

PACKAGE LEAFLET

NAZETIN 0.14 mg/spray nasal spray, solution

For spraying into the nose.

- **Active substance(s):** Each spray (0.14 ml) contains 0.14 mg azelastine hydrochloride.
- **Excipient(s):** Disodium EDTA, hydroxypropylmethyl cellulose, disodium monohydrogen phosphate dodecahydrate, citric acid monohydrate, sodium chloride, sucralose and purified water.

Read this PATIENT INFORMATION 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

What is in this leaflet:

- 1. What NAZETIN is and what it is used for?**
- 2. What you need to know before you use NAZETIN?**
- 3. How to use NAZETIN**
- 4. Possible side effects**
- 5. How to store NAZETIN**

1. What NAZETIN is and what it is used for?

- NAZETIN is an anti-allergic nasal spray presented in glass bottles containing 10 ml and 20 ml of clear solution.
- NAZETIN contains 0.14 mg azelastine hydrochloride per spray as an active ingredient.
- Azelastine is an anti-allergic drug used to relieve allergy symptoms.
- NAZETIN is used in the treatment of symptoms of seasonal and non-seasonal (year-round) allergic rhinitis (nasal itching, sneezing, nasal congestion, nasal discharge) and in the treatment and prevention of permanent discharge and congestion in the nasal mucosa (vasomotor rhinitis).

2. What you need to know before you use NAZETIN?

Consult your doctor or pharmacist before using any medicines.

Do not use NAZETIN in the following conditions:

- If you have hypersensitivity (allergy) to azelastine hydrochloride or any of the excipients of NAZETIN
- in children under 6 years of age

NAZETIN with food and drink

No interactions with food and drink have been reported to date. However, as a general rule, drinking alcohol should be avoided during medical treatment.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

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

Although it does not show any harmful (toxic) effects on the fetus in laboratory animals even at doses much higher than the doses used for treatment, the current medical approach is that NAZETIN should not be used in the first trimester of pregnancy.

Your doctor will decide on the use of NAZETIN during pregnancy.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

Since there is not enough clinical experience regarding the safety of this medicine during breastfeeding, do not use NAZETIN during breastfeeding.

Driving and using machines

While using NAZETIN, fatigue, weariness, exhaustion, dizziness or weakness may occur in individual cases due to the condition itself. If you have similar complaints, your ability to drive and use machines may be affected. You should take special care, as these effects may increase with alcohol and other drugs that have an adverse effect on reaction time to stimuli. You should be careful when driving and using machine.

Important information about some of the ingredients of NAZETIN

No effect is expected against the excipients in NAZETIN.

Other medicines and NAZETIN

No interactions with other medicines have been reported.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use NAZETIN?

- **Instructions for use and dosage/frequency of administration:**

NAZETIN should always be used as recommended by your doctor or pharmacist.

Check with your doctor or pharmacist if you are not sure.

Unless otherwise recommended by the doctor, the recommended use is as follows:

One spray of NAZETIN nasal spray into each nostril twice daily (morning and evening; total daily dose equivalent to 0.56 mg azelastine hydrochloride).

In the treatment and prevention of permanent discharge and obstruction (vasomotor rhinitis) in the nasal mucosa, 2 sprays are sprayed into each nostril twice a day.

- **Route of administration and method:**

Apply NAZETIN with your head in an upright position (Follow the figures and instructions below).



Figure 1: Remove the protective cap.

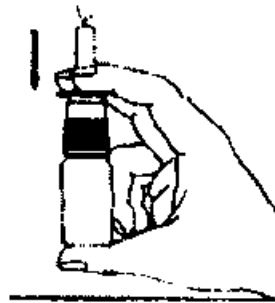


Figure 2: When using only for the first time, press the pump several times until some solution comes out.



Figure 3: While your head in an upright position, apply one spray into each nostril. Put the protective cap back on.

Duration of treatment:

The duration of treatment with NAZETIN depends on the type, severity and course of the complaints.

NAZETIN can be used for long term treatment.

- **Different age groups**

Use in children:

Do not use NAZETIN on children younger than 6 years old. It is used in children aged 12 years and above in the treatment and prevention of permanent discharge and obstruction (vasomotor rhinitis) in the nasal mucosa.

Use in elderly (65 years and older):

There are no special precautions for use in the elderly. You can use it in normal doses.

- **Special cases of use:**

There is no special use.

If you have impression that the effect of NAZETIN is very strong or weak, tell a doctor or pharmacist.

If you use more NAZETIN than you should:

If you take more NAZETIN than you should, tell your doctor or pharmacist.

NAZETIN is used locally in the nose. Even in the case of local overdose, no symptoms of intoxication are to be expected since the active substance content is very low. However, medical assistance should be provided if large amounts are used outside of its intended use (for example, swallowing the entire solution in the bottle by a child). If the overdose is very recent, gastric lavage is recommended.

There is no experience with the administration of toxic doses of azelastine hydrochloride in humans. In very high doses or poisoning, central nervous system symptoms (dizziness, confusion, loss of consciousness, fast heartbeat, low blood pressure) may be expected based on the results of animal experiments. Therefore, the treatment of these disorders should be symptomatic.

If you forget to use NAZETIN:

No particular measures are to be taken. Continue your treatment by taking the next dose at the usual time. If necessary, you can use NAZETIN between two application times.

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

If you stop using NAZETIN:

Continue your treatment with NAZETIN regularly until your symptoms are relieved.

If you stop using NAZETIN, typical symptoms of your condition may reappear in a short time.

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

4. Possible side effects?

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

Side effects were listed by frequency as following:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

If you notice any of the followings stop taking NAZETIN and immediately inform your doctor or go to the nearest emergency department:

- Hypersensitivity reactions

These are all very serious side effects. If you have one of these, it means you have a serious allergy to NAZETIN. You may need emergency medical intervention or hospitalization.

All of these very serious side effects are very rare.

Other side effects:

Common:

- Incorrect method of application (tilting the head too far backwards during administration, see 3. How to use NAZETIN) may cause bitter taste that may rarely cause nausea.

Uncommon:

- Irritation (stinging, itching) in inflamed nasal mucosa, sneezing and nosebleeds when spray is applied.

Rare:

- Nausea

Very rare:

- Rash
- Itching
- Hives (urticaria)
- Fatigue, dizziness or weakness may also be caused by the condition itself

The mentioned side effects are usually temporary. Therefore, there will be no need to take any particular measures.

If you feel a bitter taste in your mouth after using NAZETIN, you can drink a drink such as alcohol-free fruit juice or milk to remove this bitter taste.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via clicking “Reporting of Drug Side Effects” icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store NAZETIN?

Keep in the original package and out of the reach and sight of children.

Store at room temperature below 25 ° C. Do not store in the refrigerator (below +8 ° C).

If it is accidentally stored at a temperature below +8 ° C like a refrigerator for a long time, the active substance of NAZETIN starts to crystallize to a certain extent. These crystals will become visible when you hold the bottle against the light. Do not use such a solution.

However, if you leave the solution at room temperature for a few hours, the crystals will disappear completely, you can reuse this clear solution.

Use in accordance with expiry date.

Do not use this medicine after the expiry date which is stated on the packaging.

Duration of use after opening:

Do not use NAZETIN for more than 6 months after the bottle is first opened.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization Holder:

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