

PART III: CONSUMER INFORMATION

Fr RHINOCORT® TURBUHALER®

budesonide (dry powder for nasal inhalation)

This leaflet is part III of a three-part "Product Monograph" published when RHINOCORT TURBUHALER was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RHINOCORT TURBUHALER. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

This medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

What the medication is used for:

RHINOCORT TURBUHALER is used to treat:

- seasonal allergic rhinitis (hay fever);
- perennial (year-round) rhinitis;
- nasal polyps and/or prevent new nasal polyps from appearing after surgery (polypectomy).

What it does:

RHINOCORT TURBUHALER contains a medicinal ingredient that is a steroid (cortisone-like medicine). RHINOCORT TURBUHALER works by preventing and decreasing the inflammation that occurs on the lining of your nose.

When it should not be used:

Do not use RHINOCORT TURBUHALER:

- if you are allergic to budesonide;
- if you have an untreated infection:
 - fungal (yeast);
 - bacterial;
 - viral;
- if you have tuberculosis in your respiratory tract;
- if your child is younger than 6 years old.

What the medicinal ingredient is:

Budesonide.

What the nonmedicinal ingredients are:

RHINOCORT TURBUHALER contains no other ingredients.

What dosage form it comes in:

Dry powder for nasal inhalation: 100 mcg per metered dose (inhalation). Each inhaler contains 200 metered doses.

WARNINGS AND PRECAUTIONS

BEFORE you use RHINOCORT TURBUHALER talk to your doctor or pharmacist:

- if you are allergic to budesonide;
- if you have had lung tuberculosis or any other recent infection;
- if you have asthma;
- if you have thyroid problems;
- if you have or had liver problems;
- if you are taking, or have taken steroids either as an injection or by mouth within the past several months;
- if you are pregnant or planning to become pregnant;
- if you are breastfeeding;
- about **all** health problems you have now or have had in the past.

You should avoid coming into contact with people who have measles or chicken pox while taking RHINOCORT TURBUHALER. If you are exposed, tell your doctor right away.

It is not recommended to use RHINOCORT TURBUHALER for continuous, long-term treatment in children.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

Drugs that may interact with RHINOCORT TURBUHALER include:

- ritonavir and cobicistat-containing products (used to treat HIV or AIDS);
- ketoconazole, itraconazole (used to treat fungal infections).

PROPER USE OF THIS MEDICATION

- Take RHINOCORT TURBUHALER exactly as your doctor has told you to. **Follow your doctor's directions carefully. They may differ from the information in this leaflet.**
- **Do not** take more of your medicine or take it more often than your doctor tells you.
- RHINOCORT TURBUHALER is for use in the nose only. **Do not** use it in your eyes or mouth.
- RHINOCORT TURBUHALER does not relieve allergy symptoms in the eyes. If your eyes bother you, tell your doctor. He/she may be able to give you some additional medicine to relieve these symptoms.

- RHINOCORT TURBUHALER may take 2-3 days (and up to 2 weeks) to work. Take it each day without missing a dose to get the best results.
- For seasonal allergic rhinitis, RHINOCORT TURBUHALER works best if it is started before allergy season begins.
- If your nose is blocked, decongestant nose drops may be used during the first 2-3 days of the treatment.
- Do not stop taking RHINOCORT TURBUHALER even if you feel better unless told to do so by your doctor.

Tell your doctor if:

- your symptoms have not improved after 3 weeks of taking RHINOCORT TURBUHALER;
- your nose becomes irritated;
- you have a yellow or green discharge from your nose;
- you have repeated nose bleeds.

Adults and Children (6 years and older)

Rhinitis

Usual starting dose: 2 inhalations (200 mcg) into each nostril in the morning (total daily dose: 400 mcg).

Maintenance Dose: Your doctor will prescribe the lowest dose needed to control symptoms.

Depending on how RHINOCORT TURBUHALER works for you, your doctor may change your dose.

Nasal Polyps

Usual dose: 1 inhalation (100 mcg) into each nostril, morning and evening (total daily dose: 400 mcg).

If you have been prescribed RHINOCORT TURBUHALER and are taking oral steroid medication, your doctor may slowly (over a period of weeks or months) reduce the dose of your tablets. If your oral steroid medication is changed, you may experience the same symptoms you had earlier such as runny nose, and symptoms because of reduced oral steroid use such as rash, muscle and joint pain.

