

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### PROCULIN

0.3 mg / ml, eye drops, solution

NAPHAZOLINE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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#### What is in this leaflet?

1. What PROCULIN is and what it is used for
2. Before you take PROCULIN
3. How to use PROCULIN
4. Possible side effects
5. How to store PROCULIN
6. Further information

#### *1. WHAT PROCULIN IS AND WHAT IT IS USED FOR*

PROCULIN contains the active substance naphazoline hydrochloride that belongs to the group of medicines called decongestants (medicines for vasoconstriction) and antiallergics.

Proculin soothes the symptoms of redness and itching of the eyes, caused by various irritants, such as: dust; smoke; smog; coldness; wind; sun; TV-exposure, swimming; use of contact lenses; eye-intensive work. The product also successfully relieves the symptoms of allergic eye inflammation, caused by: pollen; grass; animal hair, etc.

#### *2. BEFORE YOU TAKE PROCULIN*

##### **Do not take PROCULIN**

- If you are allergic (hypersensitive) to naphazoline or any of the other ingredients;
- If you have an anatomically narrow angle or closed angle glaucoma.

##### **Take special care with PROCULIN**

- if you have an infection or injury of the eye;

- if you have heart disease;
- if you have high blood pressure;
- if you have diabetes;
- if you have hyperthyroidism (increased secretion of hormones of the thyroid gland);
- if you are receiving MAO inhibitors (antidepressants).

Patients should be advised to discontinue the use of the medicine and consult a doctor if there is no improvement after 48 hours of treatment, or if there are new or increased irritations, blurred vision, or redness or symptoms of systemic absorption e.g., dizziness, headache, nausea, lowering of body temperature and sleepiness.

If you use contact lenses, they should be removed before using the medicine.

### ***Use in children***

High doses of naphazoline administered in children can cause sedation. Eye drops are contraindicated in infants and children, because CNS depression may progress to coma and hypothermia.

### ***Taking other medicines***

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- MAO inhibitors, tricyclic antidepressants for the treatment of psychiatric disorders.
- Anaesthetics (trichlorethylene, cyclopropane, halothane)
- Concomitant use of boric acid and idoxuridine (medicine for viral infection) may result in the appearance of the precipitate; therefore the use of boric acid should be avoided during the therapy with idoxuridine

### ***Pregnancy and breastfeeding***

Before using any medicine, consult your doctor or pharmacist.

Proculin can be used during pregnancy only if it is absolutely necessary.

It is not known whether naphazoline is excreted into breast milk, and therefore caution is required when it is used by breastfeeding women.

### ***Driving and using machines***

Vision may be blurred or unstable for several minutes after applying eye drops. Be careful if you drive or perform work that requires clear vision.

### ***Other warnings***

Proculin contains benzalkonium chloride which can irritate eyes. Avoid contact with soft contact lenses. Contact lenses should be removed before instillation of the medicine, and may be put 15 minutes after instillation of the medicine.

## ***3. HOW TO USE PROCULIN***

### ***Use this medicine according to the instructions.***

If you think that the medicine is too strong or too weak, consult your doctor or pharmacist.

Instill 1-2 drops in the eye (s) up to 4 times a day. The recommended duration of treatment is 3-4 days.

Pull the lower lid down and instill the medicine in the conjunctival sac. The top of the bottle should not touch hands, nor any surface because of the risk of contamination. Contact lenses must be removed from the eye before using medicine.

Prolonged treatment is not recommended. Prolonged treatment can lead to increased blood flow and redness of the eye.

***If you use more PROCULIN than you should***

If you took a higher dose than recommended, or if you accidentally swallowed your medicine, immediately contact your doctor, pharmacist and report if you experience a decrease of body temperature, drowsiness and coma, especially in children.

***If you forget to use PROCULIN***

Do not use a double dose to make up for the forgotten tablet.

If you miss a dose, apply the next dose at the usual time and continue to use the medicine as instructed by a doctor.

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

***4. POSSIBLE SIDE EFFECTS***

Like all medicines, PROCULIN can cause side effects, although not everybody gets them.

Systemic: high blood sugar (hyperglycemia), sweating, nervousness, drowsiness, headache, dizziness, fast or slow heart rate, irregular heartbeat, high blood pressure, nausea, weakness.

Eye disorders: conjunctival irritation, increased redness (phenomenon of return), abnormal enlargement of the pupil of the eye, blurred vision, increased eye pressure, inflammation of the eye (keratitis), tearing, discomfort in the eye.

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

***5. HOW TO STORE PROCULIN***

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use PROCULIN after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

The medicine should be used within 28 days after first opening. After this period dispose of the unused medicine.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

***6. FURTHER INFORMATION***

***What PROCULIN contains***

The active substance is naphazoline.

One ml of eye drop solution contains 0.3 mg of naphazoline hydrochloride.

The other ingredients are: boric acid; borax; disodium edetate; benzalkonium chloride; sodium chloride; water for injections.

***What PROCULIN looks like and contents of the pack***

Clear solution, without color.

The solution is packed in a plastic (LDPE) bottle with PP cap.

The box contains 1 vial of 10 ml of eye drops, solution, and a patient information leaflet.

***Regime of dispensing***

The medicine is issued without doctor's prescription.

***Manufacturer***

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