

PACKAGE LEAFLET: INFORMATION FOR THE USER

TAFEN NASAL

50mcg nasal spray, suspension

BUDESONIDE

• 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.

• 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 •

What is in this leaflet?

1. What TAFEN NASAL is and what it is used for
2. Before you take TAFEN NASAL
3. How to take TAFEN NASAL
4. Possible side effects
5. How to store TAFEN NASAL

1. WHAT TAFEN NASAL IS AND WHAT IS IT USED FOR

TAFEN NASAL contains Budesonide, corticosteroids. Corticosteroids are a group of medicines that have a strong local and weak systemic effect.

TAFEN NASAL is used for

- allergic rhinitis (the internal part of the nose is inflamed and irritated)
 - vasomotor rhinitis (inflammation of the nasal mucosa of non-allergic origin)
- nasal polyps (benign formations on the mucous membranes of the nose).

2. BEFORE YOU TAKE TAFEN NASAL

Do not take TAFEN NASAL

- If you are hypersensitive (allergic) to Budesonide or to other ingredients of this medicine

Take special care with TAFEN NASAL

- If you are a child and are taking high doses of this medicine for a long time, the doctor will regularly check your height

- If you have a fungal, bacterial or viral infection of the airways, which require appropriate treatment
- If your doctor said that you have tuberculosis (bacterial infection that usually affects the lungs)
- There are potential, although less frequently than in relation to medicines from the group of corticosteroids that are taken by mouth, side effects such as Cushing's syndrome (a disorder that occurs due to excessive amounts of hormones produced by the adrenal cortex) with all its features (high blood pressure, round, plethoric face, osteoporosis, increased body hair, thin skin, difficulty in wound healing, menstrual irregularities in women, accumulation of fluid / edema /)
- If you have severe liver disease, because it may cause undesired side effects of corticosteroids

Taking other medicines

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

Please tell your doctor if you are taking:

- Ketoconazole or itraconazole (medicines used to treat fungal infections)
- Hormonal birth control pills.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

If you are pregnant or if there is a possibility of pregnancy, if you are breast-feeding, consult your doctor before using this medicine.

The use of TAFEN NASAL is not recommended during pregnancy or breastfeeding.

Driving and using machines

TAFEN NASAL has no effect on the ability to drive a car or operate machinery.

TAFEN NASAL contains potassium sorbate which may cause skin reactions (eg, contact dermatitis).

3. HOW TO TAKE TAFEN NASAL

Always use TAFEN NASAL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage

The medicine is intended for adults and children over 6 years.

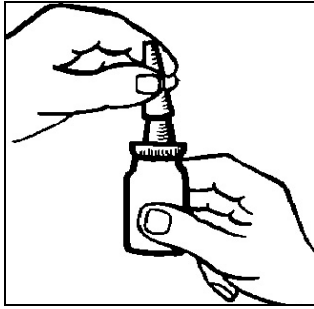
The usual starting dose is 2 sprays of 50 mcg of budesonide in each nostril twice daily. After improvement, the doctor will prescribe a maintenance dose, which is typically 1 spray in each nostril twice a day or 2 sprays in each nostril once daily in the morning. The maintenance dose should be the lowest effective dose, which prevents symptoms.

The dosage should be determined individually for each patient.

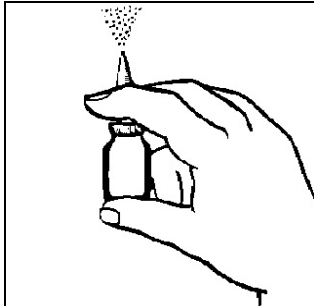
Patients should be informed that the full effect of TAFEN NASAL is achieved after several days of treatment.

The medicine should be used regularly.

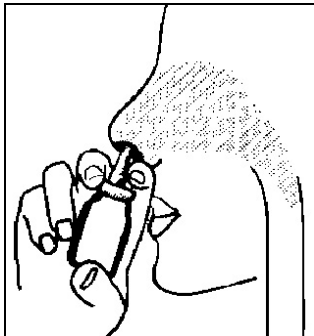
1. Gently blow your nose to clear it of mucus before using the medicine.
2. Remove the cap. Shake the bottle. The first time you use the pump spray each day, you may have to "prime" it, squirting a few times into the air until a fine mist comes out.



