NAPHCON™-A

Eye drops, solution

1. NAME OF THE MEDICINAL PRODUCT

NAPHCON™-A eye drops, solutio

2. QUALITATIVE AND QUANTITATIVE COMPOSITIO

Pheniramine maleate 3.0 mg - naphazoline hydrochloride 0.25 mg

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of eye irritations or ocular congestion caused by allergic disorders of the eye.

4.2 Posology and method of administration

Instil 1 or 2 drops into each eye every 3 to 4 hours or less frequently, until symptoms clear up. Do not continue treatment beyond the symptomatic period.

4.3 Contraindications

- Hypersensitivity to one of the constituents of this preparation.
- Do not use in patients with closed-angle glaucoma, patients predisposed to closed angle glaucoma, or infants and young children.

4.4 Special warnings and precautions for use

- Discontinue treatment if irritation persists or increases.
- Patients undergoing treatment with monoamine-oxidase inhibitors experience a severe hypertensive crisis if given a sympathomimetic drug such as naphazoline hydrochloride.
- Use in infants and children may result in depression of the central nervous system, leading to coma and a significant fall in body temperature.
- Use with caution in elderly patients with severe cardiovascular disease, including cardiac arrhythmia, patients with poorly controlled hypertension; diabetics, especially those with a tendency to diabetic ketoacidosis.
- Caution should also be exercised in patients suffering from hyperthyroidism, prostatic hypertrophy or history of urinary retention.
- Prolonged use and/or excessive dosing may lead to rebound ocular vasodilatation or congestion. Do not exceed recommended dosing or continue treatment beyond the symptomatic period.

After application of the eye drops following measures are useful to reduce systemic resorption:

- Keep the eyelid closed for 2 minutes.
- Close the lacrimal duct with the finger for 2 minutes.

As NAPHCON™-A contains the preservative benzalkonium chloride, this may cause eye irritation and is known to discolor soft contact lenses. Therefore, patients must remove contact lenses prior to application of NAPHCON™-A and be instructed to wait 15 minutes after instillation of NAPHCON™-A before inserting contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions are possible in patients undergoing treatment with monoamine-oxidase inhibitors.

4.6 Pregnancy and lactation

Pregnancy

The effects of naphazoline on animal reproduction have not yet been studied and it is not known whether administration to a pregnant woman can be harmful to the fetus and/or can affect the reproductive function.
The product should only be given to a pregnant woman if clearly needed.

Lactation

It is not known whether the drug is excreted in human milk. The product should only be given to a lactating woman if clearly needed.

4.7 Effects on ability to drive and use machines

In very rare cases, the product may cause transient mydriasis, which may impair vision in intense light.

4.8 Side effects

Ocular effects occasionally associated with use of the product include: eye pain, changes in vision, local irritation and continued redness. Pupillary dilation and increased intraocular pressure have also occurred; use should be avoided in patients with narrow-angle glaucoma. Local allergic reactions rarely occur.

Systemic effects such as headache, nausea, dizziness, cardiopathy, hypertension and hyperglycemia may occur.

4.9 Overdose

Considering the route of administration, overdosage is not likely to occur.

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, dizziness and coma; hypertension followed by hypotension.

In case of overdosage, antihistamines can cause, besides pronounced anticholinergic effects and depression, a stimulation of the central nervous system, especially in the child.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: decongestants and antiallergics - sympathomimetics used as decongestants
ATC code: S01G A 51

NAPHCON™-A combines the effects of the antihistaminic agent pheniramine maleate, an H1-receptor antagonist, and the vasoconstrictor naphazoline hydrochloride.

H1-receptor antagonists do not prevent histamine release, but reduce or obliterate most effects on smooth muscles.

Naphazoline is a sympathomimetic with substantial alpha-adrenergic activity. It is a vasoconstrictor with a fast and long-lasting activity, reducing oedema and congestion when applied to the mucosa. Through its local adrenergic activity naphazoline has a vasoconstrictive effect on the blood vessels, thereby causing a decongestion of the conjunctiva.

5.2 Pharmacokinetic properties

Repeated and/or prolonged instillation could give cause to a considerable systemic absorption of naphazoline.

5.3 Preclinical safety data

No data provided.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride 0.10 mg - boric acid - borax - disodium edetate - sodium chloride - sodium hydroxide and/or concentrated hydrochloric acid - purified water to 1 ml.

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened: 36 months: see expiry date on the packaging after the sign "Exp" (month/year).
Discard four weeks after first opening of the bottle.

6.4 Special precautions for storage

Store at room temperature (15°-25°C). Protect from light and excessive heat. Keep bottle tightly closed when not in use. Keep out of reach of children.

6.5 Nature and contents of container

15 ml DROP-TAINER™ bottle.

6.6 Instructions for use [and][,] handling [and disposal]

No special instructions.

Alcon

Manufactured by
ALCON-COUVREUR
B-2870 Puurs (Belgium)
for Alcon NV, Belgium