

Package leaflet: Information for the user
Rhinocort® Aqua, 64 micrograms, Nasal Spray
Budesonide

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

In this leaflet:

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

1. What Rhinocort Aqua is and what it is used for

Rhinocort Aqua contains a medicine called budesonide. This belongs to a group of medicines called corticosteroids.

- Corticosteroids help to reduce and prevent inflammation.
- Rhinocort Aqua is used to treat the symptoms of allergies, such as hay fever, and rhinitis (inflammation inside the nose). Symptoms may include sneezing, a runny, itchy or blocked nose.
- Regular use of this nasal spray can reduce inflammation in the nose and help prevent these symptoms.
- It is also used to treat small growths inside the nose (nasal polyps).

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

2. What you need to know before you use Rhinocort Aqua

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 Rhinocort Aqua:

- 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 Rhinocort Aqua if:

- 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 Rhinocort Aqua**.

Talk to your doctor if you experience any of the following while using Rhinocort Aqua:

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

Other medicines and Rhinocort Aqua

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 Rhinocort can affect the way some medicines work and some medicines can have an effect, on Rhinocort

and your doctor may wish to monitor you carefully.

In particular talk to your doctor 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 breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.
- If you get pregnant while using Rhinocort Aqua, **talk to your doctor straight away**.

Driving and using machines

Rhinocort Aqua 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 Rhinocort Aqua

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Read the label to remind you of what they said.

How much Rhinocort Aqua to use Allergies such as hay fever

- The recommended dose for adults and the elderly is two sprays of Rhinocort Aqua into each nostril in the morning. Alternatively, your doctor may ask you to take one spray of Rhinocort Aqua into each nostril every morning and evening.
- This may be reduced by your doctor once your symptoms have improved.

It is important to use Rhinocort Aqua regularly. Try to use it **before** you come into contact with whatever causes the allergy. For example, pollen is what causes hay fever, so you will be more at risk outdoors.

Nasal polyps

- The recommended dose is one spray of Rhinocort Aqua into each nostril every morning and evening.

Treatment for allergies such as hay fever and for nasal polyps can continue for up to 3 months.

Use in children

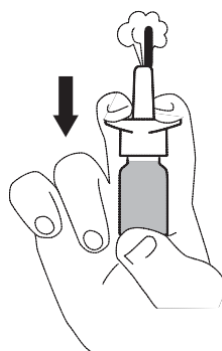
Rhinocort Aqua is not recommended for use in children.

Instructions for use

1. Priming the nozzle

Before using Rhinocort Aqua 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.

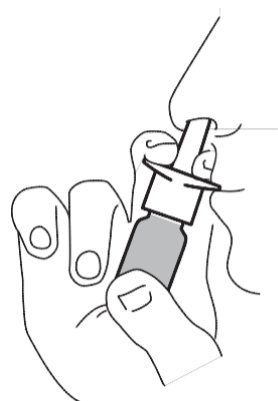


The priming effect remains for about 24 hours. If you leave a gap of more than a day before the next dose, you will need to prime the nozzle again. This time spray it into the air just once.

2. Using Rhinocort Aqua

- 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 Rhinocort Aqua 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 Rhinocort Aqua

- If you are about to have an **operation** or during times of **stress**, please tell the doctor that you use Rhinocort Aqua. The doctor may ask you to take steroid tablets as well, particularly if you have been taking a high dose of Rhinocort Aqua, 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.
- Long-term treatment:** If you use Rhinocort Aqua every day for a long time, your doctor will need to have a regular check of the inside of your nose (the nasal mucosa).
- Children and adolescents:** If a child or adolescent is prescribed Rhinocort Aqua and uses a high dose for a long time, the doctor will need to check how well they are growing.

If you use more Rhinocort Aqua than you should

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 recommends; using more, or less may make your symptoms worse.

If you take too many doses of Rhinocort Aqua, talk to your doctor or pharmacist straight away.

If you forget to use Rhinocort Aqua

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.

If you stop using Rhinocort Aqua

You may not notice any effects of the medicine for the first few days. Do not stop using this medicine. Keep taking the medicine as you have been told to. If your symptoms are not controlled **after 14 days**, talk to your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 Rhinocort Aqua 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 Rhinocort Aqua.
- Nose bleeds.

Uncommon (may affect up to 1 in 100 people)

- Muscle cramps.

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

- Slowing of the rate of growth of children and adolescents. 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 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 Rhinocort Aqua

- 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 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 to protect the environment.

6. Contents of the pack and other information

What Rhinocort Aqua contains

- The active ingredient is budesonide. Rhinocort Aqua 64 micrograms 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 Rhinocort Aqua contains 120 or 240 sprays.

What Rhinocort Aqua looks like and contents of the pack

Rhinocort Aqua is a metered pump nasal spray. Rhinocort Aqua is available in either a 10ml or 20 ml amber/brown glass bottle.

Each bottle is fitted with a spray pump and contains either 120 or 240 sprays. Not all pack sizes are marketed

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder for Rhinocort Aqua is McNeil Products Limited, Maidenhead, Berkshire, SL6 3UG, UK.

Rhinocort Aqua is manufactured by McNeil AB, Norrbroplatsen 2, 251 09 Helsingborg, Sweden.

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