

Package leaflet: Information for the user

Nezebi 0.5 mg/ml nasal spray, solution

oxymetazoline hydrochloride

[For medicines available only on prescription]

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.

[For medicines available without a prescription]

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Nezebi is and what it is used for
2. What you need to know before you take Nezebi
3. How to take Nezebi
4. Possible side effects
5. How to store Nezebi
6. Contents of the pack and other information

1. What Nezebi is and what it is used for

[For medicines available only on prescription] in RMS and

[For medicines available without a prescription] in CMS

Nezebi is used as a short-term treatment of nasal congestion due to colds and sinusitis in adults and children from 10 years of age.

Nezebi has a rapid decongestant effect, which reduces nasal and sinus congestion and therefore facilitates breathing. The effect comes on within a few minutes and lasts for up to 12 hours.

Nezebi contains also dexpanthenol that hydrates the dry nasal mucosa.

[For medicines available without a prescription] in RMS

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2. What you need to know before you take Nezebi

Do not take Nezebi

- if you are allergic to oxymetazoline hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have chronic nasal inflammation with very dry nasal passageways (atrophic rhinitis or rhinitis sicca)

Warnings and precautions

Talk to your doctor or pharmacist before taking Nezebi if you:

- have cardiovascular diseases (e.g. angina)
- have raised blood pressure
- have diabetes
- have a benign tumour of the adrenal gland (phaeochromocytoma) that produces high amounts of adrenaline and noradrenaline
- have difficulty in urinating and/or an enlarged prostate gland
- have increased pressure in the eyes (narrow-angle glaucoma)
- have overactive thyroid gland (hyperthyroidism)
- taking medicines for depression (tricyclic and tetracyclic antidepressants (e.g. amitriptyline, imipramine) or monoamine-oxidase inhibitors) or used such treatments during the last two weeks.

Children

Not for use in children below 10 years of age.

Other medicines and Nezebi

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is particularly important that you mention the following:

- Tri- and tetra-cyclic antidepressants (for depression e.g. amitriptyline, imipramine). If you are taking or have taken these medicines in the last two weeks, your blood pressure may increase significantly (hypertensive crisis).
- Monoamine oxidase inhibitors (used for treatment of depression). If you are taking or have taken these medicines in the last two weeks, your blood pressure may increase significantly (hypertensive crisis).
- Beta-blockers (for treatment of high blood pressure). Oxymetazoline in Nezebi may change the effect of some beta-blockers.
- Medicines with adrenaline like effect (e.g. ephedrine, pseudoephedrine) as they may increase the effect of Nezebi.

Pregnancy, breast-feeding and fertility

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

Pregnancy

As limited data is available on use of this product during pregnancy, as precaution shall Nezebi only be used during pregnancy if recommended by a doctor.

Breast-feeding

As no studies have been performed, it is not known whether Nezebi passes into breast milk.

Fertility

Nezebi has no known effects on fertility.

Driving and using machines

Nezebi has no or negligible influence on the ability to drive and use machines.

3. How to take Nezebi

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

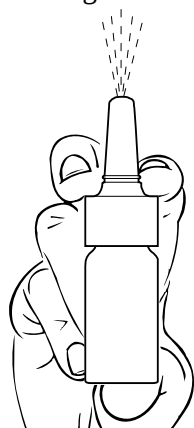
The recommended dose is:

Adults and children from 10 years of age: 2 sprays in each nostril 2-3 times daily.

Nezebi should not be used for more than 10 consecutive days and the recommended dosage should not be exceeded. When used for a long time, Nezebi can cause nasal congestion.

User instruction

The first time you use the spray, you must charge the pump. Hold the bottle upright and spray 5 times in the air until there is an even shower. If the pump has not been used for a long time, it must be recharged with 3 sprays in the air.



1. Blow your nose.
Remove the protective cap.
2. Hold the bottle as shown on the picture.
3. Insert the tip into one nostril and pump the number of doses you should take (according to the dosing instructions above). Do the same for the other nostril.
4. Put back the protective cap.

As it can be difficult to empty the bottle completely, it is filled with a little more than 7.5 ml. This ensures that the specified amount is obtained.

If you take more Nezebi than you should

[To be completed nationally]

If you take too much of any medicine, or if a child has taken the medicine by mistake always contact a doctor or hospital for risk assessment and advice

If you forget to take Nezebi

Do not take a double dose to make up for a forgotten dose.

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.

Uncommon (may affect up to 1 in 100 people): sneezing, dryness of the mouth and throat.

Rare (may affect up to 1 in 1,000 people): anxiety, irritability, local irritation of the nose, sleep disorders in children.

When used for a long time, Nezebi can cause nasal congestion.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system** listed in [Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nezebi

Keep this medicine out of the sight and reach of children.
Store below 25°C.

Do not use this medicine after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nezebi contains

- The active substance is oxymetazoline hydrochloride.
1 ml contains:
Nezebi 0.5 mg/ml nasal spray: 0.5 mg oxymetazoline hydrochloride.
- The other ingredients are dexpanthenol, disodium edetate (E386), sodium dihydrogen phosphate dihydrate (E339), disodium phosphate dihydrate (E339), sodium chloride and purified water.

Nezebi nasal spray is free of preservatives. Therefore, for technical reasons, the bottle is not completely filled.

What Nezebi looks like and contents of the pack

Nezebi 0.5 mg/ml nasal spray, solution is a clear, colourless to slightly coloured solution in a 7.5 ml plastic bottle (HDPE) and contains a nasal applicator with a dosing spray pump.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden	Nezebi
Poland	Xylorin Protect

This leaflet was last revised in 2024-05-02