

Package leaflet: Information for the user

BECONASE HAY FEVER NASAL SPRAY Beclometasone Dipropionate 50 micrograms per spray

- 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.
- 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.

What is in this leaflet:

1. What BECONASE HAY FEVER is and what it is used for
2. What you need to know before you use BECONASE HAY FEVER
3. How to use BECONASE HAY FEVER
4. Possible side effects
5. How to store BECONASE HAY FEVER
6. Contents of the pack and other information

1. WHAT BECONASE HAY FEVER IS AND WHAT IT IS USED FOR

BECONASE HAY FEVER is used to prevent and treat the common symptoms of allergic rhinitis, including HAYFEVER such as sneezing and a runny, itchy or blocked-up nose. The active ingredient is beclometasone dipropionate, a corticosteroid which, when used every day, has an anti-inflammatory action and works in a similar way to natural body chemicals to control inflammation. This nasal spray helps to control your body's reactions to allergens ('triggers') in the environment.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BECONASE HAY FEVER

Do not use BECONASE HAY FEVER:

- if you are allergic to beclometasone dipropionate or any of the other ingredients of this medicine (listed in Section 6)
- if you are under 18 years

Warnings and precautions

- Talk to your doctor or pharmacist before using BECONASE HAY FEVER if you have an infection or ulcers in your nose, or you have recently had surgery or an injury to your nose.
- If your symptoms do not improve within 14 days, talk to your doctor or pharmacist.
- Do not use for more than 3 months unless your doctor tells you to.
- Contact your doctor if you experience blurred vision or other visual disturbances.

This medicine contains 20 micrograms benzalkonium chloride in each spray. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

Other medicines and BECONASE HAY FEVER

- Talk to your doctor or pharmacist before using this medicine if you are taking any prescribed medicines; particularly corticosteroid medicines (including eczema creams, asthma inhalers, tablets, injections, nasal sprays, and eye or nose drops).
- 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 Beconase Hayfever 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.

3. HOW TO USE BECONASE HAY FEVER

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

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

BECONASE HAY FEVER Relief quickly starts to reduce inflammation and swelling in your nose, although it may take 2 or 3 days to build up to its maximum protective effect. You should use the spray regularly to get the best results from it.

Adults aged 18 years and over:

Spray two puffs into each nostril every morning and evening.

Once your symptoms have improved, you may be able to reduce the dose to one spray into each nostril every morning and evening.

Do not use more than 8 sprays (400 micrograms) in a day.

- Use the lowest dose possible to control your symptoms.
- If your symptoms do not improve with 7 days, talk to your doctor or pharmacist.
- Do not use more than the recommended dose.

If you use too many sprays

Tell your doctor.

If you forget to use the spray

Take your next dose at the usual time. Never take two doses together.

Before using a new bottle of BECONASE HAY FEVER:

- Your BECONASE HAY FEVER spray has a dust cap which protects the nozzle and keeps it clean. Remember to take it off before you use the spray. [Picture 1]
- Before you start to use a new bottle of BECONASE HAY FEVER, or if you have not used the spray for a few days, press the pump down several times until you get a fine spray.
- Hold the bottle as shown with your forefinger and middle finger on the collar either side of the nozzle and your thumb underneath the bottle.
- Keeping your thumb still, press down with your fingers to pump the spray. [Picture 2]
- When doing this make sure you do not point the nozzle at yourself or someone else.
- If the spray still doesn't work, try to clean it as described under the 'To clean the spray' section. Do not try to unblock or enlarge the tiny spray hole with a pin or other sharp objects because this will destroy the spray mechanism.

Using BECONASE HAY FEVER:

1. Shake the bottle well and remove the dust cap.
2. Blow your nose gently.
3. Close one nostril as shown and put the nozzle in the other nostril. Tilt your head forward slightly and keep the bottle upright. Hold the bottle as shown. [Picture 3]
4. Start to breathe in slowly through your nose. While you are breathing in, squirt a spray of fine mist into your nostril by pressing down firmly on the collar with your fingers.
5. Breathe out through your mouth. Repeat step 4 to take a second spray in the same nostril.
6. Remove the nozzle from this nostril and breathe out through your mouth. [Picture 4]
7. Repeat steps 3 to 6 for the other nostril. [Picture 5]
8. After using the spray, wipe the nozzle carefully with a clean tissue or handkerchief and replace the dust cap.

To clean the spray:

1. Take the dust cap off.
2. Pull upwards on the white collar to remove the nozzle [Picture 6]
3. Soak the nozzle and dust cap in warm water for a few minutes and then rinse under a running tap.
4. Shake off the excess water and allow to dry in a warm place – not too hot!
5. Re-fit the nozzle.
6. If necessary, press the pump down several times until you get a fine spray

4. POSSIBLE SIDE EFFECTS

Like all medicines, BECONASE HAY FEVER can cause side effects, although not everybody gets them:

Stop taking the medicine and seek immediate medical help if you experience:

- Allergic reactions. These may include developing a rash, swelling of the mouth or face or having difficulty breathing.

Stop taking the medicine and tell your doctor if you experience:

- Eye problems such as pain or blurred vision.
- Nasal problems such as pain and/or persistent bleeding.

The following side effects may occur:

- Sneezing after using the spray but this soon stops.
- You may notice an unpleasant taste or smell.
- Nose bleeds or irritation in the nose or throat.
- Blurred vision: Frequency 'rare' (may affect up to 1 in 1,000 people).

It is important to follow the dose instructions shown in Section 3.

Using BECONASE HAY FEVER Relief at higher doses or for longer than 1 month at a time can cause a number of changes in your body such as catching infections more easily. If you do get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 BECONASE HAY FEVER

- Keep this medicine out of the sight and reach of children. Do not use this medicine after the 'EXP' date which is stated on the pack.
- Keep the container in the outer carton to protect from light.
- Do not store above 25°C (77°F). Do not store in a fridge.

Use within three months of first use.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What BECONASE HAY FEVER contains

- The Active substance is Beclometasone Dipropionate. Each spray contains 50 micrograms.
- The other ingredients are Microcrystalline cellulose, sodium carboxymethylcellulose, dextrose, polysorbate 80, purified water, benzalkonium chloride and phenylethyl alcohol.

What BECONASE HAY FEVER looks like and contents of the pack

A plastic bottle containing 100 sprays.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is

Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland and all enquiries should be sent to this address.

The manufacturers are

Richard Bittner AG, Ossiacherstraße 7, 9560 Feldkirchen, Austria.

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The information in this leaflet only applies to BECONASE HAY FEVER.