

## NEW ZEALAND DATA SHEET

### 1. PRODUCT NAME

NAPHCAN-A Eye Drops naphazoline hydrochloride 0.025% and pheniramine maleate 0.3%.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Naphcon-A contains naphazoline hydrochloride 0.25 mg in 1 mL and pheniramine maleate 3.0 mg in 1 mL.

#### Excipient with known effect

Benzalkonium chloride 0.1 mg in 1.0 mL as a preservative.

For the full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Eye drops, solution, sterile.

### 4. CLINICAL PARTICULARS

#### 4.1. Therapeutic indications

For the symptomatic treatment of allergic conjunctivitis.

#### 4.2. Dose and method of administration

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

#### 4.3. Contraindications

The use of NAPHCAN-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 (see Section 6.1. List of excipients).

#### 4.4. Special warnings and precautions for use

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 NAPHCAN-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 NAPHCAN-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.

NAPHCN-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 NAPHCN-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 NAPHCN-A Eye Drops, treatment should be discontinued and the advice of a physician sought. NAPHCN-A Eye Drops should not be used for long- term treatment (i.e. for more than 14 days) without further evaluation of the patient.

#### Paediatric population

Safety and effectiveness in children under 12 years of age have not been established.

#### Elderly

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

#### 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 NAPHCN-A Eye Drops while soft (hydrophilic) contact lenses are in place. Soft contact lenses can be inserted 15 minutes after instillation of NAPHCN-A Eye Drops;
- to read the Patient Information Leaflet supplied with NAPHCN-A Eye Drops before using the product.

#### **4.5 Interactions with other medicinal products and other forms of interactions**

An increased risk of arrhythmias may be seen if NAPHCN-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 NAPHCN-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.

#### **4.6 Fertility, pregnancy and lactation**

##### 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. NAPHCN-A Eye Drops should only be used by a pregnant woman if clearly needed. Animal studies are insufficient with respect to reproductive toxicity.

##### Breast-feeding

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. NAPHCN-A Eye Drops should only be used by a breast-feeding woman if clearly needed.

##### Fertility

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

#### **4.7 Effects on ability to drive or use machines**

NAPHCN-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.

#### **4.8 Undesirable effects**

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

<b>System Organ Classification</b>	<b>MedDRA Preferred term (v. 14.1)</b>
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Eye disorders	Common: ocular discomfort.  Uncommon: keratitis, eye pain, eye oedema, ocular hyperaemia.
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Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data.

<b>System Organ Classification</b>	<b>MedDRA Preferred Term (v.14.1)</b>
Eye disorders	Mydriasis, eye irritation, vision blurred.

### 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.

### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting>.

## **4.9 Overdose**

A topical overdose of NAPHCN-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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764 766).

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic Group: ATC Code: ophthalmological, decongestant and antiallergics, sympathomimetics used as a decongestant, S01GA51.

#### Mechanism of action

NAPHCN-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.

#### Pharmacodynamic effects

Not available.

#### Clinical efficacy and safety

Not available.

### **5.2 Pharmacokinetic properties**

Not available.

### **5.3 Preclinical safety data**

Not available.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

Disodium edetate dihydrate  
Boric acid  
Sodium borate decahydrate  
Sodium chloride  
Hydrochloric acid  
Purified water  
Benzalkonium chloride as a preservative.

### **6.2 Incompatibilities**

Unknown.

### **6.3 Shelf life**

36 months.

### **6.4 Special precautions for storage**

Store below 25°C. Protect from light and excessive heat.

Discard contents 4 weeks after opening.

### **6.5 Nature and contents of container**

15 mL Drop-Tainer dispenser.

### **6.6 Special precautions for disposal**

No special requirements for disposal.

**7. MEDICINE SCHEDULE**

Pharmacy Only Medicine.

**8. SPONSOR**

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**9. DATE OF FIRST APPROVAL**

29 August 1980.

**10. DATE OF REVISION OF THE TEXT**

17 April 2018.

Summary Table of Changes

Data Sheet - all sections	Updated to Summary of Product Characteristics format.
8. Sponsor.	Addition of sponsor postal address.