

PACKAGE LEAFLET: Information for the user

NAFAZOLINE

Nasal spray, solution – 1 mg / ml (0.1%)

(Naphazoline nitrate)

Read this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Nafazoline is and what it is used for
2. Before you use Nafazoline
3. How to use Nafazoline
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1. WHAT NAFAZOLINE IS AND WHAT IT IS USED FOR

Nafazoline contains the active substance naphazoline nitrate, which is an agonist of the α -adrenergic receptors. It primarily promotes α_2 -receptors and in a lesser extent α_1 -receptors. Hereby, it causes the narrowing of the arterioles and of the precapillar sphincters, thereby reducing blood flow in the nasal mucosa and in the erected sinusoids. Because of the narrowing of the arterioles of the erected sinusoids, the congestion of the mucous membrane of the nose and the nasal resistance is reduced, while air flow through the nose is increased. As a result of the reduction of the amount of blood in the nasal mucous membrane, the diameter of the neck of the

paranasal sinuses is increased (the ability to dry up is improved). Mucous membranes become less edematous and so the nasal congestion sensation in the patient is less pronounced.

Nafazoline used locally (in the nasal mucosa) is rapidly absorbed; the onset of action occurs within 5 minutes, while the effect lasts 2 to 6 hours.

Nafazoline is used in the symptomatic treatment of all forms of rhinitis and sinusitis; inflammations of the middle ear (decongestion of the Eustachian tubes); nasal haemorrhage (epistaxis); preparation for rhinological examinations and surgical interventions (in addition to local anesthetics).

2. BEFORE YOU USE NAFAZOLINE

Do not use Nafazoline if:

- you are hypersensitive to naphazoline nitrate or to any of the excipients of Nafazoline;
- you suffer from closed-angle glaucoma.

Nafazoline should not be used in children.

Take special care with Nafazoline

Ask your doctor before you use Nafazoline. The patient should be warned to not extend the treatment more than 5 days. If a longer treatment is necessary, it can continue after an interval of 3 to 5 days without medication.

Nafazoline should be used with caution in:

- elderly people;
- patients with arterial hypertension or with other cardiovascular diseases;
- patients with diabetes;
- patients with hyperthyroidism;
- patients with prostate hypertrophy.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Nafazoline.

Please contact your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, including those obtained without a prescription. Do not forget to inform your

doctor for the treatment with Nafazoline if you have been given any other drug during treatment.

It is especially important to inform your doctor that you are treated with:

- tricyclic antidepressants;
- maprotiline;
- monoamine oxidase inhibitors (MAOI).

These drugs increase the pressor effect of naphazoline.

Using Nafazoline with food and drinks

It is not known any consequence of Nafazoline when it is used with food or drinks.

Pregnancy

Ask for the advice of the pharmacist or of the doctor before you use this drug.

Avoid the use.

Breastfeeding

Avoid use.

Driving and using machines

There are no data on the effect of Nafazoline in the ability to drive and use machines, however care should be taken until you see the way it affects you.

Important information about some of the excipients of Nafazoline

Nafazoline contains:

- 0.1 mg benzalkonium chloride in each 1 ml solution. It may cause irritation or swelling inside the nose, especially if used for a long time. It may also cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.

3. HOW TO USE NAFAZOLINE

Always use Nafazoline exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Nafazoline are too strong or too weak, talk to your doctor or pharmacist.

For the treatment of nasal congestion (adults) is used 1 spray in each nostril, 2 - 3 times daily.

Nasal haemorrhage (adults): wet a cotton tampon with Nafazoline solution 0.1 % and then put it in the nostril, where it is held for 2 to 5 minutes.

Nafazoline should not be used more frequently than every 4 - 6 hours.

If you use more Nafazoline

If you use more Nafazoline than you should, or if the children have used this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

The symptoms of overdose may include: temperature lowering, drowsiness, bradycardia.

If you forget to use Nafazoline

If you forget a dose (or more doses), use the next dose when it is time to use it usually.

Do not use a double dose (or higher) to make up for a forgotten dose (doses).

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

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Nafazoline can cause side effects, although not everybody manifests them.

Most of the side effects are dose-related and disappear when the dose is reduced or the treatment is stopped. Some side effects can happen at the beginning of the treatment and disappear spontaneously with treatment continuation.

After the use of Nafazoline may appear:

- temporary irritation of the mucosa;
- burning pain;
- recurrent congestion (rebound effect);
- sting;

- sneezing;
- drying mucous sensation.

Long-term use can cause:

- reactive hyperemia;
- atrophic rhinitis;
- drug dependence.

Also, systemic effects are reported after local use, like: nausea, headache and dizziness.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE NAFAZOLINE

Keep in the original packaging at a temperature 10° - 25°C.

Protect it from light and humidity.

Do not use it after the expiry date.

Keep out of the reach and sight of children. Your drug may harm them.

6. OTHER INFORMATION

What Nafazoline contains

The active substance is naphazoline nitrate.

1 ml of nasal spray, solution contains 1 mg naphazoline nitrate.

The excipients are: boric acid, benzalkonium chloride, menthol, ethyl alcohol, water for injection.

Content of the pack

Carton box with one plastic bottle of 10 ml, containing a spray pump.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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