

NASOBEC™ ALLERGY 50 MICROGRAMS AQUEOUS NASAL SPRAY

Beclometasone Dipropionate

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you start to take your medicine. It contains important information.

If you are not sure about anything, or if you want to know more, ask your pharmacist. Keep this leaflet safe, as you may want to read it again.

WHAT IS IN YOUR MEDICINE

Nasobec Allergy is a nasal spray, suspension. Each spray from the bottle contains:

- 50 micrograms of Beclometasone Dipropionate (active ingredient), and
- Phenylethyl alcohol, Benzalkonium Chloride, Polysorbate 80, Dispersible Cellulose, Dextrose Anhydrous and Purified Water (inactive ingredients). Your medicine may also contain Hydrochloric Acid to adjust the pH.

Each bottle of Nasobec Allergy contains 100 metered sprays.

WHO MAKES YOUR MEDICINE

The manufacturer of Nasobec Allergy is IVAX Pharmaceuticals s.r.o., Ostravska 29, 74770 Opava 9, Czech Republic and Norton Waterford T/A IVAX Pharmaceuticals Ireland, Unit 301, IDA Industrial Park, Cork Road, Waterford, Ireland.

The marketing authorisation holder is Norton Waterford T/A IVAX Pharmaceuticals Ireland, Industrial Park, Waterford, Ireland.

WHAT YOUR MEDICINE DOES

Nasobec Allergy contains beclometasone dipropionate, which is one of a group of medicines called corticosteroids. Nasobec Allergy is not the same as anabolic steroids which some body-builders and athletes use to increase their performance.

Your medicine has anti-inflammatory properties. The small amounts of drug sprayed into your nose may help to reduce swelling and irritation. It helps to treat and prevent the symptoms of hayfever and other seasonal allergic reactions, such as blocked, itchy or runny nose, and sneezing. When your nose is clear, this will ease the pressure and pain around your nose and eyes. Nasobec Allergy should be used every day for maximum relief, since it takes a few days to build up to give maximum effect.

BEFORE YOU TAKE YOUR MEDICINE

- Do not take this medicine if you:
- are allergic to medicines containing

beclometasone dipropionate, or any of the other ingredients listed in the 'What is in your medicine' section.

Please tell your pharmacist or doctor before you take this medicine if you:

- are pregnant, may become pregnant or are breast-feeding;
- have an infection in your nose or sinuses;
- have recently been treated with a steroid injection or taken steroid tablets for a long time;
- are taking other medicines including ones that you have bought for yourself without a prescription.

HOW TO TAKE YOUR MEDICINE

For nasal use.

Nasobec Allergy can be used by adults 18 years and over. It is not recommended for children or adolescents under 18 years.

When you first start using Nasobec Allergy take two sprays in each nostril twice a day. If you prefer take one spray in each nostril 3 or 4 times a day.

Once your symptoms are under control you should change your dosage to one spray into each nostril twice a day.

Do not take more than eight sprays in 24 hours.

You will only start to feel better after you have been taking your medicine for a few days. Therefore, to prevent the onset of symptoms start to use Nasobec Allergy two or three days before you would expect your symptoms to develop.

If your symptoms have not improved after 14 days consult your doctor.

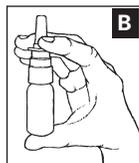
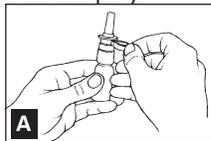
Do not use continuously for longer than 3 months without consulting your doctor.

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

BEFORE YOU USE YOUR NASAL SPRAY

Ask your pharmacist if you have any problems understanding the instructions on how to use and clean 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 take a second spray, repeat steps 7 and 8.
10. Repeat steps 6, 7, 8, 9, with your other nostril.

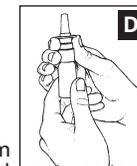


AFTER USING YOUR NASAL SPRAY

- 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.
- Don't use a pin or other sharp object to unblock or make the spray hole bigger because this will destroy the spray mechanism.



WHAT TO DO IF YOU TAKE TOO MUCH MEDICINE

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 or pharmacist recommends; using more or less may make your symptoms worse. If you have regularly taken more puffs than recommended, please tell your pharmacist as soon as possible.

IF YOU FORGET TO TAKE A DOSE

If you forget to take a dose at the right time, take it as soon as you remember, and then carry on as before.

WHAT MIGHT HAPPEN WHILE YOU ARE TAKING YOUR MEDICINE

You may have some side effects while you are taking your medicine. You may sneeze a little after using this spray but this soon stops.

Some people are allergic to medicines. Stop taking this medicine if you develop a rash or swelling or sudden wheeziness, chest pain or tightness and tell your pharmacist or doctor immediately.

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

- Dry and irritated nose or throat;
- An unpleasant smell or taste;
- Nosebleeds;
- High pressure in your eye that may cause pain or blurred vision.

Very rarely the nose septum (the dividing partition in the nose) may become perforated.

If you feel unwell in any other way, tell your doctor or pharmacist as soon as you can.

Using Nasobec Allergy will not make you feel drowsy, so your ability to drive or work machinery is unaffected. You can still drink alcohol while you are using Nasobec Allergy.

LOOKING AFTER YOUR MEDICINE

Throw your medicine away after it has been open for 3 months or after the expiry date (written as "Exp:" on the outer carton and label) whichever is sooner. The expiry date refers to the last day of that month.

- Do not store above 25°C. Keep bottle in the outer carton in order to protect from light.
- Do not refrigerate or freeze.
- **Keep all medicines out of the reach and sight of children.**

OTHER INFORMATION

This medicine is only for you. Never give it to anyone else.

This information only applies to Nasobec™ Allergy 50 micrograms Aqueous Nasal Spray which is distributed by the MA holder: Norton Waterford T/A IVAX Pharmaceuticals Ireland, Industrial Park, Waterford, Ireland.

Nasobec is a trademark.

PA number 436/28/2

This leaflet was revised in May 2011.