

PART III: CONSUMER INFORMATION

Pf PULMICORT® TURBUHALER®

budesonide dry powder for oral inhalation

This leaflet is part III of a three-part "Product Monograph" published when PULMICORT 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 PULMICORT 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:

PULMICORT TURBUHALER is used in adults and children 6 years of age and older to treat asthma, which is caused by inflammation in the airways.

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, follow their directions when you have an acute attack of asthma.

What it does:

PULMICORT TURBUHALER contains the medicine budesonide, which belongs to a group of medicines called glucocorticosteroids. It reduces and prevents inflammation in the airways.

When it should not be used:

You should not use PULMICORT TURBUHALER:

- if you are allergic to budesonide;
- to treat a sudden attack of breathlessness. You will probably need a different kind of medicine (ie. a fast-acting relief medication) in a different colour puffer than may already have been given to you. If you have more than one medicine, be careful not to confuse them;
- if you have an untreated infection (fungal, bacterial, or viral) or tuberculosis in the respiratory tract.

What the medicinal ingredient is:

Budesonide.

What are the nonmedicinal ingredients:

PULMICORT TURBUHALER contains no other ingredients.

What dosage forms it comes in:

Dry powder for oral inhalation: 100 mcg, 200 mcg, or 400 mcg per dose. Each inhaler contains 200 metered doses.

WARNINGS AND PRECAUTIONS

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

- 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 or liver problems;
- 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.

All cortisone-type medicines, especially when used for a long time, may possibly interfere with the usual growth pattern in growing adolescents. It is recommended that children being treated with steroids, including PULMICORT TURBUHALER have their height checked regularly by their doctor.

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

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 PULMICORT TURBUHALER include:

- ritonavir (used to treat HIV infection or AIDS);
- some antifungals used to treat fungal infections (such as ketoconazole and itraconazole).

PROPER USE OF THIS MEDICATION

The dosage of PULMICORT TURBUHALER is individual.

Follow your doctor's instructions carefully. They may differ from the information in this leaflet. It is important that you use PULMICORT TURBUHALER daily at the intervals recommended by your doctor.

IMPORTANT: DO NOT EXCEED THE DOSE PRESCRIBED BY YOUR DOCTOR. IF DIFFICULTY IN BREATHING PERSISTS, CONTACT YOUR DOCTOR OR PHARMACIST.

DO NOT STOP TAKING PULMICORT TURBUHALER ON YOUR OWN. Treatment with PULMICORT TURBUHALER should not be stopped abruptly, but tapered off gradually. Follow your doctor's directions.

Suggested **starting doses** are:

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

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

Maintenance Dose:

Adults and Children 12 Years of Age and Older: 200-400 mcg daily, divided into 2 administrations. Your doctor will prescribe the lowest dose necessary to control symptoms.

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

Children 6 to 12 Years Old: Your doctor will prescribe the lowest dose necessary to control symptoms.

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.

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.

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, contact your doctor.

Missed 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 has been more than 6 hours, 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.

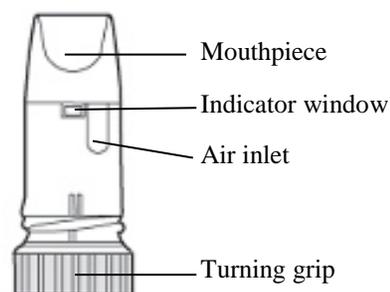
Overdose:

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 PULMICORT TURBUHALER INHALER

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 a multidose inhaler from which very small amounts of powder are administered. When you breathe in through PULMICORT TURBUHALER the powder is delivered to the lungs. It is therefore important that you **inhale as deeply and strongly** as you can through the mouthpiece.



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:**".

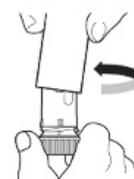
For regular use of your inhaler follow the steps under "**B. How to take a dose:**".

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).

