

Nasobec™ Aqueous

50 micrograms 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

Nasobec Aqueous is used to treat and prevent the symptoms of allergic reactions to pollens (hayfever), house dust, and animal fur, such as itchy or runny nose and sneezing.

2 What you need to know before you use Nasobec Aqueous

Do not use Nasobec Aqueous

- if you are allergic 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 Aqueous if you:

- have an **infection** or **ulcers** in your nose.
- have recently had **surgery** or an **injury** to your nose.
- have had steroids for a long time, either as an injection or by your mouth.

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

Other medicines and Nasobec Aqueous

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

Some medicines may increase the effects of Nasobec Aqueous and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Nasobec Aqueous with food and drink

You can use Nasobec Aqueous at any time of day, with or without food.

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 Aqueous is not likely to affect you being able to drive or use any tools or machines.

Nasobec Aqueous contains benzalkonium chloride

This medicine contains 0.040 mg benzalkonium chloride in each 100 milligrams.

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.

3 How to use Nasobec Aqueous

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

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

Always shake well before use. Only use in the nose. Do not swallow.

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

The usual 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 eight sprays (400 micrograms) in 24 hours.

You will only start to feel better after you have been using your medicine for a few days.

Once your symptoms are under control your doctor will change your dosage to 1 spray into each nostril twice a day.

It is very important to reduce your dose as soon as your symptoms are under control.

If your symptoms then get worse, your dosage may then be increased back to the starting dose.

Do not use more than the recommended dose.

If you use high doses of Nasobec Aqueous

There are times when your doctor may need to adjust the dose of the steroid you are given or the way in which you take it. These times are:

- times of extreme stress
- during admission to hospital after a serious accident, injury or illness
- before or after a surgical operation.

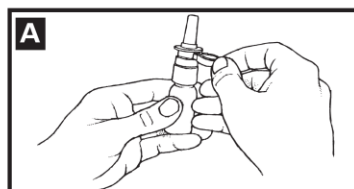
If you think that any of these apply to you whilst using Nasobec Aqueous, speak to your doctor or pharmacist.

Use in children less than six years old

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

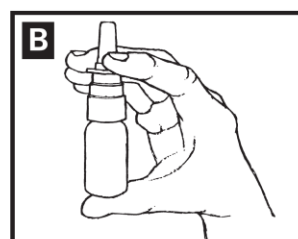
Before you use your nasal spray

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).

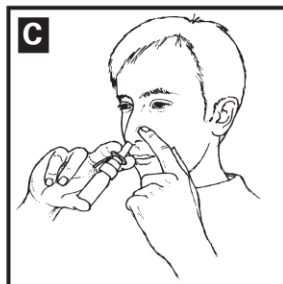


4. To make sure your pump is working, test spray it into the air before you use it for the first time, and

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.

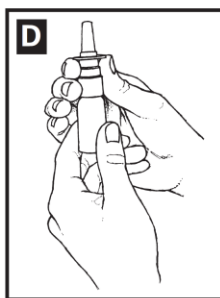
10. Repeat steps 6, 7, 8 and 9, with your other nostril.

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 Aqueous than you should

It is important that you take your dose as stated in the "How to use" section of this leaflet or as advised by your doctor. You should not exceed the recommended dose; 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 Aqueous

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 Aqueous

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 product, ask your doctor or pharmacist.

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Possible side effects

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

Allergic reactions: get a doctor's help straight away

A small number of people get allergic reactions to Nasobec Aqueous, which can develop into a more serious, even life-threatening problem if not treated. Symptoms include:

- becoming very wheezy or having difficulty with breathing
- swelling around the face or throat

If this happens, tell your doctor straight away – you may need urgent medical treatment.

Immediately after you use your spray

- You may sneeze a little, but this soon stops
- Very occasionally you may find you get an unpleasant taste or smell.

Tell your doctor as soon as possible if you notice any of the following side effects:

Common (may affect up to 1 in 10 people)

- A dry or painful nose or throat
- Bad nose bleeds
- Mild allergic reactions including skin rashes or redness, itching or weals like nettle rash or hives.

Rare (may affect up to 1 in 1,000 people)

- Blurred vision

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

- High pressure in your eye that may cause pain or blurred vision
- Clouding of the lens (cataract)
- The nose septum (the dividing partition in the nose) may become perforated

The following side effects may occur:

- Blood stained crusts in the nose

Very rarely, the normal production of steroids in your body may be affected. This is more likely to happen if you use high doses for a long time. Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms. In children this side effect can rarely cause them to grow more slowly than others, have sleeping problems, depression or feeling worried, restless, nervous, over excited or irritable. Children who receive this treatment for a long period of time will have their height checked regularly by their doctor.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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How to store Nasobec Aqueous

Keep this medicine out of the sight and reach of children.

Keep your medicine below 30°C in the original carton away from light. Do not put your medicine in the fridge.

Do not use this medicine after it has been open for 3 months or after the expiry date which 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 protect the environment.

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Contents of the pack and other information

What Nasobec Aqueous contains

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

What Nasobec Aqueous looks like and contents of the pack

Nasobec Aqueous is a nasal spray.

Each bottle of Nasobec Aqueous contains 200 sprays.

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

TEVA Czech Industries s.r.o., Opava, Czech Republic

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