

Composition:

Nazin Eye Drops: Each ml contains Naphazoline Nitrate BP 0.05 mg and Zinc Sulphate BP 0.2 mg. Preservative: Benzalkonium Chloride Solution BP 0.02%.

Vehicle: HPMC USP 0.5%.

Pharmacology:

Zinc ions, the active compound of zinc sulphate, have an astringent, i.e. tissue-sealing and slightly anti-septic effect. Naphazoline constricts the blood vessels and reduces the inflammation and swelling of the conjunctiva. This effect of naphazoline, a substance of the benzylimidazoline group, is due to direct binding to α -adrenergic receptor sites on unstriated muscle cells in the blood vessels.

Indications:

Acute and chronic non-infectious conjunctivitis, nonspecific conjunctival irritation; also after successful treatment of bacterial and viral conjunctivitis. Irrigation of the tear ducts.

Dosage and administration:

Adults: One drop in the conjunctival sac, three to four times per day.

Children: Nazin has not been studied in children. Generally, in children the dosage of vasoconstrictors should be low and selected with caution.

Adverse reactions:

Mydriasis and a slight increase of intraocular pressure in isolated cases. A slight and transient burning sensation may occur after instillation, which does not affect the success of the treatment. Long term use may result in reactive redness of the eye (rebound effect).

Systemic effects:

In very rare cases systemic cardiovascular effects, such as hypertension and arrhythmia, may occur. Nonspecific fatigue has been observed in some patients.

Contraindications:

Hypersensitivity to zinc sulphate, Naphazoline and other ingredients. It is contraindicated in patients suffering from narrow-angle glaucoma, dry eye and especially keratoconjunctivitis sicca (Sjogren's syndrome). Nazin must not be used in infants.

Drug interactions:

Naphazoline containing products should not be administered during treatment with MAO-blockers nor during 10 days after discontinuation of such treatment. The effects of Naphazoline may be increased by concomitant use of tricyclic antidepressants.

Precaution:

Uncontrolled use of Naphazoline & Zinc Sulphate over extended periods of time should be avoided. If no improvement is seen after 2 days, treatment should be discontinued and other therapeutic measures should be considered. If ocular discomfort or visual disturbance occurs during this treatment, the therapy this must be discontinued. Caution is indicated in patients with predisposition to glaucoma and in patients suffering from hypertension, cardiovascular diseases, pheochromocytoma, aneurysm, hyperglycemia and hyperthyroidism.

Pregnancy and lactation:

(Pregnancy category C) There are neither controlled animal studies nor studies in pregnant women available. Therefore, during pregnancy the product should only be used if the benefit out-weighs the risk to the fetus. The effects of Naphazoline & Zinc Sulphate treatment during lactation has not been investigated.

Storage:

- Store in a cool, dry place and away from light.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

Packing:

Nazin Eye Drops: Each LDPE dropper bottle contains 10 ml Sterile & Pyrogen free Eye Drops.



