NEW ZEALAND DATA SHEET

1. **PRODUCT NAME**

NAPHCON FORTE Eye Drops 0.1%

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Naphcon Forte contains naphazoline hydrochloride 1.0 mg in 1 mL (0.1%).

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 use as a topical ocular vasoconstrictor.

4.2. **Dose and method of administration**

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

4.3. **Contraindications**

NAPHCON FORTE Eye Drops are contraindicated in patients who have narrow-angle glaucoma or who have hypersensitivity to naphazoline hydrochloride or to any of the ingredients in the medicine (see Section 6.1. List of excipients).

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

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.

**Paediatric population**

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.

4.5 **Interactions with other medicinal products and other forms of 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.

4.6 **Fertility, pregnancy and lactation**

**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.

**Breast-feeding**

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

**Fertility**

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

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

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.

4.8 **Undesirable effects**

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.
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.

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

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

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

Boric acid  
Disodium edetate dihydrate  
Hydrochloric acid  
Potassium chloride  
Sodium carbonate monohydrate  
Sodium chloride  
Purified water  
Benzalkonium chloride as a preservative.

6.2 Incompatibilities

Unknown.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

15 mL bottle dropper, Drop-Tainer™.

6.6 Special precautions for disposal

No special requirements for disposal.

7. MEDICINE SCHEDULE

Pharmacy Only Medicine.

8. SPONSOR

Pharmaco (NZ) Ltd  
4 Fisher Crescent  
Mount Wellington  
Auckland 1060  
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Auckland 1140  
New Zealand.

Free Phone: 0800 804 079.
9. **DATE OF FIRST APPROVAL**

23 September 1976.

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

17 April 2018.

Summary Table of Changes

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<tr>
<th>Data Sheet - all sections</th>
<th>Updated to Summary of Product Characteristics format.</th>
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<td>8. Sponsor.</td>
<td>Addition of sponsor postal address.</td>
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