3. Tilt your head forward slightly. Breathe out slowly.
4. Hold the pump bottle with your thumb at the bottom and your index and middle fingers on top. Use a finger on your other hand to close your nostril on the side not receiving the medicine.



5. Squeeze the pump as you begin to breathe in slowly through your nose. Repeat these steps for the other nostril. If you are using more than one spray in each nostril, follow steps 2 through 5 again.



6. Clean the sprayer with a clean cloth (handkerchief) and put the cover cap.
7. Keep the bottle in an upright position.

Cleaning TAFEN NASAL

You should regularly clean plastic sprayer, or if it is clogged. If this happens, first check whether the dispenser is filled with medicine (see previous part of the text). If after filling the sprayer does not pump well, clean the sprayer following the instructions below:

- Remove the plastic sprayer with a tissue and wash in warm, not hot, water.
- Rinse the sprayer thoroughly, dry it and then back again to the top of the bottle.
- Never try to unblock the sprayer with a needle or other sharp object.

After cleaning the sprayer must be recharged (ie. filled with medicine) before use.

If you use more TAFEN NASAL than you should

If you take more TAFEN NASAL than necessary, continue to take the usual doses. In the case of occasional overdose, you probably will not experience any health problems.

However, if you are taking higher doses for a long time, immediately contact your doctor.

If you forget to take TAFEN NASAL

If you forgot to apply TAFEN NASAL eye drops do it as soon as possible and then continue as usual. Do not apply double dose to make up for a forgotten dose.

Do not stop taking TAFEN NASAL, even if you feel better, unless your doctor told you to.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **TAFEN NASAL** can cause side effects, although not everybody gets them.

Uncommon serious side effects (affecting 1-10 out of 1,000 users):

- swelling of the lips, face, throat

You should immediately contact a doctor if you notice these serious side effects. It could be an allergic reaction.

Other possible side effects

Common side effects (affecting 1 to 10 of 100 patients) are:

- Irritation of mucous membranes of the nose
- Mild leakage of bloody secretions in the nose
- bleeding in the nose (epistaxis)

Uncommon side effects (affecting 1-10 out of 1,000 users) are:

- hives (itchy rashes that looks like nettle rash of annealing)
- rash
- itching
- inflammation of the skin with rash.

Rare side effects (affecting 1 to 10 users in 10,000) are:

- glaucoma (increased pressure in the eye)
- fogging of the eye lenses
- symptoms of systemic side effects of corticosteroids (growth problems and a negative impact on the function of the adrenal glands).

Very rare side effects (affecting less than 1 in 10,000 users) are:

- inflamed nose ulcers
- perforation of the membrane that separates the nostrils (nasal septum)
- anaphylactic reaction (sudden hypersensitivity reaction)

Reporting of suspected 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.

5. HOW TO STORE TAFEN NASAL

Keep out of the reach and sight of children.

Store below 25 °C.

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.

The shelf life of medicine is 2 years from the date of manufacture indicated on the packaging of the medicine.

6. FURTHER INFORMATION

What TAFEN NASAL contains

The active substance is budesonide. A single dose of nasal spray contains 50 micrograms of budesonide.

Other ingredients:

microcrystalline cellulose, disodium edetate, methyl parahydroxybenzoate, propyl parahydroxybenzoate, polysorbate 80, simethicone emulsion, propylene glycol, sucrose, hydrochloric acid (for pH control), purified water

What TAFEN NASAL looks like and contents of the pack

TAFEN NASAL is packed in glass bottles with sprayer for the nose and cap (glass bottles hydrolytic group III, polypropylene sprayer for the nose and cap of low density polyethylene)

Each bottle contains 200 doses of inhalation, and each inhalation contains 50 micrograms (mg) of budesonide.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Lek farmacevtska družba d.d., Verovškova 57, 1526 Ljubljana, Slovenia

Manufacturer of the medicinal product

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