

INFORMATION FOR THE CONSUMER

IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT

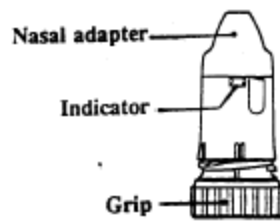
Pr RHINOCORT[®] TURBUHALER[®]

budesonide (powder for nasal inhalation)

BEFORE using RHINOCORT TURBUHALER, please read this leaflet carefully. It contains general points about RHINOCORT TURBUHALER 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 TURBUHALER.

WHAT IS RHINOCORT TURBUHALER USED FOR AND HOW DOES IT WORK?



RHINOCORT is a brand name for a drug called budesonide. RHINOCORT is a nasal inhalation form of the drug budesonide. It belongs to a group of medicines called corticosteroids which are used to reduce inflammation. Rhinitis is caused by inflammation of the nasal mucosa. RHINOCORT TURBUHALER reduces and prevents this inflammation. In some cases, 1-2 weeks of regular use may be needed before the full effect is seen. RHINOCORT TURBUHALER can also be used to treat nasal polyps and/or prevent new nasal polyps from appearing again after surgery (polypectomy).

TURBUHALER is the brand name for a multiple-dose, dry-powder inhaler. When you breathe in through the inhaler, your indrawn breath provides the necessary force to deliver the drug to your nasal passages.

WHAT IS IN RHINOCORT TURBUHALER?

RHINOCORT TURBUHALER contains budesonide as the active ingredient and comes in one strength: 100 µg per inhalation.

If you happen to shake the inhaler, the sound you hear is the drying agent built into the turning grip. This is not the medication and cannot be inhaled. RHINOCORT TURBUHALER contains no other ingredients.

WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING RHINOCORT TURBUHALER?

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";
- 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 TURBUHALER.

HOW DO I TAKE RHINOCORT TURBUHALER PROPERLY?

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

NOTE: You may not taste or feel any medication when inhaling from RHINOCORT TURBUHALER. This is common.

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

Using the inhaler

To administer a dose, simply follow the instructions below.

Fig. 1

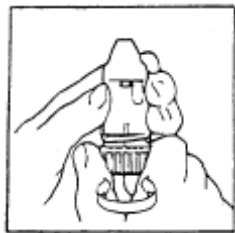


Fig. 2



Blow your nose. Unscrew and lift off the cover.

TURN

Hold the inhaler upright with the grip downwards (Fig. 1). To load the inhaler with a dose **turn the grey grip as far as it will go in one direction and then back to the original position.**

CLICK

The "click" you heard means the inhaler is ready to use. **Breathe out.** Do not breathe out through the nasal adapter.

INHALE

Place the nasal adapter so the nostril fits tightly around the adapter and block the opposite nostril with a finger. Sniff **quickly** and

forcefully (Fig. 2).

Remove RHINOCORT TURBUHALER from your nose, before breathing out.

Repeat the above steps for the other nostril. Replace the cover and screw it shut.

If you accidentally drop, shake or breathe out into RHINOCORT TURBUHALER after it is loaded, you will lose your dose. If this happens, you should load a new dose and inhale it.

Cleaning: Clean the outside of the nasal adapter once a week with a **dry** tissue. **Never** use water or any other fluid for cleaning the nasal adapter. If fluid enters RHINOCORT TURBUHALER it may not work properly.

HOW DO I KNOW WHEN RHINOCORT TURBUHALER IS EMPTY?



Approx. 20 doses left

DISCARD

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. 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 when you shake the inhaler is produced by a drying agent, not the medication. RHINOCORT TURBUHALER cannot be re-filled with drug and should be discarded.

HOW MUCH RHINOCORT TURBUHALER SHOULD I TAKE?

The dosage of RHINOCORT TURBUHALER is individual.

Follow your doctor's directions carefully. They may differ from the information in this leaflet.

IMPORTANT: DO NOT EXCEED THE DOSE PRESCRIBED BY YOUR DOCTOR.

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

Rhinitis

Initial Dose: **Adults:** Two applications into each nostril in the morning (total daily dose: 400 µg). **Children** (6 years and older): Two applications into each nostril in the morning (total daily dose: 400 µg). This dose should not be exceeded in children.

Maintenance Dose: Adults and Children (6 years and older): Use the lowest effective dose necessary to control symptoms.

Nasal Polyps

One application (100 µg) into each nostril, morning and evening (total daily dose: 400 µg).

CAUTION: RHINOCORT TURBUHALER is not intended to give immediate relief of your nasal symptoms and 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,
- nasal irritation occurs,
- coloured (yellow or green) nasal secretions appear,
- repeated nasal bleeding occurs.

WHAT DO I DO IF I MISS A DOSE?

Rhinitis

If you miss a dose of RHINOCORT TURBUHALER 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. Just take the next dose on time.

Nasal Polyps

If you miss a dose of RHINOCORT TURBUHALER 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. Just take the next dose on time.

Never take a double 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.

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

Treatment with RHINOCORT TURBUHALER should not be stopped abruptly, but tapered off gradually. Follow your doctor's directions.

If you have been prescribed RHINOCORT TURBUHALER and are still using "cortisone" tablets, your doctor may gradually (over a period of weeks or months) reduce your dose of tablets. You may even be able to eventually stop using the tablets.

NOTE: If your medication is changed from "cortisone" tablets to RHINOCORT TURBUHALER, you may temporarily regain symptoms which may have bothered you earlier, e.g. runny nose, rash, pain in muscle and joints. If any of these symptoms bothers you, or if you get symptoms such as headache, tiredness, nausea or vomiting, contact your doctor.

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 TURBUHALER.

ARE THERE ANY SIDE EFFECTS?

Like any medication, RHINOCORT TURBUHALER may cause side effects in some people.

Common side effects include: 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 like skin rash may occur in association with local corticosteroid therapy. Very few people who have used steroids in the nose, such as RHINOCORT TURBUHALER, 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, contact your doctor.

WHERE SHOULD I KEEP RHINOCORT TURBUHALER?

Remember to keep RHINOCORT TURBUHALER out of the reach of children.

Always replace the cover after using RHINOCORT TURBUHALER. Store the inhaler at room temperature (15-30°C) in a dry place, away from moisture.

Do not keep or use RHINOCORT TURBUHALER 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 TURBUHALER.

NOTE: This INFORMATION FOR THE CONSUMER 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

or by contacting the sponsor, AstraZeneca Canada Inc. at:

Customer inquiries – 1 (800) 668-6000,

Renseignements – 1 (800) 461-3787.

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AstraZeneca Canada Inc.

Mississauga, Ontario

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Last Revised: December 23, 2008