

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

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 marketed in the UK and Malta is AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU.

Rhinocort Aqua is manufactured by AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

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RSP 14 0042

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Please be ready to give the following information:

Product name **Rhinocort Aqua, 64 micrograms, nasal spray**

Reference number 17901/0074

This is a service provided by the Royal National Institute of Blind People.



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 prevent inflammation.
- Rhinocort Aqua is used to treat the effects of allergies, such as hay fever, and inflammation inside the nose (rhinitis).
- It can also stop these effects from coming on.
- It is also used to treat small growths inside the nose (nasal polyps).

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

Do not use Rhinocort Aqua:

- If you are allergic to budesonide or any of the other ingredients of this medicine (listed in section 6).

If you are not sure if this applies to you, talk to your doctor or pharmacist before using Rhinocort Aqua.

Warnings and Precautions

Talk to your doctor or pharmacist before using Rhinocort Aqua if:

- You have TB (tuberculosis).
- You have a chest infection.

If you are not sure if either of the above apply to you, talk to your doctor or pharmacist before using Rhinocort Aqua.

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.

In particular, talk to your doctor if:

- You are taking medicines to treat fungal infections (such as itraconazole or ketoconazole).
- You have been taking steroid tablets. Your doctor may ask you to take fewer of them after starting to use Rhinocort Aqua. If you notice any unusual effects as a result of this, tell your doctor.
- You are taking oestrogens and contraceptive steroids.

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 is not likely to affect you being able to drive or use any tools or machines.

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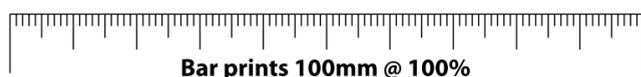


Technical Info



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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 older people 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

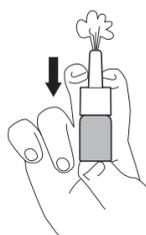
Rhinocort Aqua is not recommended for use in children.

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. Spray once (or more if the doctor has told you to). 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 you have an allergy which 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 use 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 you still feel no different after a few more 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 talk to your doctor straight away:

- Skin rash, itching, lumpy rash (hives), blistering of the skin. Swelling of your face, lips, tongue or throat (this may make it difficult to swallow). These are uncommon, affecting less than 1 in 100 people.
- In addition to the above, sudden wheezing and/or feeling faint may occur. It is not known how often these occur; however they are very unlikely.

If any of the above occurs, you may be having an allergic reaction.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Occasional sneezing, dry nose, or stinging in your nose. These can happen straight after using Rhinocort Aqua.
- Slight bleeding from the nose.

Rare (may affect up to 1 in 1000 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.

The above is much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

Very rare (may affect up to 1 in 10,000 people)

- Sore patches on the inside of the nose.
- Perforation of the membrane separating the nostrils (the nasal septum).
- Severe allergic reaction.

Not known (frequency cannot be estimated from the available data)

- Glaucoma (increased pressure in the eye).
- Cataract.

If any of these side effects occur, they usually go away after a short time.

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 (see details below). By Reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Malta

ADR Reporting

The Medicines Authority

Post-Licensing Directorate

203 Level 3, Rue D'Argens

GŻR-1368 Gżira

Website: www.medicinesauthority.gov.mt

E-mail: postlicensing.medicinesauthority@gov.mt

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