PS10481

**Package leaflet: Information for the user**

# Rhinocort® Turbohaler® 100 micrograms per metered dose Nasal Powder

budesonide

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**


1. What Rhinocort Turbohaler is and what it is used for
2. What you need to know before you use Rhinocort Turbohaler
3. How to use Rhinocort Turbohaler
4. Possible side effects
5. How to store Rhinocort Turbohaler
6. Contents of the pack and other information


## 1. What Rhinocort Turbohaler is and what it is used for

The name of your medicine is Rhinocort Turbohaler, 100 micrograms per metered dose, Nasal Powder (called Rhinocort Turbohaler in the rest of this leaflet).

Rhinocort Turbohaler contains a medicine called budesonide. This belongs to a group of medicines called corticosteroids.

- Corticosteroids help to reduce and prevent inflammation.
- Rhinocort Turbohaler is used to treat the effects of allergies, such as hay fever, and inflammation inside the nose (rhinitis).
- It can also stop these effects from coming on.
- It is also used to treat small growths inside the nose (nasal polyps).
- When you sniff through the Turbohaler, the medicine is delivered to the inside of your nose.

## 2. What you need to know before you use Rhinocort Turbohaler

**Do not use Rhinocort Turbohaler:**
- If you are allergic to budesonide.

If you are not sure if this applies to you, talk to your doctor of pharmacist before using Rhinocort Turbohaler.

**Warnings and precautions**

Talk to your doctor or pharmacist before using Rhinocort Turbohaler:
- If you have TB (tuberculosis).
- If you have a cold or chest infection.
- If you have, or have recently had, an infection in your nose.
- If you have liver problems.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Rhinocort Turbohaler.

Contact your doctor if you experience blurred vision or other visual disturbances.

**Other medicines and Rhinocort Turbohaler**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Rhinocort can affect the way some medicines work and some medicines can have an effect on Rhinocort and your doctor may wish to monitor you carefully.

In particular, talk to your doctor if:
- You are already taking a corticosteroid medicine that you inhale or take by mouth.
- You are taking medicines for fungal infections (such as ketoconazole and itraconazole).
- You are taking HIV medicines (such as ritonavir or cobicistat-containing products).
- You are taking cimetidine.
- You are taking oestrogens and contraceptive steroids.
- You are going to have an 'ACTH stimulation' blood test, treatment with Rhinocort may give false results (low values).

**Pregnancy, breast-feeding and fertility**
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine
- If you get pregnant while using Rhinocort Turbohaler, **talk to your doctor straight away**.

**Driving and using machines**

Rhinocort Turbohaler is not likely to affect you being able to drive or use any tools or machines.

## 3. How to use Rhinocort Turbohaler

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Read the label to remind you of what they said.

**How much Rhinocort Turbohaler to use**

**Allergies such as hay fever**
- The recommended dose for adults and the elderly is two sniffs of Rhinocort Turbohaler in each nostril in the morning. Alternatively, your doctor may ask you to take one sniff of Rhinocort Turbohaler in each nostril every morning and evening.
- This may be reduced by your doctor once your symptoms have improved.

It is important to use Rhinocort Turbohaler regularly. Try to use it **before** you come into contact with whatever causes the allergy. For example, pollen is what causes hay fever, so you will be more at risk outdoors.

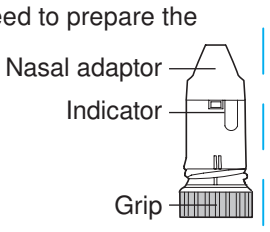
**Nasal polyps**
- The recommended dose is one sniff of Rhinocort Turbohaler in each nostril every morning and evening.

You may not notice any effects of the medicine for the first few days. Don't stop taking it. Keep taking the medicine as you have been told to. If you still feel no different after a few more days, talk to your doctor.

**How to prepare a new Turbohaler for use**

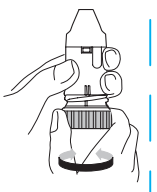
Before using Rhinocort Turbohaler **for the first time** you need to prepare the Turbohaler for use.

Unscrew the cover and lift it off.




Hold the Turbohaler upright with the grey grip at the bottom.

Do not hold the nasal adaptor when you turn the grip. **Turn the grey grip as far as it will go in one direction. Then turn it as far as it will go in the other direction**. It does not matter which way you turn first. You should hear a click sound. Perform the procedure twice.



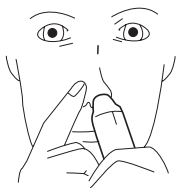
The Turbohaler is now ready for use, and **you should not repeat the above procedure again**. To take a dose, please follow the instructions below.

