

Benacort® 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.
- You must talk to a doctor or pharmacist if you do not feel better or if you feel worse after 14 days.

What is in this leaflet

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

1. What Benacort® is and what it is used for

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

- Corticosteroids help to reduce and prevent inflammation.
- Benacort® is used to treat the symptoms of allergies to such things as pollen (hay fever) including sneezing, a runny, itchy or blocked-up nose.
- Regular use of this nasal spray can reduce inflammation in the nose and help prevent these symptoms.

2. What you need to know before you use Benacort®

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Do not use Benacort®:

- If you have ever had a **bad reaction** to budesonide or any of the other ingredients of this medicine (listed in section 6).
- If you are **under 18 years of age**.

Warnings and precautions**Talk to your doctor or pharmacist before using Benacort® if:**

- You have an **infection of your nose or sinuses**.
- You have had **recent nose ulcers or nose surgery** or you have a **nose injury** that hasn't 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 **glaucoma** (increased pressure in the eye), or **cataracts**.
- You have an **eye infection**.
- You have **diabetes**.
- You have **liver problems**.
- You are taking any **corticosteroid medicines** (including eczema creams, asthma inhalers, tablets, injections, nasal sprays, eye or nose drops).

If any of these apply to you, **get advice from a doctor or pharmacist without taking Benacort®**

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

- **Blurred vision** or other **visual disturbances**.
- Any signs of an **infection** such as a **persistent fever**.

Other medicines and Benacort®

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® can affect the way some medicines work and some medicines can have an effect on Benacort® and 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 **HIV medicines** (such as *atazanavir*, *indinavir*, *nelfinavir*, *ritonavir*, *saquinavir* or *cobicistat-containing products*).

- You are taking **oestrogens** such as **hormone replacement therapy or contraceptives** ('the pill').

- You are taking another **corticosteroid medicine** (including eczema creams, asthma inhalers, tablets, injections, nasal sprays, eye or nose drops).

- You have just stopped **corticosteroid tablets** such as **prednisolone**.

Pregnancy, breast-feeding and fertility

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- If you get pregnant while using this nasal spray, **talk to your doctor or pharmacist straight away**.

Driving and using machines

Benacort® may cause blurred vision. If affected, do not drive or operate 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®

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

How much Benacort® to use

Do not use more than two sprays into each nostril in a day.

Using the nasal spray once a day:

- The recommended dose is two sprays into each nostril in the morning.
- If your symptoms improve, reduce this to one spray into each nostril in the morning.

Using the nasal spray twice a day:

- If you prefer, you can use one spray into each nostril every morning and evening.
- If your symptoms improve, reduce this to one spray into each nostril in the morning.

When to start using the nasal spray

Try to start using this nasal spray before you come into, contact with whatever causes the allergy. For example, if it is a particular type of pollen that causes your hay fever, use this nasal spray before and during the time when you are exposed to it.

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.
- The full effect of treatments like this nasal spray are not achieved until after a few days of treatment. You therefore may not notice any effects for the first few days.
- If your symptoms are not controlled **after 14 days**, talk to your doctor or pharmacist.
- Do not use this nasal spray continuously for longer than 3 months.

Use in children

This nasal spray 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 (that is, fill it with the medicine). To do this:

- Shake the bottle and remove the protective cap.

- Hold the bottle upright as shown in the picture.

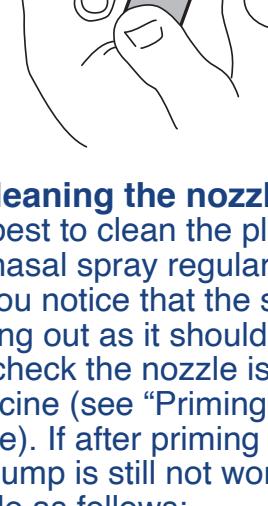
- Pump the nozzle up and down several times (5 to 10 times), spraying into the air until you see an even mist.



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 it into the air just once.

2. Using Benacort®

- **Blow your nose.** Shake the bottle. Remove the protective cap.
 - Hold the bottle as shown in the picture.
 - Put the tip of the nozzle into your nostril, as shown. Direct the nozzle to the side of the nose, and away from the middle of the nose (the 'nasal septum'). Spray once (or twice if using the nasal spray once a day). 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 in an upright position.**



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" above). 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.

Additional information about using Benacort®

- If you are about to have an operation or during times of **stress**, please tell your doctor that you use this nasal spray. 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.
- **Eye problems:** If your allergy is also causing eye problems, you may need to take another medicine as well.

If you use more Benacort® than you should

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

If you take too many doses of this nasal spray, talk to your doctor or pharmacist straight away.

If you forget to use Benacort®

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 this nasal spray 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 or 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)

- Corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. This is much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.
- Perforation of the membrane separating 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 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®

- 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. The expiry date refers to the last day of the 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 opened 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 protect the environment.

6. Contents of the pack and other information

What Benacort® 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 120 sprays.

What Benacort® looks like and contents of the pack

This nasal spray is a metered pump nasal spray. Benacort® is available in a 10ml amber/brown glass bottle. Each bottle is fitted with a spray pump and contains 120 sprays.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder for Benacort® is McNeil Products Limited, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Benacort® is manufactured by McNeil AB, Norrbroplatsen 2, 251 09 Helsingborg, Sweden.

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