

Benacort® Hayfever Relief for Adults 64 micrograms, Nasal Spray

Budesonide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- Talk to a doctor or pharmacist if you do not feel better or if you feel worse after 7 days.
- The full name of the medicine is Benacort® Hayfever Relief for Adults 64 micrograms, Nasal Spray. For the rest of the leaflet it will be referred to as “Benacort® Hayfever Relief”.

In this leaflet:

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

1 What Benacort® Hayfever Relief is and what it is used for

This nasal spray contains a medicine called budesonide. This belongs to a group of steroid medicines called ‘corticosteroids’.

- Corticosteroids help to reduce inflammation.
- This nasal spray is used to treat adults with inflammation in the nose caused by an allergy to pollen (hayfever). Symptoms may include sneezing and/or a runny, itchy or blocked nose.
- Regular use of this nasal spray can reduce inflammation in the nose and help relieve these symptoms.

If your allergy is also causing eye problems, you may need to take another medicine as well.

2 What you need to know before you use Benacort® Hayfever Relief

This medicine is suitable for most people, but a small number of people should not use it. If you are unsure, talk to your doctor or pharmacist.

Do not use Benacort® Hayfever Relief if:

- you have ever had a bad reaction to budesonide or any of the other ingredients of this medicine (listed in section 6)
- you are under 18 years of age
- you are taking HIV medicines (such as atazanavir, indinavir, nelfinavir, ritonavir, saquinavir or cobicistat-containing products).

Warnings and Precautions

Talk to your pharmacist or doctor before using Benacort™ Hayfever Relief if:

- you have had recent nose ulcers, nose surgery or you have a nose injury that has not healed properly
- you get heavy or frequent nose bleeds
- you have TB (tuberculosis), a chest infection, chicken pox or measles, or you have been in contact with somebody who has TB, chicken pox or measles
- you have ever had increased pressure in the eye (glaucoma), or cataracts
- you have an eye infection
- you have diabetes
- you have liver problems.

Talk to your pharmacist or doctor if you get any of the following while using Benacort® Hayfever Relief:

- blurred vision or other visual problems
- any signs of an infection, such as a fever that won't go away.

Operations or during times of stress

Tell your doctor that you are using Benacort® Hayfever Relief if:

- you are about to have an operation or during times of stress. Your doctor may ask you to take steroid tablets as well, particularly if you have been taking a high dose of this nasal spray, or a similar medicine, for a long time.

Other medicines and Benacort® Hayfever Relief

Do not use Benacort® Hayfever Relief if:

- you are taking HIV medicines (such as atazanavir, indinavir, nelfinavir, ritonavir, saquinavir or cobicistat-containing products).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Benacort® Hayfever Relief can affect the way some medicines work, and some medicines can have an effect on Benacort® Hayfever Relief. So, your doctor may wish to monitor you carefully. In particular talk to your doctor or pharmacist if:

- you are taking medicines to treat fungal infections (such as itraconazole or ketoconazole).
- you are taking antibiotics (such as clarithromycin).
- you are taking oestrogens such as hormone replacement therapy or contraceptives (‘the pill’).
- you are taking, or have recently taken another corticosteroid medicine (including eczema creams, asthma inhalers, tablets, injections, nasal sprays, eye or nose drops).

Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your pharmacist or doctor for advice before using this medicine.
- If you get pregnant while using Benacort® Hayfever Relief, talk to your doctor straight away.

Driving and using machines

Benacort® Hayfever Relief may cause blurred vision. If affected, do not drive or use any machinery.

Some ingredients can cause problems

This product contains Potassium sorbate (E202) which may cause local skin reactions, (e.g. contact dermatitis).

3 How to use Benacort® Hayfever Relief

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

How much Benacort® Hayfever Relief to use

The recommended starting dose is two sprays into each nostril in the morning. Once your symptoms improve, you may be able to reduce this to one spray in each nostril in the morning. However, if your symptoms return, you can go back to the original starting dose.

- Do not use more than 4 sprays in a day.
- Only use in the nose.
- Do not swallow.

How long to use the nasal spray for

Use this nasal spray regularly. Keep using it until you are no longer exposed to whatever is causing your allergy.

- You may not feel the medicine working for the first few days. It takes a few days to feel the full protective effect of this nasal spray,
- Talk to a doctor or pharmacist if you do not feel better, or if you feel worse after 7 days.
- Do not use this nasal spray continuously for longer than 1 month, unless your doctor tells you to.

Use in children

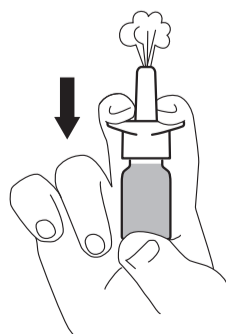
Benacort® Hayfever Relief should not be used in children and adolescents under 18 years.

