Olopat Eye Drops

(Olopatadine HCl) Sterile Solution 0.1%

Composition:

Each ml contains:

OLOPATEYE DROPS
 Olopatadine hydrochloride equivalent to Olopatadine 1.0mg
 (USP Specs.)
 Benzalkonium chloride as preservative

2. OLOPAT-DS EYE DROPS

Olopatadine hydrochloride equivalent to Olopatadine 2.0mg (USP Specs.) Benzalkonium chloride as preservative

Category: Anti histaminic, mast cell stabilizer.

Pharmacodynamics:

Olopatadine is a potent selective antihistaminic and mast cell stabilizing agent that exerts its effects through multiple distinct mechanisms of action. It antagonizes histamine (the primary mediator of allergic response in humans) and prevents histamic induced inflammatory cytokine production by human conjunctival epithelial cells. Olopatadine is a selective H,-receptor antagonist that inhibits Type I hypersensitivity reactions. It has been shown to inhibit the release of pro-inflammatory mediators from human conjunctival mast and epithelial cells.

Pharmacokinetics:

The half life in plasma is approximately 8-12 hours and elimination is predominantly through renal excretion. Approximately 60-70% of the dose is recovered in the urine as parent drug.

Indications:

OLOPAT or **OLOPAT-DS** ophthalmic solution is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

Dosage and administration:

• The recommended dose of Olopat is one drop in each affected eye two times per day at an interval of 6 to 8 hours & dose of Olopat DS is one drop in each affected eye once a day.

- Place the dropper directly over eye and instill the prescribed number of drops.
- Look downward and gently close your eye for 1 to 2 minutes.
- Place one finger at the corner of the eye near the nose and apply gentle pressure. This will prevent
 the medication from draining away from the eye.
- Try not to blink and do not rub the eye.
- Do not wear contact lenses while you are using the medicine.

Olopat-DS Eye Drops (Olopatadine HCl) Sterile Solution 0.2%

Contraindications:

Olopatadine hydrochloride ophthalmic solution is contraindicated in persons with a known hypersensitivity to olopatadine hydrochloride or any component of the formulation.

Warnings & precautions:

Only for Ophthalmic use. Not for injection or oral use. Instillation of **OLOPAT or OLOPAT-DS** may cause transient blurring of vision. Caution should be taken when driving or operating machinery if blurred vision is experienced.

Pregnancy:

There are no adequate and well-controlled studies in pregnant women. **OLOPAT** or **OLOPAT-DS** should be used in pregnant women only if the potential benefit to the mother justifies the potential risk of the embryo or fetus.

Pediatric use:

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

Nursing Mothers:

Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when Olopatadine is administered to nursing mothers.

Adverse Effects:

Headache has been reported at an incidence of 7%. The following undesirable effects have been reported in less than 5% of patients: Asthenia, Blurred vision, Burning or Stinging, Cold syndrome, Dry eye, Foreign body sensation, Hyperemia, Hypersensitivity, keratitis, Lid edema, Nausea, Pharyngitis, Pruritus, Rhinitis, Sinusitis, and Taste perversion. Some of these events were similar to the underlying disease being studied.

Storage and precautions:

- Store below 30°C.
- Protect from heat and sunlight.
- Keep out of the reach of children.
- Use the solution within four weeks after first opening the bottle

Presentation:

OLOPAT Eye Drops and OLOPAT-DS Eye drops are available as 5ml plastic dropper bottle.

خوراک ذائم کی ہوایات کی مطابق استعال کریں۔ مہدایات : دواکو ہوپ ادرگری ہے بچا نمیں۔ مہتذ گری ینٹی کریڈ ہے کم درچہ کرارت پر کچیں۔ تمام ادویات بچوں کی پیچی ہے دور رکچیں ۔ پہلی دفعہ یوتو کھولنے مے اچھ دواکو پا دغتوں تک استعال کیا جاسکتا ہے۔



Manufactured by: Vega Pharmaceuticals (Pvt.) Ltd. 30 Km, Multan Road, Lahore, Pakistan.