If your oral steroid is reduced, you should contact your doctor if you get symptoms such as:

- Headache;
- Tiredness;
- Nausea or vomiting.

Missed Dose:

Rhinitis

If you miss a dose and remember within 12 hours, you should take your usual dose as soon as possible. Then go back to your regular schedule. If it is more than 12 hours when you remember, do not take the missed dose. Take the next dose at the usual time.

Nasal Polyps

If you miss a dose and remember within 6 hours, you should take your usual dose as soon as possible. Then go back to your regular schedule. If it is more than 6 hours when you remember, do not take the missed dose. Take the next dose at the usual time.

Do NOT double the dose of RHINOCORT TURBUHALER to make up for a missed dose. If you are still unsure, check with your doctor or pharmacist to see what you should do.

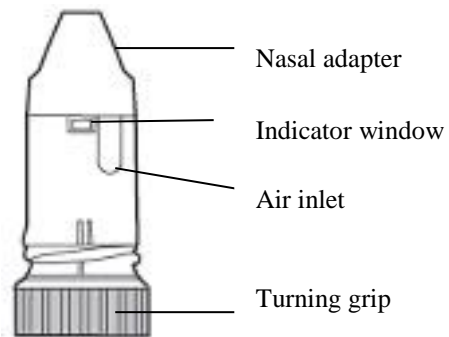
Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

HOW TO USE YOUR RHINOCORT TURBUHALER INHALER (for nasal inhalation)

Before you start using RHINOCORT TURBUHALER for the first time, it is important that you read the instructions below and follow them carefully.

TURBUHALER is a multidose inhaler from which very small amounts of powder are administered. When you sniff RHINOCORT TURBUHALER the powder is delivered to your nasal passages.



Before you use a **NEW** inhaler for the first time you must prepare the inhaler for use. Follow the steps under “**A. How to prepare a NEW inhaler for use:**”.

For regular use of your inhaler follow the steps under “**B. How to take a dose:**”.

A. How to prepare a NEW inhaler for use:

You only need to prepare your **NEW** inhaler for use **once**. You do not need to repeat these steps even if your inhaler is not used regularly.

STEP 1 Unscrew and lift off the cover (Figure 1).

Figure 1

STEP 2 Hold the inhaler upright. Do not hold the inhaler by the nasal adaptor.

- Turn the **grey grip** as far as it will go in one direction (clockwise or counter-clockwise, it does not matter which way you turn it first).
- Then turn the grey grip as far as it will go in the opposite direction (Figure 2).
- At some point when you are turning the grip you will hear a “**click**”. This is part of the preparation process.

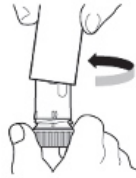


Figure 2



STEP 3 Repeat **STEP 2** one more time. Then, follow the steps under “**B. How to take a dose:**”, starting at **STEP 2**.

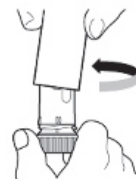
B. How to take a dose:

To properly take a dose, follow these 5 steps:

STEP 1 Blow your nose.

STEP 2 Unscrew and lift off the cover (Figure 1).

Figure 1



STEP 3 Hold the inhaler upright. Do not hold the inhaler by the nasal adaptor.

- Turn the **grey grip** as far as it will go in one direction (clockwise or counter-clockwise, it does not matter which way you turn it first).
- Then turn the grey grip as far as it will go in the opposite direction (Figure 2).

Figure 2



A dose has now been loaded.

- At some point when you are turning the grip you will hear a “**click**”. This is part of the preparation process.

NOTE: If you accidentally drop, shake or breathe out into RHINOCORT TURBUHALER after the dose has been loaded, you will lose your dose. If this happens, repeat **STEP 3** to load a new dose.

STEP 4 While your nose is away from the nasal adaptor, **breathe out**. Then, place the adapter inside your nostril. Make sure it fits tightly around the adaptor. Block the opposite nostril with your finger (Figure 3).

STEP 5 **Breathe in** (sniff) **quickly and hard** through your nose (Figure 3).

- When you breathe in, your indrawn breath provides the force needed to bring the drug to your nasal passages.
- Take the nasal adapter out from the nostril.
- When you breathe out, **do not** breathe into your TURBUHALER.
- The amount of medicine that you inhale is very small. You may not be able to feel it or taste it after you have used it. If you have followed the instructions, you will have inhaled the medicine.

