

PATIENT INFORMATION LEAFLET

Rhinocort Aqua 64mcg/dose nasal spray

budesonide

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What Rhinocort Aqua is used for

Rhinocort Aqua is used for running nose, nasal congestion, sneezing and/or itching in the nose caused by allergy and also for so-called vasomotor rhinitis where the cause may be e.g. smoke or perfume.

Rhinocort Aqua is also used for polyps in the nose and after surgery for polyps in order to reduce the risks of the development of new polyps.

How Rhinocort Aqua works

Rhinocort Aqua is a cortisone preparation that suppresses inflammation and allergic reactions in the nose.

Before you take Rhinocort Aqua

When you must not take it

Do not use Rhinocort Aqua if you are allergic (hypersensitive) to budesonide or to any of the other ingredients of Rhinocort Aqua.

Before you start to take it

Take special care with Rhinocort Aqua

- avoid Rhinocort Aqua coming into contact with the eyes. If you get it in your eyes, rinse them immediately with water.
- talk to your doctor before you start using Rhinocort Aqua if you have any of the following conditions:
 - fungal or herpes infection in the nose
 - tuberculosis
 - severe liver disease

Long-term treatment with high doses can cause serious cortisone side effects. In children this may manifest itself as retarded growth.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

How to take Rhinocort Aqua

How much to take

Always use Rhinocort Aqua exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

If you have seasonal allergic rhinitis (hay fever), you should try to start the treatment with Rhinocort Aqua a few days before the allergy season starts. You usually gain the full effect within a few days, but you may feel some relief after just a few hours. Use of Rhinocort Aqua by children should take place under the supervision of an adult so that the spraying is carried out correctly and that the dosage is in accordance with the doctor's prescription.

As it can be difficult to empty the bottle completely, it is overfilled. In this way it is ensured that the stated amount is supplied. i.e. 120 doses.

If your nose is blocked, you may use decongestant nasal drops for the first 2-3 days of treatment.

If allergy symptoms affecting your eyes bother you, your doctor may also give you other medication to relieve the symptoms.

Instructions for use



Before you use a new bottle of Rhinocort Aqua nasal spray, you must prime the pump by shaking the bottle and spraying into the air until there is an even mist.

If you do not use the nasal spray every day, the pump must be primed in the same way again, but this time it is sufficient to spray just once into the air.

1. Blow your nose.
Shake the bottle.
Remove the protective cap.
2. Hold the bottle as shown in the pictures.
3. Insert the tip into one nostril and spray the prescribed number of doses. Follow the same procedure for the other nostril.



4. Replace the protective cap.

Do not exceed the dosage!

When to take it

Use Rhinocort Aqua as prescribed by your doctor or pharmacist

How long to take it

Use Rhinocort Aqua as advised by your doctor or pharmacist

If you forget to take it

on occasion it is not necessary to make up for the missed dose. Take the next dose as usual.

If you take too much (overdose)

If you have used too much Rhinocort Aqua on a single occasion you should not experience any unpleasant effects. If you have any questions after taking too large a dose, always contact a doctor or hospital for assessment of the risk and advice.

While you are using Rhinocort Aqua

Things you must do

Use Rhinocort Aqua as advised by your doctor or pharmacist

Things you must not do

Do not stop using Rhinocort unless advised by your doctor or pharmacist

Things to be careful of

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Experience of use during pregnancy does not indicate any increased risk of malformations. Nevertheless, talk to your doctor if you use Rhinocort Aqua more than occasionally during pregnancy.

Budesonide passes into breast-milk. However, a risk of effects on the breast-fed infant is considered unlikely with therapeutic doses of Rhinocort Aqua. Rhinocort Aqua may be used while breast-feeding.

Driving and using machines

Rhinocort Aqua does not affect ability to drive or use machines.

Side effects

Like all medicines, Rhinocort Aqua can cause side effects, although not everybody gets them. The side effects that may occur are usually mild and last only a short time.

Common (more than 1 person in 100 is affected): Irritation in the nose, nose-bleeding.

Uncommon (fewer than 1 person in 100 is affected): Allergic swelling, rash, itching, nettle rash, inflammation in the skin, angioedema*.

Very rare (fewer than 1 person in 10,000 is affected): Ulcers on the nasal mucous membrane, perforation of the wall separating the nostrils, severe allergic reaction.

* Stop taking Rhinocort Aqua and contact a doctor immediately if you have any of the following symptoms (angioedema)

- swelling of the face, tongue or throat
- difficulties in swallowing
- nettle rash and breathing difficulties.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Storage and Disposal of Rhinocort Aqua

Keep out of the reach and sight of children.

Do not store above 30°C. Do not freeze.

Do not use after the expiry date, which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Product description

What Rhinocort Aqua looks like and contents of the pack:

Brown glass bottles with a spray pump and nasal applicator.

Pack size:

120 doses

Ingredients

The active substance is budesonide 64 micrograms/dose.

The other ingredients are microcrystalline cellulose, carmellose sodium, anhydrous glucose, polysorbate 80, disodium edetate, the preservative potassium sorbate (E 202) 0.06 mg, hydrochloric acid for adjustment of the pH and water.

The other ingredients are present in order to give the nasal spray the right properties.

Malaysian registration number:

Rhincort Aqua 64mcg/dose: MAL20000013A

Manufacturer

Manufactured by AstraZeneca AB, Södertälje, Sweden.

Date of revision

The text was revised in August 2011

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