

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### PULMICORT® TURBOHALER® 100 micrograms, Inhalation powder PULMICORT® TURBOHALER® 200 micrograms, Inhalation 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 Pulmicort Turbohaler is and what it is used for
2. What you need to know before you use Pulmicort Turbohaler
3. How to use Pulmicort Turbohaler
4. Possible side effects
5. How to store Pulmicort Turbohaler
6. Contents of the pack and other information

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

The name of your medicine is ‘Pulmicort Turbohaler 100, 200 or 400 micrograms Inhalation Powder’. It is referred to as ‘Pulmicort Turbohaler’ in the rest of this leaflet.

Pulmicort Turbohaler is an inhaler. It contains a medicine called budesonide. This belongs to a group of medicines called ‘corticosteroids’. It works by reducing and preventing swelling and inflammation in your lungs.

Your doctor has prescribed this medicine to treat asthma or chronic obstructive pulmonary disease (COPD).

#### Asthma

For asthma, your doctor will prescribe two asthma inhalers: Pulmicort Turbohaler and a separate ‘reliever inhaler’.

- Use Pulmicort Turbohaler every day, as your doctor has told you to. This helps to prevent asthma symptoms from happening.
- Use your ‘reliever inhaler’ when you get asthma symptoms, to make it easier to breathe again.

#### Chronic obstructive pulmonary disease (COPD)

Pulmicort Turbohaler can also be used to treat the symptoms of COPD in adults. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking.

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

##### Do not use Pulmicort Turbohaler:

- If you are allergic to budesonide.

##### Warning and precautions

Talk to your doctor or pharmacist before using Pulmicort Turbohaler if:

- You have a cold or chest infection or any problems with your breathing.
- You have or have ever had tuberculosis (TB).
- You have liver problems.
- You have an infection of the airways.
- You have any current infections.

##### Other medicines and Pulmicort 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 Pulmicort Turbohaler can affect the way some medicines work and some medicines can have an effect on Pulmicort Turbohaler.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Steroid medicines.
- Medicines to treat fungal infections (such as itraconazole and ketoconazole).
- Medicines used to treat the HIV infection, known as HIV protease inhibitors (such as ritonavir and nelfinavir)
- Medicines that may be used as a form of birth control or hormone replacement therapy also known as oestrogen and contraceptive steroids.

##### 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 - do not use Pulmicort Turbohaler unless your doctor tells you to.
- If you get pregnant while using Pulmicort Turbohaler, do not stop using Pulmicort Turbohaler but talk to your doctor immediately.

##### Driving and using machines

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

##### Information you may have to carry while you are using Pulmicort Turbohaler

If you are using a high dose of Pulmicort Turbohaler your doctor may ask you to carry a steroid warning card. This explains to others about your medication.

#### 3. How to use Pulmicort 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.
- If Pulmicort Turbohaler is to be used by your child, make sure they use it correctly as your doctor has told you.
- It is important to use Pulmicort Turbohaler every day, even if you have no asthma or COPD symptoms at the time.
- If you are using Pulmicort Turbohaler for asthma, your doctor will want to regularly check your symptoms.
- Your breathing may improve within 2 days. However it can take up to 4 weeks for the medicine to have its full effect.

#### Important information about your asthma or COPD symptoms

If you feel you are getting breathless or wheezy while using Pulmicort Turbohaler, you should continue to use Pulmicort Turbohaler but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- Your breathing is getting worse or you often wake up at night with asthma.
- Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.

These signs could mean that your asthma or COPD is not being properly controlled and you may need different or additional treatment immediately.

#### Asthma

**Use your Pulmicort Turbohaler every day.** This helps to prevent asthma symptoms from happening. Your doctor will advise you of the correct dose to treat your asthma. Your doctor will reduce your medication to the lowest dose needed to control your asthma.

#### Adults (including the elderly)

- The recommended dose is 1 or 2 inhalations, twice a day (in the morning and in the evening).
- Your doctor may ask you to take your medicine once a day.
- The maximum dose is 1600 micrograms a day.
- If your asthma is getting worse and you are using your ‘reliever inhaler’ more often or you have more symptoms:
  - double your dose of Pulmicort Turbohaler immediately and talk to your doctor as soon as possible
  - double your dose by taking twice as many inhalations each time.

#### Use in children (5 years and above)

- The recommended dose is 1 or 2 inhalations, twice a day (in the morning and in the evening).
- The doctor may ask your child to take the medicine once a day.
- The maximum dose is 800 micrograms a day.

Pulmicort Turbohaler is not recommended for children under 5 years. This is because they may not be able to handle the device properly.

#### Use your separate ‘reliever inhaler’ to treat asthma symptoms when they happen.

Always keep your ‘reliever inhaler’ with you to use when you need it. Do not use Pulmicort Turbohaler to treat asthma symptoms - use your ‘reliever inhaler’.

