

INFORMATION FOR THE CONSUMER

IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT

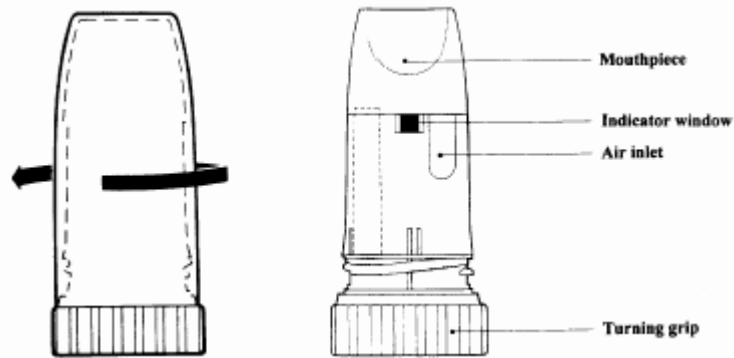
Pr PULMICORT® TURBUHALER®

budesonide powder (for oral inhalation)

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

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



PULMICORT is a brand name for a drug called budesonide. PULMICORT is an inhaled form of the drug budesonide. It belongs to a group of medicines called corticosteroids which are used to reduce inflammation. Asthma is caused by inflammation in the airways. PULMICORT TURBUHALER reduces and prevents this inflammation. In some cases, 1 - 2 weeks of regular use may be needed before the full effect is seen.

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 drugs to your lungs.

PULMICORT TURBUHALER is not meant to relieve an asthma attack that has already started. Other inhalers containing fast-acting bronchodilators provide rapid relief. If your doctor prescribed one of these, you should follow his or her directions when you have an acute attack of asthma.

WHAT IS IN PULMICORT TURBUHALER?

PULMICORT TURBUHALER contains budesonide as the active ingredient and comes in concentrations of either 100 µg, 200 µg, or 400 µg per inhalation.

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

WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING PULMICORT 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 breast feeding;
- if you take medications against fungal infections or Ritonavir (medication used to treat HIV infection or AIDS). These medications may interact with PULMICORT TURBUHALER.

WHILE TAKING PULMICORT TURBUHALER

If you develop an infection or a respiratory infection, contact your doctor to see if you can continue taking PULMICORT TURBUHALER.

DO NOT TAKE PULMICORT TURBUHALER IF

You are allergic to budesonide.

HOW DO I TAKE PULMICORT TURBUHALER PROPERLY?

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

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

TURBUHALER is an inhaler from which very small amounts of powder are administered. When you breathe in through TURBUHALER the powder is delivered to the lungs. It is therefore important that you **inhale forcefully and deeply** through the mouthpiece.

PULMICORT TURBUHALER is very easy to use.

NOTE: You may not taste or feel any medication when inhaling from PULMICORT 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

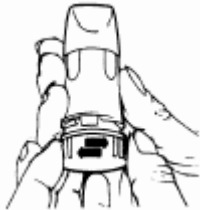


Fig. 2



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 brown 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 mouthpiece.
- INHALE** Place the mouthpiece gently between your teeth, close your lips and breathe in **forcefully and deeply** through your mouth (Fig. 2). Do not chew or bite on the mouthpiece.

Note: Do not use TURBUHALER if it has been damaged or if the mouthpiece has become detached.

Remove the inhaler from your mouth, before breathing out.

If more than one dose has been prescribed, repeat the above steps. Replace the cover.

Rinse your mouth out with water.

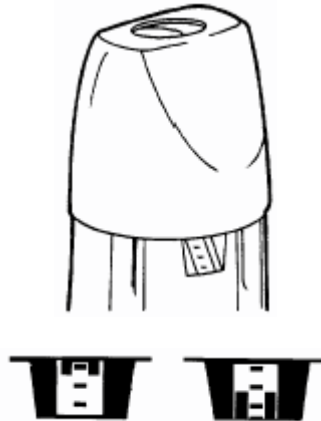
If you accidentally drop, shake or breathe out into PULMICORT TURBUHALER after it is loaded, you will lose your dose. If this happens, you should load a new dose and inhale it.

Note: Never breathe out through the mouthpiece. Always replace the cover properly after use.

As the amount of powder dispensed is very small, you may not be able to taste it after inhalation. However, you can still be confident that the dose has been inhaled if you have followed the instructions.

Cleaning: Clean the outside of the mouthpiece once a week with a **dry** tissue. **Never** use water or any other fluid. If fluid enters the inhaler it may not work properly.

HOW DO I KNOW WHEN PULMICORT TURBUHALER IS EMPTY?



Approx. 20 doses left

DISCARD

PULMICORT TURBUHALER has a dose indicator. When a red mark first appears in the little window underneath the mouthpiece, 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 medication. PULMICORT TURBUHALER cannot be re-filled with drug and should be discarded.

HOW MUCH PULMICORT TURBUHALER SHOULD I TAKE?

The dosage of PULMICORT TURBUHALER is individual.

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

IMPORTANT: DO NOT EXCEED THE DOSE PRESCRIBED BY YOUR DOCTOR. IF DIFFICULTY IN BREATHING PERSISTS, CONTACT YOUR DOCTOR. DO NOT STOP TAKING PULMICORT TURBUHALER ON YOUR OWN. Your doctor may want to slowly reduce your dose, especially if you have been using PULMICORT TURBUHALER for a long time.

Suggested **starting doses** are:

Adults and Children 12 Years of Age and Older: 400-2400 µg daily, divided into 2-4 administrations.

Children 6 to 12 Years Old: 200-400 µg daily, divided into 2 administrations.

Maintenance Dose:

Use the lowest dose necessary to control symptoms.

Adults and Children 12 Years of Age and Older: 200-400 µg daily, divided into 2 administrations.

Children 6 to 12 Years Old: Use the lowest dose necessary to control symptoms.

In adults who require 400 µg daily, PULMICORT TURBUHALER may be taken once daily, either in the morning or evening.

WHAT DO I DO IF I MISS A DOSE?

If you miss a dose of PULMICORT 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 PULMICORT TURBUHALER to make up for missed doses. 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 PULMICORT TURBUHALER. However, 1 - 2 weeks may pass before the full effect is achieved. Don't forget to take it even when you feel well.

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

If you have been prescribed PULMICORT 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 PULMICORT 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, please 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 PULMICORT TURBUHALER.

ARE THERE ANY SIDE EFFECTS?

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

The most common side effects are cough, throat irritation, and hoarseness.

Other side effects include bad taste, headache, nausea, and dryness of the throat. There have been occasional reports of tiredness, thirst, and diarrhea.

Occasionally, throat or mouth infections may occur. Rare side effects include skin reactions like rash, skin bruising, and increase in chest tightness, nervousness, restlessness, depression, and behavioural disturbances in children. These may not be caused by PULMICORT TURBUHALER in your case, but only a doctor can tell this. In rare cases, severe allergic reactions may occur following the use of PULMICORT TURBUHALER.

If you take PULMICORT for a long period and at higher doses you may develop symptoms of adrenal insufficiency. If you develop symptoms such as tiredness, headache, nausea, vomiting, pain in muscles and joints, please contact 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.

If you have to go into the hospital for an operation, take your PULMICORT TURBUHALER with you and tell your doctor what medicines(s) you are taking.

WHERE SHOULD I KEEP PULMICORT TURBUHALER?

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

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

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 PULMICORT TURBUHALER.**

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing. Please refer to the Consumer Information Leaflet located at www.astrazeneca.ca, to see if more up-to-date information has been posted.

Consumer Inquiries: 1 (800) 668-6000

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