

OPTILERG

Anti-allergic Eye Drops

Composition:

Each ml of solution contains:

Antazoline HCl..... 0.5mg.

Tetrahydrozoline HCl 0.4mg.
(Vega Specs)

Vehicle: Hydroxypropyl Methylcellulose.

Preservative: Benzalkonium Chloride.

Properties and action:

Tetrahydrozoline a sympathomimetic agent closely related to naphazoline causes a contraction of the conjunctival arterioles through an adrenergic stimulation thereby reducing the inflammatory irritation and swelling of the conjunctiva. Tetrahydrozoline HCl may lead to a slight reduction in the intraocular pressure.

Antazoline, the antiallergic active agent contained in Optilerg competitively blocks the H₁ receptors in the effector cells. This reduces the effects caused by the histamine which is released into the tissue, such as increased permeability and dilatation of the capillaries, contraction of the smooth musculature, formations of edema itching, and lacrimation.

The combination of active ingredients in Optilerg is intended for a sympathomimetic treatment of allergic disorders of the conjunctiva primarily conditions caused by histamine release. Lacrimation is slightly reduced, while pupil diameter, accommodation and intraocular pressure are practically not affected.

Pharmacokinetics:

The pharmacokinetic behaviour of Optilerg has not been investigated neither in humans nor animals. The effect of Tetrahydrozoline appears rapidly and may last for 4 to 8 hours. Like any other oesymphatomimetic agent, Tetrahydrozoline is rapidly absorbed systemically through the blood vessels. H₁-antihistaminic agents (antazoline) are usually well and rapidly resorbed. However, no specific data on the degree of resorption are available.

Indications:

Non-infectious irritative conjunctivitis, allergic-inflammatory of the conjunctiva, hay fever and conjunctivitis vernalis.

Dosage/use:

Instill 1 drop after every three hours during the acute phase, for maintenance therapy 1 drop 2-3 times per day is sufficient. 1-2 drops per day are sufficient for children or as directed by the physician.

Contra-indications:

- Hypersensitivity to substances contained in Optilerg.
- Patients with glaucoma caused by a narrow iridocorneal angle (narrow angle glaucoma) as well as in case of dry eye syndrome.
- Small children under the age of 2 years.

Information for carriers of contact lenses:

Contact lenses should be removed before the administration of the product. Thereafter wait at least 15 minutes before placing the lenses back into the eyes. Optilerg may temporarily reduce tear production, resulting in reduced tolerance for contact lenses.

Precautions:

Use carefully in children.

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Other therapeutic measures of medications should be chosen in case of chronic recurring allergies. The preparation is not intended for long term medication. If a treatment longer than 2-3 days is foreseen, it should be prescribed and monitored by a physician.

Care is indicated in the case of rhinitis sicca. Due to systemic sympathomimetic effects care should be exercised when treating diabetics or patients suffering from severe heart disease, hypertension, hyperthyroidism or pheochromocytoma with the preparation. Eye infections can be masked.

Pregnancy and Lactation:

Pregnancy category C:

No controlled studies in animals, pregnant women or infants are available. The drug should therefore only be prescribed in those cases where the potential benefit exceeds the risk for the fetus or the risk for the infant. It is not known whether antazoline or Tetrahydrozoline is transferred into mother's milk.

Adverse reactions:

Occasionally a slight transient burning sensation may be felt immediately after instillation of the preparation, mydriasis is seen in rare instances.

After discontinuation of the treatment a reactive hyperaemia may develop. In rare cases headache, drowsiness and tachycardia may occur particularly in small children, as well as perspiration, tremor, rise in blood pressure, agitation and pectanginous symptoms.

Interactions:

Preparations containing Tetrahydrozoline may not be used in patients receiving MAO inhibitors until ten days after the last treatment with such active ingredients (increase in blood pressure resulting from the concomitant use of MAO inhibitors and tricyclic antidepressives).

Overdose:

Overdosing is not to be expected from the correct ophthalmic use of the preparation. Accidental ingestion of Optilerg usually does not lead to severe effects in adults. On the other hand, nausea, somnolence, arrhythmia/tachycardia and possibly shock may occur in children under 2 years.

Additional Information:

Close the bottle immediately after use. The unopened pack Optilerg can be used until the expiry date indicated with "EXP" on the pack.

For ophthalmic use only, Store below 30°C.

Protect from heat and sunlight.

Keep out of the reach of children.

Use within four weeks after first opening the bottle.

خوراک: ذرا کڑکری ہوایات کی مطابقت استعمال کریں۔

ہدایات: گرمی اور دھوپ سے بچائیں۔

3-4 ڈگری سینٹی گریڈ سے کم اور چار گرت پر رکھیں۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

پہلی دفعہ بوتل کھولنے کے بعد دو ماہ یا رفتوں تک استعمال کیا جاسکتا ہے۔



Manufactured by:

Vega Pharmaceuticals (Pvt.) Ltd.

30 Km, Multan Road, Lahore, Pakistan.