NEW ZEALAND DATA SHEET

NAPHCONE-A
Naphazoline hydrochloride and pheniramine maleate.

PRESENTATION

Eye Drops: NAPHCONE-A Eye Drops are a combination of an antihistamine (pheniramine maleate) and a decongestant (naphazoline hydrochloride) prepared as a sterile solution for ophthalmic use.

NAPHCONE-A Eye Drops contain 0.25 mg/mL naphazoline hydrochloride and 3.0 mg/mL pheniramine maleate, together with the excipients disodium edetate dihydrate, boric acid, sodium borate decahydrate, sodium chloride, hydrochloric acid, sodium hydroxide and purified water. The solution is preserved with benzalkonium chloride (0.1 mg/mL).

USES

Actions
NAPHCONE-A Eye Drops combine the effects of the antihistamine, pheniramine maleate, and the decongestant, naphazoline hydrochloride.

Naphazoline hydrochloride is a direct acting sympathomimetic amine. It 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
For the symptomatic treatment of allergic conjunctivitis.

DOSAGE AND ADMINISTRATION

One to two drops of NAPHCONE-A Eye Drops should be instilled into the affected eye(s) three to four times daily.

CONTRAINDICATIONS

The use of NAPHCONE-A Eye Drops is contraindicated in patients who are known to experience narrow-angle glaucoma or who have known hypersensitivities to one or more of the components of this preparation.
WARNINGS AND PRECAUTIONS

Patients being treated with monoamine oxidase inhibitors (MAOIs) may experience a severe hypertensive crisis if given a sympathomimetic drug. Patients already using an eye product obtained on prescription should use NAPHCON-A only after consultation with a doctor or pharmacist.

Patients known to be sensitive to other ophthalmic sympathomimetic preparations may also experience sensitivity reactions to NAPHCON-A Eye Drops.

This preparation should be used with caution in children, the elderly, patients with cardiovascular disease including cardiac arrhythmia, patients with poorly controlled hypertension, patients with diabetes (especially when the diabetes is not adequately controlled) and patients who have urinary retention or prostate hypertrophy. Use with caution in patients with sympathetic denervation (e.g. patients with insulin dependent diabetes, orthostatic hypotension, hypertension, hyperthyroidism) due to the risk for possible systemic effects. Caution should also be taken if patients are known to suffer from pyloroduodenal obstruction or epilepsy.

Prolonged and / or excessive use may lead to rebound ocular vasodilatation or congestion.

NAPHCON-A 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-A and wait at least 15 minutes before reinsertion.

If a diminution of symptoms is not seen or the condition worsens in the first 72 hours of treatment with NAPHCON-A Eye Drops, treatment should be discontinued and the advice of a physician sought. NAPHCON-A Eye Drops should not be used for long-term treatment (i.e. for more than 14 days) without further evaluation of the patient.

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

Use in pregnancy - CATEGORY A
Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

There are no or a limited amount of data from the use of topical ophthalmic naphazoline or pheniramine in pregnant women; naphazoline hydrochloride may be absorbed systemically following ophthalmic administration. NAPHCON-A Eye Drops should only be used by a pregnant woman if clearly needed. Animal studies are insufficient with respect to reproductive toxicity.
Use in lactation
There are no well-controlled studies in breast-feeding women; naphazoline hydrochloride may be absorbed systemically following ophthalmic administration. It is unknown whether topical naphazoline / metabolites are excreted in human milk. However, a risk to the breastfed child cannot be excluded. NAPHCON-A Eye Drops should only be used by a breast-feeding woman if clearly needed.

Use in children
Safety and effectiveness in children under 12 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 of ability to drive and use machines
NAPHCON-A 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.

Patient instructions
Patients should be advised:
• to avoid touching the dropper tip to the eyelids, surrounding areas or any other surface as this may contaminate the product;
• to contact a doctor or pharmacist if the symptoms persist for more than 72 hours or worsen;
• not to use NAPHCON-A Eye Drops while soft (hydrophilic) contact lenses are in place. Soft contact lenses can be inserted 15 minutes after instillation of NAPHCON-A Eye Drops;
• to read the Patient Information Leaflet supplied with NAPHCON-A Eye Drops before using the product.

ADVERSE REACTIONS
The following adverse reactions have been reported during clinical trials with NAPHCON-A Eye Drops. They are classified according to the subsequent convention: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥ 1/1,000 to <1/100), rare (≥ 1/10,000 to <1/1,000) and very rare (<1/10,000). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness.

<table>
<thead>
<tr>
<th>System Organ Classification</th>
<th>MedDRA Preferred term (v. 14.1)</th>
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<tbody>
<tr>
<td>Eye disorders</td>
<td>Common: ocular discomfort</td>
</tr>
<tr>
<td></td>
<td>Uncommon: keratitis, eye pain, eye oedema, ocular hyperaemia</td>
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Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data.
Paediatric population
Excessive use of naphazoline-pheniramine in infants and young children may cause depression of the central nervous system and significant reduction in body temperature.

INTERACTIONS
An increased risk of arrhythmias may be seen if NAPHCON-A Eye Drops are administered concomitantly with cardiac glycosides, quinidine or tricyclic antidepressants.

The sedative effects of central nervous system depressants such as alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and neuroleptics may be potentiated if administered concomitantly with NAPHCON-A Eye Drops.

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.

OVERDOSAGE
A topical overdose of NAPHCON-A Eye Drops may be flushed from the eyes with warm tap water.

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. Protect from light and excessive heat.
Discard container 4 weeks after opening.
Keep NAPHCON-A Eye Drops and all other medicines out of the reach of children.
Remove contact lenses before using (see WARNINGS AND PRECAUTIONS).

MEDICINE CLASSIFICATION
Pharmacy Only Medicine.
PACKAGE QUANTITIES

15 mL DROP-TAINER dispenser.

NAME AND ADDRESS

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DATE OF PREPARATION

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