

NASOBEC™ 50 micrograms AQUEOUS NASAL SPRAY
Beclometasone dipropionate

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.

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1. WHAT NASOBEC IS AND WHAT IT IS USED FOR

Nasobec contains beclometasone dipropionate, which belongs to a group of medicines called corticosteroids. Your medicine has anti-inflammatory properties.

Nasobec is used to prevent and treat:

- Inflammation in the lining of your nose (rhinitis) due to seasonal allergies, such as hayfever
- Inflammation in the lining of your nose (rhinitis) due to year round (perennial) allergies, such as animal allergies.

Nasobec can also be used to delay the recurrence of polyps after a nasal polypectomy.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NASOBEC

Do not use Nasobec if you:

- are allergic (hypersensitive) to beclometasone dipropionate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Nasobec if you:

- suffer from or have a history of tuberculosis
- suffer from a lowered resistance to disease (immunosuppression)
- have an infection in your nose
- have been taking steroids for a long time
- are switching to Nasobec from any systemic steroid treatments.

Contact your doctor if you experience blurred vision or other visual disturbances.

Children and adolescents

- Children or adolescents who are using Nasobec for prolonged periods may grow more slowly and your doctor will want to monitor their growth.
- Nasobec should **not** be used in the treatment of children **under the age of 6 years**.

Other medicines and Nasobec

- Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- Some medicines may increase the effects of Nasobec and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

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.

Driving and using machines

Nasobec is not expected to affect your ability to drive or operate machinery.

Nasobec contains benzalkonium chloride

This medicine contains the ingredient benzalkonium chloride, which is an irritant and may cause skin reactions.

3. HOW TO USE NASOBEC

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults (including the elderly) and Children over six years old

The recommended dose is either:

- **2 sprays into each nostril twice a day**, or if you prefer, **1 spray into each nostril 3 or 4 times a day**.
- Do not use more than 8 sprays in 24 hours.
- You will only start to feel better after you have been using your medicine for a few days.
- As you become better, your doctor may ask you to use a lower dose.
- It is very important to reduce your dose as soon as your symptoms are under control.

Tell your doctor if you have watery or itchy eyes. He or she may give you another medicine to treat your eyes.

Use in children

- Nasobec is **not recommended for use in children less than six years old**.

Before you use your nasal spray

1. If you are using your nasal spray for the first time, remove the clip (diagram A).
2. Shake the bottle gently and then remove the dust cap.
3. Hold the bottle upright with your thumb under the bottle and your index finger and middle finger on either side of the nozzle (diagram B).
4. To make sure your pump is working, test spray it into the air before you use it for the first time, and whenever you have not used it for a week or more. Hold the bottle away from you and press down until you can see a fine mist.

Using your nasal spray

5. Gently blow your nose.

6. Close one nostril by pressing your finger against it and place the nozzle of the spray in your other nostril. Tilt your head slightly so that the bottle is kept upright (diagram C).
7. Breathe in through your open nostril and, at the same time, press the nozzle once with your fingers to release the spray.
8. Breathe out through your mouth.
9. If you need to use a second spray, repeat steps 7 and 8.
10. Repeat steps 6, 7, 8 and 9, with your other nostril.

After using your nasal spray

- Wipe the nozzle with a clean tissue and put the dust cap back on.

Cleaning your nasal spray

- You should clean the pump at least once a week to stop it from getting blocked up. Gently press upwards on the white collar to pull the nozzle off (diagram D)
- Wash the nozzle and dust cap in warm water. Put them in a warm place to dry, but do not use too much heat. Put the nozzle and dust cap back on.

If you use more Nasobec than you should

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse. If you use more than 8 sprays in 24 hours, tell your doctor immediately.

If you forget to use Nasobec

If you forget to use your medicine at the right time, use it as soon as you remember, and then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop using Nasobec

Do not stop using your medicine without talking to your doctor first even if you feel better.

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.

Stop using the spray and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but a very rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor if you suffer from any of the following:

Rare side effects (affecting more than 1 person in 10,000 but less than 1 person in 1,000):

- an unpleasant smell or taste
- dry and irritated nose or throat
- nose bleeds or blood stained crusts in the nose
- blurred vision.

Other side effects that have been reported:

- eye problems such as glaucoma, raised intraocular pressure, clouding of the lens of the eye (cataracts), or a condition known as central serous retinopathy
- nose septum (the dividing partition in the nose) may become perforated.

Additional side effects in children and adolescents

Children or adolescents who are using Nasobec for prolonged periods may grow more slowly and your doctor will want to monitor their growth.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NASOBEC

Keep out of the sight and reach of children.

Store below 25°C. Keep the bottle in the outer carton.

Do not use Nasobec after it has been open for 3 months or after the expiry date that is stated on the outer packaging, whichever is sooner. 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nasobec contains:

- The active substance is beclometasone dipropionate. Each 100 mg spray contains 50 micrograms beclometasone dipropionate.
- The other ingredients are phenylethyl alcohol, benzalkonium chloride, polysorbate 80, microcrystalline cellulose and carmellose sodium, glucose anhydrous and purified water. Your medicine may also contain hydrochloric acid to adjust the pH.

What Nasobec looks like and contents of the pack:

- Nasobec is a nasal spray. The spray is a white opaque suspension, free from any visible matter.
- Each bottle of Nasobec contains 200 sprays.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva B.V., Swensweg 5, 2031GA Haarlem, Netherlands.

Manufacturer

Teva Czech Industries s.r.o., Ostravská 29, č.p. 305, 747 70 Opava – Komárov, Czech Republic.

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