PRESENTATION

Eye Drops: NAPHCON FORTE Eye Drops contain naphazoline hydrochloride, a decongestant prepared as a sterile solution for ophthalmic use.

NAPHCON FORTE Eye Drops contain 1 mg/mL naphazoline hydrochloride, together with the excipients boric acid, disodium edetate dihydrate, hydrochloric acid, potassium chloride, sodium carbonate monohydrate, sodium chloride and purified water. The solution is preserved with benzalkonium chloride (0.1 mg/mL).

USES

Actions
NAPHCON-FORTE Eye Drops have a vasoconstrictive action through a local adrenergic mechanism on conjunctival blood vessels.

Indications
For use as a topical ocular vasoconstrictor.

DOSAGE AND ADMINISTRATION

Instil one or two drops in the conjunctival sac(s) every three to four hours as needed.

CONTRAINDICATIONS

NAPHCON FORTE Eye Drops are contraindicated in patients who have narrow-angle glaucoma or who have hypersensitivity to any of the ingredients.

WARNINGS AND PRECAUTIONS

Do not use in presence of narrow angle glaucoma. Patients being treated with monoamine oxidase inhibitors (MAOIs) may experience a severe hypertensive crisis if administered a sympathomimetic drug. Use in infants and children may result in CNS depression leading to coma and marked reduction in body temperature.

Use with caution in children, the elderly, in patients with cardiovascular disease or in patients with sympathetic denervation (e.g. patients with insulin dependent diabetes, orthostatic hypotension, hypertension, hyperthyroidism) due to the risk for possible systemic effects.

Prolonged or excessive use may lead to rebound ocular vasodilatation or congestion.
Systemic absorption may occur and cause interaction with other therapy, particularly antihypertensive drugs.

NAPHCON FORTE Eye Drops contain benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to application of NAPHCON FORTE Eye Drops and wait at least 15 minutes before reinsertion.

To prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding area with the dropper tip of the bottle.

**Fertility**
Studies have not been performed to evaluate the effect of topical ocular administration of NAPHCON FORTE Eye Drops on human fertility.

**Use in pregnancy**
There are no or a limited amount of data from the use of topical ophthalmic naphazoline in pregnant women. Animal studies are insufficient with respect to reproductive toxicity.

**Use in lactation**
It is unknown whether topical naphazoline/metabolites are excreted in human milk. However, a risk to the breastfed child cannot be excluded.

**Use in children**
Safety and effectiveness in children under twelve years of age have not been established.

**Use in the elderly**
No well-controlled studies in elderly populations have been conducted, however, no potential issues have been identified since marketing the product.

**Effects on the ability to drive and use machinery**
NAPHCON FORTE Eye Drops may cause transient mydriasis, temporary blurred vision or other visual disturbances that may affect the ability to drive or use machines. If there is mydriasis or if blurred vision occurs after instillation, the patient must wait until the vision clears before driving or using machinery.

**ADVERSE REACTIONS**
The following adverse reactions have been identified from post-marketing surveillance following administration of NAPHCON FORTE Eye Drops. Frequency cannot be estimated from the available data.

<table>
<thead>
<tr>
<th>System Organ Classification</th>
<th>MedDRA Preferred Term (v.14.1)</th>
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</thead>
<tbody>
<tr>
<td>Eye disorders</td>
<td>Mydriasis, ocular hyperaemia</td>
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**Paediatric population**
Excessive use of naphazoline in infants and young children may cause depression of the central nervous system and significant reduction in body temperature.
INTERACTIONS

Patients being treated with monoamine oxidase inhibitors (MAOIs) may experience a severe hypertensive reaction if administered with a sympathomimetic drug. Although this reaction has not specifically been reported with naphazoline, the possibility of such an interaction should be considered.

OVERDOSAGE

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. Treatment of an oral overdose is symptomatic and supportive.

PHARMACEUTICAL PRECAUTIONS

Store below 25°C. Discard contents one month after opening.

MEDICINE CLASSIFICATION

Pharmacy Only Medicine.

PACKAGE QUANTITIES

Eye Drops, 0.1%, 15 mL.

NAME AND ADDRESS

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DATE OF PREPARATION

July 2014