

Naphazoline Hydrochloride and Pheniramine Maleate sterile eve drops

Description

Napcon® eye drops is a sterile topical ophthalmic solution containing Naphazoline as Hydrochloride form and Pheniramine as Maleate form. Napcon® eye drops combine the effects of the antihistamine, Pheniramine Maleate, and the decongestant, Naphazoline Hydrochloride is a direct acting sympathomimetic amine which acts on alpha-adrenergic receptors in the arterioles of the conjunctiva to produce vasoconstriction, resulting in decreased conjunctival congestion. Pheniramine Maleate is an alkylamine derivative with antimuscarinic and central sedative properties which is used for the symptomatic relief of hypersensitivity reactions including conjunctivitis.

Indications

Napcon® eye drops is indicated for the temporary relief of redness and itching of the eye(s) due to ragweed, pollen, grass, animal dander and hair.

Dosage & administration

Adults and children 6 years and over: 1 or 2 drops should be applied to the affected eye(s) up to 4 times daily.

Children under 6 years: Should be consulted with doctor.

Use in pregnancy and lactation

Pregnancy

There are no or a limited amount of data from the use of topical ophthalmic Naphazoline or Pheniramine in pregnant women. It should only be used by a pregnant woman if clearly needed.

Lactation

There are no well-controlled studies in breast-feeding women. It should only be used by a breast-feeding woman if clearly needed.

Side effects

The most common side effect is temporary pupil enlargement causing light sensitivity. More eye redness may occur due to overuse. Using this combination should be stopped and patient should ask doctor if there are any occurrence of eye pain, change in vision and persistence of redness or irritation more than 72 hours.

Contraindications

This combination is contraindicated in patients with known hypersensitivity to any ingredients of it.

Precautions

This combination should be used with caution in patients with narrow angle glaucoma, heart disease, high blood pressure, trouble urinating and diabetes. Caution should also be taken if patients are known to suffer from pyloroduodenal obstruction or epilepsy. It may cause blurred vision that may affect the ability to drive or use machines.

Warnings

This combination of eye drops should not be used while soft (hydrophilic) contact lenses are in place. Soft contact lenses can be inserted 15 minutes after instillation of this eye drops.

Drug interactions

Arrhythmia may occur if this preparation is administered concomitantly with cardiac glycosides, tricyclic antidepressants or quinidine. Patients being treated with monoamine oxidase inhibitors may experience a severe hypertensive reaction if given a sympathomimetic drug. Although this reaction has not specifically been reported with Naphazoline, the possibility of such an interaction should be considered.

Overdose

In case of overdosage or accidental ingestion, Naphazoline can cause the following, particularly in children: depression of the central nervous system with a clear fall in body temperature and symptoms of bradycardia, excessive sweating, drowsiness and coma; hypertension followed by hypotension. A topical overdose of Napcon® eye drops may be flushed from the eye(s) with warm tap water.

Pharmaceutical precautions

- Store in a cool (below 25°C) and dry place protected from light.
- Do not use after one month once the cap is opened.

Presentation

Napcon® Eye Drops: Each ml contains Naphazoline Hydrochloride USP 0.25 mg and Pheniramine Maleate BP 3 mg.

Package quantities

Napcon® Eye Drops: Plastic dropper bottle of 10 ml.

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