

**INFORMATION FOR THE PATIENT**  
**IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT**

**P** RHINOCORT<sup>®</sup> AQUA<sup>™</sup>

budesonide (aqueous nasal spray)

**BEFORE using RHINOCORT AQUA, read this leaflet carefully.** It contains general points about RHINOCORT AQUA and should add to more specific advice from your doctor or pharmacist.

Please keep this leaflet to refer to until you have used up all medication in RHINOCORT AQUA.

**WHAT IS RHINOCORT AQUA USED FOR AND HOW DOES IT WORK?**

RHINOCORT is a brand name for a drug called budesonide. RHINOCORT is an intranasal spray of the drug budesonide. It belongs to a group of medicines called corticosteroids which are used to reduce inflammation. RHINOCORT AQUA reduces and prevents the inflammation.

You should use RHINOCORT AQUA when you experience symptoms such as congestion (blocked nose), runny nose, sneezing and nasal itching. These symptoms may be felt when you are exposed to pollen such as ragweed or grass (hay fever) or dust in your house.

RHINOCORT AQUA can also be used to treat nasal polyps. It can prevent new polyps from appearing as well as get rid of ones you already have.

**WHAT IS IN RHINOCORT AQUA?**

RHINOCORT AQUA contains budesonide as the active ingredient and comes in a concentration of 64 µg per spray.

Most medicines contain more ingredients than just the active drug. Check with your doctor if you think you might be allergic to any of these items (listed in alphabetical order): budesonide, carboxymethylcellulose sodium, disodium edetate, glucose anhydrous, hydrochloric acid, microcrystalline cellulose, polysorbate 80, potassium sorbate, and purified water.

**WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING RHINOCORT AQUA?**

- Tell your doctor:
- About all health problems you have now or have had in the past, especially if you have had lung tuberculosis or any other recent infection;
- about other medicines you take, including ones you can buy without a prescription;
- if you take, or have taken steroid medicines within the past several months;

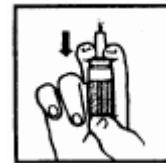
- if you have ever had a bad, unusual or allergic reaction to budesonide or any of the other ingredients;
- if you are pregnant, plan to become pregnant or are breastfeeding;
- if you take medications against fungal infections or ritonavir (medication used to treat HIV infection or AIDS). These medications may interact with RHINOCORT AQUA.

### HOW DO I TAKE RHINOCORT AQUA PROPERLY?

It is important that you use RHINOCORT AQUA daily at the intervals recommended by your doctor. Do not stop or change dosage without asking your doctor.

**If you follow the instructions below, you will receive the medication.**

1. Before use, turn the bottle upside-down 3 to 4 times. Remove the protective cap from the nose piece.
2. When using the spray for the first time, you must load the pump by pressing downwards on the collar. Use your index and middle fingers while supporting the base of the bottle with your thumb (as illustrated). Press down 5 to 10 times until a fine mist spray appears. The spray is now ready for use. If not used daily the pump must be loaded again. This time it is sufficient to pump just once into the air.
3. Gently blow your nose. Hold the bottle as shown. Tilt your head forward slightly, close one nostril with a finger and gently insert the tip of the nose piece into the other nostril.
4. For each spray your doctor has instructed you to take, press firmly downwards once on the collar. Breathe gently inwards through the nostril, then breathe out through the mouth.
5. Repeat the procedure for the other nostril.
6. Replace the protective cap on the nose piece. Keep the bottle in an upright position. Store at 15-30°C.



**Cleaning:** Clean the nose piece and protective cap regularly. To clean the nose piece, remove the protective cap, press upwards on the collar and the nose piece will come off. Wash the nose piece and protective cap under lukewarm water. Air dry and replace the nose piece and the protective cap back on the bottle and reload as in Instruction #2. **Do not try to clean the nasal applicator by using a pin or sharp object.**

## **HOW MUCH RHINOCORT AQUA SHOULD I TAKE?**

The dosage of RHINOCORT AQUA is individual. Follow your doctor's directions carefully. They may differ from the information in this leaflet.

