

Oculosan®

Composition:

Active substances: Naphazoline nitrate, zinc sulphate heptahydrate, witch hazel, orange flower oil, lavender oil, euphrasia (eyebright) tincture

Excipients: 0.1 mg benzoxonium chloride per ml, vehicle excipients

Pharmaceutical form and quantity of active substance per unit

Dropper bottle & the quantity/dropper bottle:

Eye drops; 0.05 mg naphazoline nitrate per ml, 0.2 mg zinc sulphate heptahydrate per ml, 40 mg witch hazel per ml, 0.005 mg orange flower oil per ml, 0.0018 mg lavender oil per ml, 0.8 mg euphrasia (eyebright) tincture per ml

Indications / Potential uses

Potential uses

Acute and chronic forms of non-infectious conjunctivitis, non-specific conjunctival irritation (including that experienced after healing of bacterial or viral conjunctivitis). Irrigation of the nasolacrimal duct.

Dosage and Administration

Adults

1 drop, instilled into the conjunctival sac of the affected eye 3–4 times daily.

Children and adolescents

The use and safety of Oculosan have not been investigated in children and adolescents. Generally speaking, caution is required when administering vasoconstrictors to children, and low doses should be used.

Contraindications

Hypersensitivity to zinc sulphate, naphazoline or any other component of the formulation.

Oculosan is contraindicated above all in patients with keratoconjunctivitis sicca (Sjögren's syndrome), as well as in those with narrow-angle glaucoma and dry eyes.

Oculosan must not be given to children under 6 years of age.

Concomitant use of MAO inhibitors.

Warnings and Precautions

Oculosan should not be used for more than 3 days without medical supervision: If eye irritation does not improve within this time, the product should be withdrawn and suitable alternative treatment considered. If patients experience eye pain or disturbed vision during treatment, Oculosan must be withdrawn immediately.

Caution is required in children and adolescents, in patients predisposed to glaucoma, and in patients with hypertension, heart disease, phaeochromocytoma, aneurysms, hyperglycaemia or hyperthyroidism.

Note for contact lens wearers

Contact lenses should be removed before each instillation, and only reinserted 15 minutes after instillation.

Interactions

Products containing naphazoline should not be used in patients undergoing treatment with MAO inhibitors until 10 days after administration of the final dose of the MAO inhibitor. The effects of tricyclic antidepressants may also be potentiated by concomitant use of naphazoline.

Nonetheless, there have been no known interactions to date involving Oculosan eye drops. When concomitantly administering other eye products, there should be an interval of at least 15 minutes between each instillation.

Pregnancy and Lactation

There have been no controlled studies in animals or in pregnant women. The product should therefore not be used in women who are pregnant or breastfeeding unless clearly necessary.

There have been no studies of use of the product in breastfeeding women.

Effects on ability to drive and use machines

No relevant studies have been carried out. The ability to use machines or drive may be impaired for a brief period immediately after instillation of the product. The patient should not engage in the above-mentioned activities until vision has returned to normal. Fatigue may occur in rare cases.

Adverse effects

Eye disorders

Common: A mild burning sensation and blurred vision may briefly occur after instillation, but this does not affect the success of treatment.

Excessively prolonged use may cause reddening of the eyes (rebound effect). Very rare: Mydriasis, with slightly elevated intraocular pressure.

Cardiovascular system

In rare cases, there may be systemic circulatory effects (hypertension, tachycardia, palpitations or headache). There have been reports of fatigue in some patients.

Overdose

The following symptoms may occur following accidental oral ingestion: changes in pulse rate and rhythm, pallor, sweating, dilated pupils, elevated blood pressure, drowsiness and a drop in body temperature. Bradycardia or even coma may occur, particularly in infants.

Properties and Actions

ATC code: S01GA51

Mechanism of action

Zinc ions provide the basis for the astringent and slightly antiseptic action of zinc sulphate. Naphazoline, a benzylimidazoline, acts as a vasoconstrictor and relieves inflammatory irritation and swelling of the conjunctiva by binding directly to receptors in vascular smooth muscle. Extracts of hamamelis (witch hazel) and euphrasia enhance the anti-inflammatory effect.

Pharmacokinetics

There have been no studies of the pharmacokinetics of Oculosan following topical application to the eye. Therefore, no information can be provided on absorption, distribution in eye fluids and tissues, or elimination.

Like all alpha-sympathomimetic agents, naphazoline is absorbed systemically through the blood vessels. However, no data are available on the amount absorbed.

Preclinical data

No preclinical data are available on Oculosan.

Other information

Incompatibilities

None known to date.

Effect on diagnostic tests

Tonometry results are falsified by prior use of Oculosan.

Shelf-life

When stored in the unopened package, Oculosan eye drops may be used until the expiry date (= EXP) printed on the pack.

Special precautions for storage

Oculosan eye drops should be stored in the unopened original package at 15–25°C. Close the bottle immediately after use. After opening, do not use for more than 1 month.

Pack sizes

Country specific pack sizes

Manufacturer

See folding Box

Information last revised

November 2005

Approval date (text)

14 August 2006

® = registered trademark

Novartis Pharma AG, Basle, Switzerland

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists