RHINOCORT AQUA 64mcg/dose

Budesonide

What is in this leaflet

- 1. What RHINOCORT AQUA is used for
- 2. How RHINOCORT AQUA works
- 3. Before you use RHINOCORT AQUA
- 4. How to use RHINOCORT AQUA
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of RHINOCORT AQUA
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

What RHINOCORT AOUA is used for

RHINOCORT AQUA is used to relieves symptoms of seasonal or perennial allergic rhinitis (nasal congestion, runny nose, sneezing and itchy nose). It is also used for the treatment of allergic rhinoconjuctivitis (nasal congestion, runny nose, sneezing, itchy and watery eyes).

RHINOCORT AQUA is also used for treatment and prevention of nasal polyps after polypectomy and relieves vasomotor rhinitis.

How RHINOCORT AQUA works

RHINOCORT AQUA is a cortisone preparation that suppresses inflammation and allergic reactions in the nose.

Before you use RHINOCORT AQUA

- When you must not use it

Do not use

- If you are allergy to budesonide or to any of the other ingredients.
- If you are pregnant, trying to get pregnant or think you may be pregnant.
- If you are breast-feeding.
- <u>Before you start use it</u>

Consult your doctor if you:

- are using a steroid medicine for conditions such as asthma, allergies or skin rash.
- have ever been diagnosed with glaucoma (abnormally high pressure in the eye), cataract (cloudy areas in lens of the eye), or have an eye infection, or if you have diabetes.
- have or have been exposed to someone who has tuberculosis, chicken pox or measles.

- have severe or frequent nosebleeds, recent nose ulcers, nose surgery or have a nose injury that has not healed
- develop signs or symptoms of an infection such as persistent fever

Pregnancy and lactation

This product should not be used during pregnancy or lactation. Consult your doctor before use.

This product may slow the growth rate in some children when used in combination with other steroids.

Take special care with RHINOCORT AQUA

- 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

- 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 use RHINOCORT AOUA

- How much to use

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' prescription.

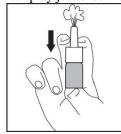
As it can be difficult to empty the bottle completely, it is overfilled. In this way it is ensured that the stated amount is supplied. i.e. 120 doses.

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

- Instruction 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. Administer the tip into the other nostril in the same way.



4. Replace the protective cap.
Do not use RHINOCORT AQUA more often than prescribed.

- When to use it

Use RHINOCORT AQUA as prescribed by your doctor or pharmacist.

- How long to use it
 Use RHINOCORT AQUA as advised by your doctor or pharmacist.
- If you forget to use it

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

If you use 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 it

Things you must do
 Use RHINOCORT AQUA as advised by your doctor or pharmacist.

Stop use and consult your physician if you have any changes in vision.

Consult your doctor or pharmacist if you develop signs or symptoms of an infection such as persistent fever.

Things you must not do
 Do not stop using RHINOCORT AQUA
 unless advised by your doctor or
 pharmacist.

Do not exceed the dosage.

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.

Things to be careful of

Avoid RHINOCORT AQUA come into contact with the eyes. If you get it in your eyes, rinse them immediately with water.

Driving and using machines
There is no evidence that RHINOCORT
AQUA has an effect on the 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.

Tell your pharmacist or doctor if you notice any of the following:

• Irritation in the nose

- nose bleeds
- rash
- itching
- headache

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of RHINOCORT AQUA

- Storage

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.

- <u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines. These measures will help to protect the environment.

Product Description

What it looks like
 Brown glass bottles with a spray pump and nasal applicator.

- Ingredients
 - Active ingredient Budesonide 64 micrograms/dose.
 - Inactive ingredients

Microcrystalline cellulose and carboxymethylcellulose sodium, glucose anhydrous, polysorbate 80, disodium edetate, potassium sorbate, hydrochloric acid, purified water.

- <u>MAL number:</u> MAL20000013A

Manufacturer

McNeil AB, Helsingborg, Sweden.

Product Registration Holder

JNTL (Malaysia) Sdn. Bhd. Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor, Malaysia.

Date of revision

23/10/2023

Serial Number

NPRA (R1/2) 04012024/011