**CAUTION:** RHINOCORT AQUA does not give immediate relief of your nasal symptoms. It may take a few days (and up to 2 weeks) before you notice any improvement. Contact your doctor if:

- no improvement occurs after 3 weeks,
- the inside of your nose becomes sore (nasal irritation),
- coloured (yellow or green) nasal secretions appear,
- repeated bleeding from the nose occurs.

### **Adults and Children Over 6 Years**

#### Rhinitis

Suggested **starting doses** are: Total daily dose 4 sprays (256 µg). In children, do not exceed this dose. RHINOCORT AQUA can be taken once or twice daily.

Once Daily: 2 sprays (128 µg) into each nostril, once in the morning.

Twice Daily: 1 spray (64 µg) into each nostril, morning and evening.

Maintenance Dose: Use lowest effective dose.

#### Nasal Polyps

1 spray (64 µg) into each nostril, morning and evening (total daily dose 256 µg).

**IMPORTANT:** Use regularly as directed by your doctor. **DO NOT EXCEED THE DOSE PRESCRIBED BY YOUR DOCTOR.**

## **WHAT DO I DO IF I MISS A DOSE?**

If you miss a dose of RHINOCORT AQUA, take it as soon as possible. Then go back to your regular schedule. If it is almost time to take your next dose, skip the missed dose and take the next dose on time.

**Never take a double dose of RHINOCORT AQUA to make up for ones you missed.** If you are still unsure, check with your doctor or pharmacist to see what you should do.

You may notice that your symptoms improve after the first dose of RHINOCORT AQUA. However, several weeks may pass before the full effect is achieved. Don't forget to take RHINOCORT AQUA even when you feel well.

Treatment with RHINOCORT AQUA should not be stopped abruptly, but tapered off gradually.

## **WHAT SHOULD I DO IN CASE OF OVERDOSE?**

Telephone your doctor or go to your nearest hospital right away if you think that you or anyone else may have taken too much RHINOCORT AQUA.

## **ARE THERE ANY SIDE EFFECTS?**

Like any medication, RHINOCORT AQUA may result in side effects in some people.

Common side effects are nasal and throat irritation, nasal bleeding and crusting. Other side effects include itching throat, sore throat, cough, fatigue, nausea/dizziness and headache.

Uncommon side effects include allergic conditions such as asthma or a skin rash. These may not be caused by RHINOCORT AQUA in your case, but only a doctor can tell this. Very few people who have used steroids in the nose, such as RHINOCORT AQUA, have experienced a severe allergic reaction, or have found small holes or ulcers in the skin inside the nose. The likelihood of these side effects occurring is very rare. If you notice anything unusual about the skin inside your nose, talk to your doctor.

Medicines affect different people in different ways. Just because side effects have occurred in other patients does not mean you will get them. If any side effects bother you, please contact your doctor.

**Do not stop taking RHINOCORT AQUA on your own.** Your doctor may want to slowly reduce your dose, especially if you have been using RHINOCORT AQUA for a long time. Although rare, symptoms of steroid withdrawal (i.e. fatigue, muscle or joint aches) may occur if RHINOCORT AQUA is stopped too quickly.

## **WHERE SHOULD I KEEP RHINOCORT AQUA?**

Remember to **keep RHINOCORT AQUA out of the reach of children** when you are not using it.

Store the bottle at room temperature (15-30°C) in a dry place, away from moisture.

Do not keep or use RHINOCORT AQUA after the expiry date indicated on the label.

**Important Note:**      **This leaflet alerts you to some of the times you should call your doctor. Other situations which cannot be predicted may arise. Nothing about this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using RHINOCORT AQUA.**

NOTE: This INFORMATION FOR THE PATIENT leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at:

[www.astrazeneca.ca](http://www.astrazeneca.ca)

or by contacting the sponsor, AstraZeneca Canada Inc. at:  
Customer Inquiries – 1 (800) 668-6000,  
Renseignements – 1 (800) 461-3787.

RHINOCORT<sup>®</sup> and the AstraZeneca logo are trade-marks of the AstraZeneca group of companies.

AstraZeneca Canada Inc.  
Mississauga, Ontario  
L4Y 1M4

Last revised: December 23, 2008