

## PATIENT INFORMATION LEAFLET

### **Pulmicort Turbuhaler 100 mcg/dose & 200 mcg/dose**

budesonide

#### **Read all of this leaflet carefully before you start using this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **What Pulmicort Turbuhaler is used for**

Pulmicort Turbuhaler is used for the regular treatment of asthma.

#### **How Pulmicort Turbuhaler works**

Pulmicort Turbuhaler relieves and prevents inflammation in the airways caused by asthma.

Pulmicort Turbuhaler is intended for regular use and not for rapid relief of acute asthma conditions. It may take some weeks before you receive the full effect of the treatment.

#### **Before you take Pulmicort Turbuhaler**

##### ***When you must not take it***

If you are allergic (hypersensitive) to budesonide.

##### ***Before you start to take it***

If you switch from cortisone tablets to Pulmicort Turbuhaler, as your previous allergic symptoms such as a runny nose and eczema may return in certain cases. You may also experience tiredness, headaches, muscle and joint pain and occasionally nausea and vomiting. This is because the total amount of cortisone in the body is reduced when the disease is treated locally in the lungs. These symptoms disappear after you have received treatment for some time.

It is important that you tell your doctor if you have impaired liver function.

You should rinse your mouth out with water after each dosage to minimise the risk of fungal infection in your mouth and throat.

You must contact your doctor if your asthma gets worse. This may mean that the dosage needs to be changed or that you need other treatment.

In an acute asthma attack you must use your fast-acting asthma medicine.

##### ***Taking other medicines***

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may affect or be affected by treatment with Pulmicort Turbuhaler, for example medicines containing ketoconazole or itraconazole (present in medicines for fungal infections).

## How to take Pulmicort Turbuhaler

### How much & when to take

Always use Pulmicort Turbuhaler exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor prescribes the correct dose for you.

The number of doses varies according to the severity of your asthma.

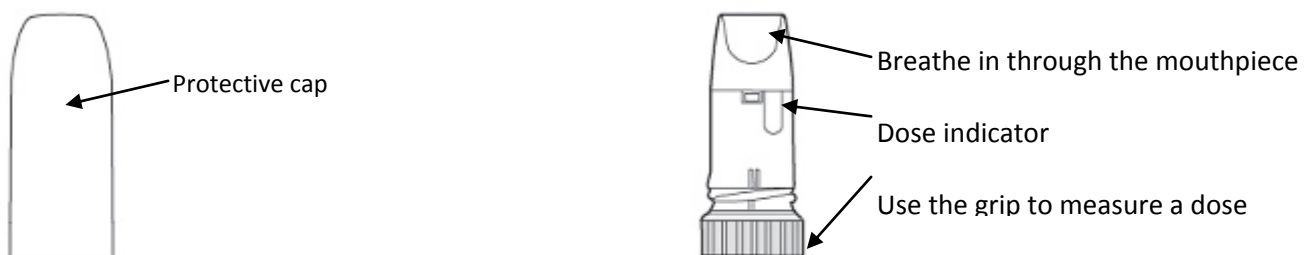
You must use Pulmicort Turbuhaler regularly, i.e. each day, even if you have no symptoms.

Pulmicort Turbuhaler is entirely driven by your own inhalation. The medicine follows the inhaled air down to the airways. Therefore, it is important to breathe in deeply and forcefully when you take your dose, see "Instructions for use".

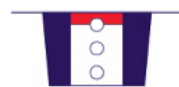
Note that the amount of medicine is very small and it can be very hard to notice.

You might not be able to taste or detect the medicine in any way. However, if you follow the instructions for use, you can be sure that you have inhaled the dose.

### Instructions for use



When there are about 20 doses left, a red mark appears in the dose indicator window. When the mark reaches the bottom edge of the window there are no doses left and the inhaler must be discarded. There may be medicine left in the inhaler, but not enough for further doses.



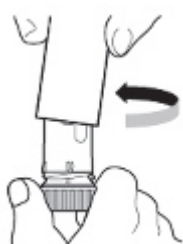
20 doses remaining



The medicine is finished

### This is how you take a dose of Pulmicort Turbuhaler

1. Unscrew the protective cap.



2. Hold the inhaler upright with the grip downwards. Do not hold the mouthpiece. Load one dose by turning the grip in one direction as far as it will go and then back to the original position. If you are not sure whether you have loaded one dose, load another one. You can never get more than one dose from the inhaler at a time.