**Instructions for use**

Read the following instructions carefully. The Turbohaler is very easy to use. The parts of your Turbohaler are shown in the pictures above.

1. Blow your nose.
2. Unscrew the cover and lift it off.
3. **Hold your Turbohaler upright** with the grey grip at the bottom.
4. Do not hold the nasal adapter when you load the Turbohaler. To load your Turbohaler with a dose, **turn the grey grip as far as it will go in one direction**. **Then turn it as far as it will go in the other direction.** It does not matter which way you turn it first. You should hear a click sound. Your Turbohaler is now loaded and ready to use. Only load your Turbohaler when you need to use it.

5. Place the nasal adapter in your nostril. Make sure that your nostril fits tightly round the adapter.
6. Block the other nostril with a finger. Then breathe in (sniff), **quickly and hard** through your nose. When you breathe out, **do not** breathe out through your inhaler.



The amount of medicine that you inhale is very small. This means that you may not feel or smell anything. If you have followed the instructions, you can still be confident that you have inhaled the medicine.
7. Repeat steps 3 to 6 for the other nostril.
8. If you have been told to take a second sniff in each nostril, repeat steps 3 to 7.
9. **Replace the cover** by screwing it back on tightly after use.

**Cleaning your Turbohaler**

Wipe the outside of the nasal adapter once a week with a dry tissue. Do not use water or liquids.

**When to start using a new Turbohaler**

- The Turbohaler contains 200 sniffs when it is full.
- There is a small window on the side of your Turbohaler. When you first see a red mark at the top of the window, there are approximately 20 sniffs left. When the red mark reaches the bottom of the window, start using your new Turbohaler.



Note:
- The grip will still twist and 'click' even when your Turbohaler is empty.
- The sound that you hear as you shake your Turbohaler is produced by a drying agent and not the medicine. Therefore the sound does not tell you how much medicine is left in your Turbohaler.

**If you use more Rhinocort Turbohaler than you should**

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse. If you take too many doses of Rhinocort Turbohaler, talk to your doctor or pharmacist straight away.

**If you forget to take Rhinocort Turbohaler**

- If you forget to take a dose of Rhinocort Turbohaler, skip the missed dose. Then take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If any of the following happen to you, stop using your Turbohaler and talk to your doctor straight away:**

- Skin rash, itching, lumpy rash (hives), blistering of the skin. Swelling of your face, lips, tongue or throat (this may make it difficult to swallow). These are uncommon, affecting less than 1 in 100 people.
- In addition to the above, sudden wheezing and/or feeling faint may occur. It is not known how often these occur; however they are very unlikely.

If any of the above occurs, you may be having an allergic reaction.

**Other possible side effects:**

**Common (may affect up to 1 in 10 people)**
- Occasional sneezing, dry nose, or stinging in your nose. These can happen straight after using Rhinocort Turbohaler.
- Slight bleeding from the nose.

**Uncommon (may affect up to 1 in 100 people)**
- Skin reactions including rash, skin irritation (dermatitis) and itching. These may happen straight after using Rhinocort Turbohaler or may be delayed.
- Muscle cramps

**Rare (may affect up to 1 in 1,000 people)**
- Slowing in the rate of growth of children and adolescents.
- Effect on the adrenal gland (a small gland next to the kidney).
- Severe allergic reaction.
- Perforation of the membrane separating the nostrils (the nasal septum).
- Nasal ulcer.
- Loss of voice.
- Bruising of the skin.
- Blurred vision.

**Very rare (may affect up to 1 in 10,000 people)**
- Sore patches on the inside of the nose.

**Not known (frequency cannot be estimated from the available data)**
- Increased pressure in the eyes (glaucoma).
- Cataract (clouding of the lens in the eye).

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

Do not be concerned by this list of possible side effects. You may not get any of them.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

## 5. How to store Rhinocort Turbohaler

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and the label. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Keep the cap screwed onto your Rhinocort Turbohaler when you are not using it.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

**What Rhinocort Turbohaler contains**
- The active substance is budesonide. Each metered dose contains 100 micrograms of budesonide.
- There are no other ingredients. It does not contain any propellants, preservatives or additives.

**What Rhinocort Turbohaler looks like and contents of the pack**

Rhinocort Turbohaler is a white nasal powder. Each Turbohaler will deliver 200 metered doses.

**Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation for Rhinocort Turbohaler is held by AstraZeneca UK Ltd, 600 Capability Green, Luton, LU1 3LU, UK.

Rhinocort Turbohaler is manufactured by AstraZeneca AB, S-151 85, Södertälje, Sweden and AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

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