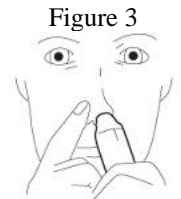


Figure 3

Repeat STEPS 3 to 5 for the other nostril.

When you have taken the prescribed amount of doses, **replace the cover of the inhaler by screwing it back on.**

I cannot remember how many times I turned the grey grip. What should I do?

The TURBUHALER is designed to load only one dose at a time. If you can’t remember how many times you have turned the grey grip, you can start the process again. Follow the steps below. You will not end up loading two doses.

If you are using a **NEW** inhaler for the first time, start at the beginning of **STEP 2** under the section “**A. How to prepare a NEW inhaler for use:**”.

For regular use of your inhaler, start at the beginning of STEP 3 under the section “**B. How to take a dose:**”.

How do I know my dose has been loaded?

By turning the grey grip all the way in **BOTH** directions, you will properly load a dose of your medication. At some point when you are turning the grip you will hear a “click”. This is part of the loading process. If you are not sure you heard the “click”, repeat from the beginning of STEP 3 under the section “**B. How to take a dose:**”. This will not result in two doses being loaded. The TURBUHALER is designed to load only one dose at a time. If you do not hear the “click” sound when the turning grip is rotated, you will not receive any medication. If this problem persists, you need to replace the RHINOCORT TURBUHALER.

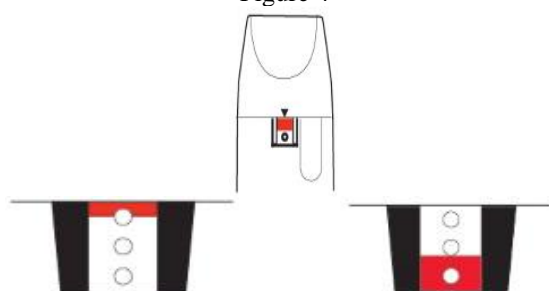
How do I clean my inhaler?

Clean the outside of the nasal adapter once a week with a **dry** tissue. **Never** use water or any other fluid.

How do I know when to start a new inhaler?

RHINOCORT TURBUHALER has a dose indicator. When a red mark first appears in the little window underneath the nasal adapter, there are approximately 20 doses left (Figure 4). Now is the time to obtain your next inhaler. When the red mark reaches the bottom of the window, you should discard your inhaler. The sound you hear if you shake the inhaler is produced by a drying agent, not the medication. RHINOCORT TURBUHALER cannot be refilled with drug and should be thrown away.

Figure 4



Approximately 20 doses left

EMPTY

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- nose and throat irritation;
- nosebleeds and crusting;
- itchy and sore throat;
- cough;
- fatigue;
- nausea or dizziness;
- headache;
- skin rash.

Side effects that may occur with the use of local corticosteroids are:

- itching and swelling in the face;
- slower healing of wounds. Do not use RHINOCORT TURBUHALER until your nose has healed if you have a sore in your nose, if you have surgery on your nose, or if your nose has been injured;
- slower growth in children. Your doctor should monitor growth regularly for children;
- worsening of the symptoms of infections such as existing tuberculosis, fungal, bacterial or viral infections.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and immediately seek emergency medical attention
		Only if severe	In all cases	
Very rare	small holes or ulcers in the skin inside the nose		X	
	Allergic reactions: such as swelling of the face, lips, tongue, and/or throat (which may cause difficulty in breathing or swallowing), hives, rash and itching			X
Un-known	Cushing's Syndrome: (hypercorticism) Rapid weight gain especially around the body and face; round “moon” face, excess sweating; thinning of the skin with easy bruising and dryness; muscle and bone weakness.		X	

This is not a complete list of side effects. For any unexpected effects while taking RHINOCORT TURBUHALER, contact your doctor or pharmacist.

HOW TO STORE IT

Keep RHINOCORT TURBUHALER out of the reach and sight of children.

Store the inhaler at room temperature (15-30°C).

Always replace the cover after using RHINOCORT TURBUHALER.

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

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Call toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

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

The Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: www.astrazeneca.ca, or by contacting the sponsor, AstraZeneca Canada Inc. at: 1-800-668-6000.

This leaflet was prepared by:
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