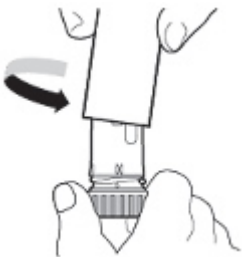


3. Breathe out (but not through the inhaler).

- Place the mouthpiece between your teeth and close your lips around the mouthpiece.
- Breathe in deeply and forcefully through your mouth. Do not bite or chew the mouthpiece.
- Remove the inhaler from your mouth before you breathe out. If you have to take several doses at a time, repeat steps 2-3.



4. Screw the protective cap back on. Rinse your mouth with water after each dose to get rid of any medicine remaining in your mouth.



#### NB

- Keep the inhaler upright with the grip downwards when you load the dose.
- Do not breathe out through the mouthpiece.
- Always replace the cover properly after use.
- Do not try to remove or turn the mouthpiece. It must be kept in place.
- Clean the mouthpiece regularly (once a week) with a sheet of soft paper. Never use water or any other fluid.
- When the red mark reaches the bottom edge of the dose indicator window there are no doses left and the inhaler must be discarded. There may be medicine left in the inhaler, but not enough for further doses.
- The sound heard when you shake the inhaler does not come from the medicine but from the drying agent in the grip.
- Do not use the Turbuhaler if it has been damaged or if the mouthpiece has become loose.

**How long to take it**

Your doctor prescribes the correct dose for you.

The number of doses varies according to the severity of your asthma.

You must use Pulmicort Turbuhaler regularly, i.e. each day, even if you have no symptoms.

**If you forget to take it**

If you have forgotten to take one dose, take the next dose as usual.

**If you take too much (overdose)**

If you have taken a larger dose than your doctor has prescribed on one occasion, you will probably not suffer from any side effects. However, if you use a larger dose than your doctor has prescribed over a longer period of time (months), there is a risk that you will suffer from side effects. If you think that you are suffering from side effects, contact your doctor or hospital for information about the risk and advice.

It is important that you take the dose stated on the label of the packaging or as your doctor has told you. Do not increase or decrease the dose without contacting your doctor.

**While you are using Pulmicort Turbuhaler****Things you must do**

Use Pulmicort Turbuhaler as directed by your doctor

**Things you must not do**

Do not stop using Pulmicort Turbuhaler unless advised by your doctor

**Things to be careful of**Pregnancy and breast-feeding

Experience from usage during pregnancy does not show any increased risk of malformations. However, you must talk to your doctor before using Pulmicort Turbuhaler during pregnancy because the severity of the asthma may change and the treatment may need to be adjusted.

Budesonide is excreted in breast milk. However, no effects on the nursing child are anticipated with therapeutic doses of Pulmicort Turbuhaler. Pulmicort Turbuhaler can be used during breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Pulmicort Turbuhaler does not affect your ability to drive a car or use machines.

**Side effects**

Like all medicines, Pulmicort Turbuhaler can cause side effects, although not everybody gets them.

Common (more than 1 in 100 people are affected): Mild irritation of the throat, coughing, hoarseness, fungal infection in the mouth cavity and throat.

Rare (less than 1 in 1000 people are affected): Hives and other skin rashes, angiooedema (swelling of the face, lips, tongue and/or throat, occasionally combined with difficulty breathing or swallowing), bronchospasm (contraction of the airway muscles), bruising.

The following have been reported (occur in an unknown number of users): Sleep disturbances, depression, nervousness, restlessness, anxiety, feeling of being very upset and/or irritable. These side effects are more likely to occur in children.

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:

- Changes in bone mineral density (thinning of the bones)
- Cataract (clouding of the lens in the eye)
- Glaucoma (increased pressure in the eye)
- Decreased growth rate in children and adolescents
- An effect on the adrenal gland (a small gland next to the kidney).
- These effects are much less likely to happen with inhaled corticosteroids than with cortisone tablets.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **Storage and Disposal of Pulmicort Turbuhaler**

Keep out of the reach and sight of children.

Do not store above 30°C. Keep the protective cap on the inhaler.

Do not use Pulmicort Turbuhaler after the expiry date which is stated on the inhaler and the packaging (EXP). The expiry date refers to the last day of that month.

#### **Product description**

Each inhaler contains 200 doses.

#### **Ingredients**

The active substance is budesonide. One dose (inhalation) contains 100 micrograms or 200 micrograms budesonide, respectively.

#### **Malaysian registration numbers:**

Pulmicort turbuhaler 100 mcg/dose: MAL19910818A

Pulmicort turbuhaler 200 mcg/dose: MAL19910817A

#### **Manufacturer**

AstraZeneca AB, 15185 Sodertalje, Sweden

#### **Date of revision**

The text was revised in November 2011

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