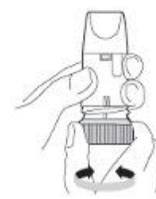
Figure 1



STEP 2 Hold the inhaler upright. Do not hold the inhaler by the mouthpiece.

Figure 2

- Turn the **brown 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 brown 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.

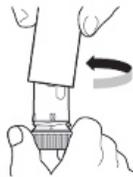
STEP 3 **Repeat STEP 2** one more time. Then follow the steps under “**B. How to take a dose:**”, starting at **STEP 2**.

B. How to take a dose:

To properly take a dose, follow these 4 steps:

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 mouthpiece.

- Turn the **brown 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 brown 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 loading process.

NOTE: If you accidentally **drop, shake** or **breathe out** into PULMICORT TURBUHALER after the dose has been loaded, you will lose your dose. If this happens, repeat STEP 2 to load a new dose.

STEP 3 **Breathe out**, with your mouth away from the mouthpiece (Figure 3). Then, place the mouthpiece gently between your teeth.

Figure 3



STEP 4 Now close your lips over the mouthpiece. Do not bite or chew the mouthpiece.

- **Inhale as deeply and strongly** as you can (Figure 4).
- You may not feel or taste the medication when inhaling. This is common.
- Before you exhale, remember to remove the inhaler from your mouth.

Figure 4



Repeat STEPS 2-4 if more than one dose has been prescribed. When you have taken the prescribed amount of doses, **replace the cover of the inhaler by screwing it back on.** With each inhalation some medication may stick to the inside of your mouth and throat. To reduce the risk of side effects rinse your mouth with water, and do not swallow.

Note: Do not try to remove the mouthpiece or to twist it unnecessarily. It is fixed to the inhaler and must not be taken off. Do not use PULMICORT TURBUHALER if it has been damaged or if the mouthpiece has become detached.

I cannot remember how many times I turned the brown 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 brown 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:**".

If you are already regularly using your inhaler, start at the beginning of STEP 2 under the section "**B. How to take a dose:**".

How do I know my dose has been loaded?

By turning the brown 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 2 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 PULMICORT TURBUHALER.

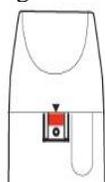
How do I clean my inhaler?

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.

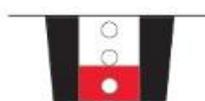
How do I know when to start a new inhaler?

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 (Figure 5). Now is the time to obtain your next inhaler. When the red mark reaches the bottom of the window, you should throw out your inhaler and start a new inhaler. The sound you hear if you shake the inhaler is made by a drying agent, not the medication. PULMICORT TURBUHALER cannot be refilled with drug and should be thrown away when it is empty.

Figure 5



Approximately 20 doses left



EMPTY

The most common side effects are:

- cough;
- throat irritation;
- thrush (fungal infection) in the mouth;
- hoarseness.

Other side effects are:

- bad taste;
- headache;
- nausea;
- dryness of the throat.

There have been occasional reports of:

- tiredness;
- thirst;
- diarrhea;
- throat or mouth infections.

Rare side effects include:

- skin reactions like rash;
- skin bruising;
- increase in chest tightness;
- nervousness, restlessness, depression;
- behavioural disturbances in children.

If you take PULMICORT TURBUHALER 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, contact your doctor.

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 | |
| Rare | Bronchospasm: shortness of breath, chest tightness which causes wheezing | | | X |
| | Severe Allergic Reactions: swelling of the face, lips, tongue, and/or throat (which may cause difficulty in breathing or swallowing), hives, rash and itching | | | X |

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

This is not a complete list of side effects. For any

unexpected effects while taking PULMICORT TURBUHLAER, contact your doctor or pharmacist.

HOW TO STORE IT

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

Always replace the cover after using PULMICORT TURBUHALER. Store the inhaler at room temperature (15-30°C).

REPORTING 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
- Calling 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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