAGE AND ADMINISTRATION

Route of administration :

Alercon™ : The recommended dose is 1-2 drops in each affected eye two times per day. Maximum duration of treatment is four months.

Alercon™ DS : The recommended dose is one drop in each affected eye once daily.

CONTRAINDICATION

Alercon™ Eye Drops is contraindicated in patients with hypersensitivity to Olopatadine or any other component of the preparation.

PRECAUTION

Alercon™ (Olopatadine Hydrochloride) eye drops is for topical use only and not for injection or oral use.

- Patients should be advised not to wear contact lens if their eye is red.
- **Alercon™** (Olopatadine Hydrochloride) eye drops should not be used to treat contact lens related irritation.
- Patients who wear soft contact lenses and whose eyes are not red should be instructed to wait at least ten minutes after instilling **Alercon™** (Olopatadine Hydrochloride) eye drops before they insert their contact lenses.

SIDE EFFECTS

Local irritation; less commonly keratitis, dry eye, local oedema, photophobia, headache, asthenia, dizziness; dry nose are reported.

USE IN PREGNANCY & LACTATION

Pregnancy : Pregnancy category C.

Lactation : Caution should be exercised when Olopatadine Hydrochloride eye drops is administered to a nursing mother.

USE IN CHILDREN & ADOLESCENTS

Safety and effectiveness in paediatric patients below the age of 3 years have not been established.

STORAGE

Store below 30° C, protected from light & moisture.

Keep all medicines out of reach of children.

PACKING

Alercon™ : Each plastic dropper bottle contains 5 ml sterile eye drops.

Alercon™ DS : Each plastic dropper bottle contains 5 ml sterile eye drops.

* Further information is available on request.



Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness

07 1194/02

Olopatadine Hydrochloride USP

Composition

Alercon™ 5 Tablet: Each film-coated tablet contains Olopatadine Hydrochloride USP 5 mg.

Pharmacology

Olopatadine Hydrochloride is a dual acting anti-allergic medication. It works primarily by blocking histamine H-1 receptors and stabilizing mast cells, thereby inhibiting the production and release of various chemicals (including leukotrienes, thromboxanes, platelet activating factor). It also blocks neurotransmitters called tachykinins, which significantly reduces allergy symptoms (such as sneezing, runny nose, itching).

Indications

Olopatadine is highly effective for three primary symptoms (sneezing, nasal discharge & nasal congestion) of allergic rhinitis and urticaria. It is also indicated for itching resulting from skin diseases (eczema/dermatitis, prurigo, pruritus cutaneous, psoriasis vulgaris, multiform exudative erythema).

Dosage & Administration

Route of administration : Oral.

For children 7 years or older: 1 tablet (5 mg) at a time, twice daily.

For adults: 1 tablet (5 mg) at a time, twice daily. The dosage may be adjusted according to the disease, age or symptoms.

If the dose is missed in the morning & noticed until noon, it should be taken as soon as possible. If it is noticed late in the day, it should be skipped & the next scheduled dose should be taken.

Contraindications

It is contraindicated in persons with a known hypersensitivity to any component of this product.

Warning & Precautions

Olopatadine Hydrochloride should be administered with care in patients with impaired renal function & patients with hepatic dysfunction. Since it may induce drowsiness, patients should be cautioned against engaging in potentially hazardous activities requiring alertness such as operating machinery or driving a car. In case it is administered in the patients who have been under chronic treatment with steroids, dose reduction of the steroid should be made gradually under careful supervision.

Side Effects

Common Side Effects: Headache, dizziness, loss of appetite and dry mouth.

Rare Side Effects: Itching, numbness, constipation and heartburn.

Use in Pregnancy & Lactation

Pregnancy : Olopatadine Hydrochloride should be used in pregnant women or in women who may possibly be pregnant considering the risk-benefit ratio. Safety of the administration during pregnancy has not been established.

Lactation : Lactating women should not be given Olopatadine Hydrochloride. If treatment with this drug is essential, breast feeding must be discontinued during treatment.

Use in Children and Adolescents

The safety of Olopatadine Hydrochloride in newborns, infants or children has not been established.

Use in Geriatrics

Since elderly patients often have reduced physiological function and are more likely to develop adverse reactions, Olopatadine Hydrochloride should be administered cautiously by starting at a low dose while monitoring the patient's condition.

Drug Interactions

Specific drug interaction studies have not been conducted with Olopatadine Hydrochloride tablet.

Overdose

No case of overdose has been reported.

Storage

Store below 30° C temperature and in dry place, protected from light.

Keep all medicines out of reach of children.

Packing

Alercon™ 5 Tablet: Each commercial box contains 3 x 10 tablets in Alu-Alu blister strips.

***Further information is available on request.**



Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness

21007011/01