Instructions for use

1. Priming the nozzle

Before using this nasal spray for the first time you must prime the nozzle (this means, fill it with the medicine). To do this:

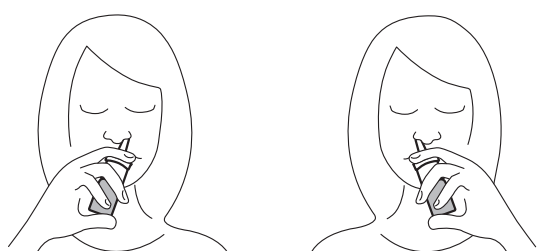
- a) Shake the bottle and remove the protective cap.
- b) Hold the bottle upright as shown in the picture.
- c) Pump the nozzle up and down 5 to 10 times, spraying into the air until you see an even mist.



The priming effect remains for about 24 hours. If you leave a gap of more than a day before the next dose, you will need to prime the nozzle again. This time, spray into the air just once.

2. Using Benacort® Hayfever Relief

- Blow your nose.
- Shake the bottle. Then, remove the protective cap.
- Hold the bottle as shown in the picture.
- Put the tip of the nozzle into one nostril, as shown. To avoid the risk of injury, direct the nozzle to the side of the nose, and away from the middle of the nose (the 'nasal septum'). Spray once or twice depending on your required dose. Use the spray in the other nostril in the same way — note, you do not need to breathe in at the same time as you spray.
- Wipe the nozzle with a clean tissue and replace the protective cap
- Store the bottle upright**



3. Cleaning the nozzle

It is best to clean the plastic nozzle of this nasal spray regularly. Also clean it if you notice that the spray is not coming out as it should. If this happens, first check the nozzle is primed with medicine (see 'Priming the nozzle'). If after priming the nozzle again the pump is still not working, clean the nozzle as follows:

- Remove the plastic nozzle with a clean tissue and wash it in warm (not hot) water.
- Rinse the nozzle thoroughly, dry it, and then replace it on the top of the bottle.
- Never try to unblock the nozzle by using a pin or other sharp object.
- Prime the nozzle again (by filling it with medicine) before use.

If you use more Benacort® Hayfever Relief than you should

It is important that you take your dose as stated in this leaflet.

If you take too many doses of Benacort® Hayfever Relief, talk to your doctor or pharmacist straight away.

If you forget to use Benacort® Hayfever Relief

If you forget to take a dose, take it as soon as you remember. However, if it is almost time to take the next dose, wait until then. Do not take a double dose to make up for a forgotten dose.

4 Possible side effects

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

If any of the following happen to you, stop using Benacort® Hayfever Relief and get medical advice straight away:

- Sudden signs of an allergic reaction such as:
 - rash, itching, hives or redness of the skin
 - swelling of the face, lips, mouth, tongue or other parts of the body
 - shortness of breath, wheezing or difficulty in swallowing or breathing
 - feeling faint.

Other effects which may occur include:

Common (may affect up to 1 in 10 people)

- nasal irritation (sneezing, dry nose, or stinging in your nose). These can happen straight after using this nasal spray
- nose bleeds.

Uncommon (may affect up to 1 in 100 people)

- muscle cramps.

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

- hole in the wall between the nostrils (the nasal septum)
- nasal ulcers
- change in voice
- bruising
- blurred vision.

Other effects which may occur but it is unknown how often:

- glaucoma (increased pressure in the eye)
- cataract.

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 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.

5 How to store Benacort® Hayfever Relief

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton or label. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not freeze or store in the fridge.
- Store the bottle in an upright position.
- Use within 2 months of opening the bottle. You may find it helpful to write on this leaflet when you first open the bottle:

Date bottle opened

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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 Benacort® Hayfever Relief contains

- The active ingredient is budesonide. This nasal spray contains 64 micrograms of budesonide in each spray.
- The other ingredients are disodium edetate, potassium sorbate (E202), glucose (anhydrous), microcrystalline cellulose (E460), carboxymethylcellulose sodium (E466), polysorbate 80 (E433), hydrochloric acid and purified water.
- Each bottle of this nasal spray contains 60 sprays.

What Benacort® Hayfever Relief looks like and contents of the pack

Benacort® Hayfever Relief is a liquid nasal spray available in a 10ml brown glass bottle. Each bottle is fitted with a spray pump and contains 60 sprays.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder for Benacort® Hayfever Relief is McNeil Products Limited, Maidenhead, Berkshire, SL6 3UG, UK.

Benacort® Hayfever Relief is manufactured by McNeil AB, Norrebroplatsen 2, 251 09, Helsingborg, Sweden.

This leaflet was last revised: December 2020

More about Hayfever

Hayfever is thought to affect more than one in five people in the UK at some point in their lives.

What are the symptoms?

Symptoms of hayfever include sneezing, a runny, itchy or blocked nose and itchy eyes.

What are the causes?

Hayfever is caused when a person has an allergic reaction to pollen. When the tiny particles of pollen come into contact with your mouth, nose, eyes and throat, they cause an irritation and inflammation which triggers an allergic reaction.

Avoiding exposure

Try and stay indoors and avoid grassy areas when the pollen count is high. The pollen count is a measure of how much pollen is in the air and it's usually highest on hot, sunny days.