

Package leaflet: Information for the user

Naphcon™-A

Relieves Itching & Redness

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Naphcon™-A Eye Drops, Solution is and what it is used for
2. What you need to know before you use Naphcon-A Eye Drops, Solution
3. How to use Naphcon-A Eye Drops, Solution
4. Possible side effects
5. How to store Naphcon-A Eye Drops, Solution
6. Contents of the pack and other information

1. What Naphcon -A Eye Drops, Solution is and what it is used for

NAPHCON-A Eye Drops, Solution is a - combination of an antihistamine, pheniramine maleate and a decongestant, naphazoline hydrochloride prepared as a sterile topical ophthalmic solution.

Each ml contains:

Actives: Naphazoline Hydrochloride 0.025 %, Pheniramine Maleate 0.3 %.

Preservative: Benzalkonium Chloride 0.01 %. Boric Acid, Sodium Chloride, Sodium Borate, Disodium Edetate, Sodium Hydroxide and/or Hydrochloric Acid and Purified Water.

NAPHCON-A Eye Drops, Solution is used for relief of ocular irritation and/or congestion or for the treatment of allergic or inflammatory ocular conditions.

2. What you need to know before you use Naphcon-A Eye Drops, Solution

Do not use Naphcon-A Eye Drops, Solution:

- If you are allergic to naphazoline, pheniramine or any of the other ingredients of this medicine (listed in section 6).
- If you have narrow angle glaucoma.

Warnings and Precautions Talk to your doctor or pharmacist before using Naphcon-A Eye Drops, Solution.

- Only use NAPHCN-A Eye Drops, Solution for dropping in your eye(s).
- If you are being treated with monoamine oxidase (MAO) inhibitors.
- In children, as they may be more susceptible to side effects from the medication.
- In elderly, in patients with heart disease, or in patients with insulin-dependent diabetes, decreases in blood pressure related with postural changes, high blood pressure, or thyroid gland disorders.
- Prolonged and/or excessive use may lead to rebound widening of blood vessels in your eye or congestion.
- Stop use and ask a doctor if symptoms persist or condition worsens or lasts for more than 72 hours.

Other medicines and Naphcon-A Eye Drops, Solution

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Especially tell your doctor if you are taking:

- monoamine oxidase inhibitors (MAOIs)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, you think you may be pregnant or you are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines You may find your vision is blurred for a time after you use NAPHCN-A Eye Drops, Solution. Do not drive or use machines until this has worn off.

NAPHCN-A Eye Drops, Solution contains benzalkonium chloride

A preservative in NAPHCN-A Eye Drops, Solution (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses.

If you wear contact lenses you should remove them before using NAPHCN-A Eye Drops, Solution and wait at least 15 minutes before putting your lenses back in.

3. How to use NAPHCN-A Eye Drops, Solution

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- One or two drops topically in the eye(s) three to four times daily.
- 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.

The following measure is useful to limit the amount of medicine that will come into the blood after application of eye drops:

- Keep the eyelid closed, while simultaneously applying gentle pressure to the lachrymal canal with a finger for at least 1 minute.

If a drop misses your eye, try again.

If you use more NAPHCN-A Eye Drops, Solution than you should, rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.

If you experience side effects, or in case of accidental intake/ingestion of an overdose of NAPHCN-A Eye Drops, Solution, seek immediate medical attention, advice from your doctor, pharmacist or a poison control centre.

Taking substantially more of NAPHCN-A Eye Drops, Solution than the recommended dose, for example if NAPHCN-A Eye Drops, Solution is accidentally swallowed, may lead to severe side effects affecting the heart and blood circulation. Symptoms may include: decreased heart rate (bradycardia), severe headache, nausea, vomiting, problems with breathing, increased heart rate (tachycardia), and chest pain. Other serious reactions such as a fall in body temperature, drowsiness or other symptoms of depression of the central nervous system may occur (especially in children).

If you forget to use NAPHCN-A Eye Drops, Solution continue with the next dose as planned. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose to make up.

If you are using other eye drop or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been seen with NAPHCN-A Eye Drops, Solution:

Common may affect up to 1 in 10 people:

- Effects in the eye: Eye discomfort,

Uncommon may affect up to 1 in 100 people:

- Effects in the eye: eye surface inflammation, eye pain, eye swelling, eye redness,

The following side effects have been seen from post-marketing experience with NAPHCN-A Eye Drops, Solution, for which the frequency is not known:

- Effects in the eye: increase in ocular pressure, increase in pupil size, eye irritation, blurred vision,
- General side effects: hypertension, cardiac irregularities, hyperglycemia.

Additional side effects in children

Excessive use of Naphazoline-Pheniramine in infants and young children may cause serious reactions such as a fall in body temperature, drowsiness or other symptoms of depression of the central nervous system.

Use in infants and children may result in CNS depression leading to coma and marked reduction in body temperature.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store NAPHCN-A Eye Drops, Solution

Do not store above 25° C. Keep bottle tightly closed when not in use. Protect from light and excessive heat. Discard 4 weeks after opening.

6. Contents of the pack and other information**Each ml contains:**

Actives: Naphazoline Hydrochloride 0.025%, Pheniramine Maleate 0.3%

Preservative: Benzalkonium Chloride 0.01%, Boric Acid, Sodium Chloride, Sodium Borate, Disodium Edetate, Sodium Hydroxide and/or Hydrochloric Acid and Purified Water.

What NAPHCN-A Eye Drops, Solution looks like and contents of the pack

In 15 ml plastic DROPTAINER™ Dispenser.

Manufacturer: Refer to folding box

Alcon

ALCON SINGAPORE MANUFACTURING PTE. LTD.
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