#### Chronic Obstructive Pulmonary Disease (COPD)

- Only to be used by adults (aged 18 years and above).
- The recommended dose is 400 micrograms, twice a day (in the morning and in the evening).
- Your doctor or pharmacist will tell you how many inhalations to use. This will depend on which strength of Turbohaler you are given.

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

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

Unscrew the white cover and lift it off.

**Hold your Turbohaler** upright with the brown base at the bottom. Do not hold the mouthpiece when you turn the grip. **Turn the brown base as far as it will go in one direction. Then turn it back 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.

#### How to take an inhalation

Every time you need to take an inhalation, follow the instructions below.

1. Unscrew the white cover and lift it off.
2. **Hold your Turbohaler upright** with the brown base at the bottom.
3. Do **not** hold the mouthpiece when you load your Turbohaler. To load your Turbohaler with a dose, **turn the brown base 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.
4. Hold your Turbohaler away from your mouth. **Breathe out gently** (as far as is comfortable). Do **not** breathe out **through** your Turbohaler.
5. Place the mouthpiece gently between your teeth. Close your lips. **Breathe in as deeply and as hard** as you can through your mouth. Do not chew or bite on the mouthpiece.
6. **Remove your Turbohaler from your mouth. Then breathe out gently.** The amount of medicine that is inhaled is very small. This means you may not be able to taste it after inhalation. If you have followed the instructions, you can still be confident that you have inhaled the dose and the medicine is now in your lungs.
7. If you are to take a second inhalation, repeat steps 2 to 6.
8. **Replace the cover** by screwing it back on tightly after use.
9. **Rinse your mouth out with water after inhaling your prescribed dose.**

Do not try to remove or twist the mouthpiece. It is fixed to your Turbohaler and must not be taken off. Do not use your Turbohaler if it has been damaged or if the mouthpiece has come apart from your Turbohaler.

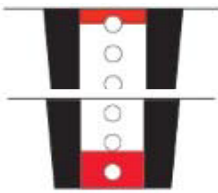
#### Cleaning your Turbohaler

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



**When to start using a new Turbohaler**

When you first see a red mark in the indicator window, there are about 20 doses left. You will then need to see your doctor for another prescription. When the red mark has reached the bottom of the indicator window, you must start using your new Turbohaler.



**Note:**

- The brown base 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 load your Turbohaler more than once by mistake before taking your dose, you will still only receive one dose.

**If you use more Pulmicort 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 not increase or decrease your dose without seeking medical advice. If you use more Pulmicort Turbohaler than you should, contact your doctor or pharmacist for advice.

**If you forget to use Pulmicort Turbohaler**

If you forget to take a dose, skip the missed dose and take the next dose as usual. Do not use a double dose to make up for a forgotten dose.

**If you stop using Pulmicort Turbohaler**

Do not stop using Pulmicort Turbohaler without talking to your doctor or pharmacist. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

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

**If either of the following happens to you, stop using Pulmicort Turbohaler and talk to your doctor immediately:**

- Swelling of your face, particularly around your mouth. This may mean that you are having an allergic reaction. This happens rarely, affecting less than 1 in 1,000 people.
- Sudden wheezing after inhaling your medicine. If this happens, also use your ‘reliever’ inhaler straight away. This happens very rarely, affecting less than 1 in 10,000 people.

**Other possible side effects:**

**Common (may affect up to 1 in 10 people)**

- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your Turbohaler.
- Mild sore throat, coughing and a hoarse voice.
- Pneumonia (infection of the lung) in COPD patients.

Tell your doctor if you have any of the following while taking budesonide, they could be symptoms of a lung infection:

- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties.

**Uncommon (may affect up to 1 in 100 people)**

- Feeling worried, restless or nervous.
- Depression.
- Trembling or shaking.
- Cataract (clouding of the lens in the eye).
- Muscle cramps.

**Rare (may affect up to 1 in 1,000 people)**

- Rash, itching, contact dermatitis (a skin problem), raised itchy rash (can be red and bumpy in appearance).
- Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing comes on suddenly after using Pulmicort Turbohaler stop using Pulmicort Turbohaler and use your ‘reliever inhaler’ straight away. Talk to your doctor immediately.
- Sleeping problems, aggression, over-excited or irritable. These effects are more likely to occur in children.
- Bruising of the skin.
- Loss of voice.
- Hoarse voice (rare in children)
- Behavioural changes (mainly in children)
- Feelings of extreme restlessness accompanied by an increase in motor activity including muscle spasms, tremors and twitching, pacing, crossing and uncrossing the legs and other nervous activity.

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)
- glaucoma (increased pressure in the eye)
- a slowing of the rate of growth of children and adolescents (rare). Height of children should be monitored.
- an effect on the adrenal gland (a small gland next to the kidney) (rare).

These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

**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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Pulmicort 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 or on the label of your Turbohaler. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- When not in use, Pulmicort Turbohaler should be stored with the cover tightened.
- 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 Pulmicort Turbohaler contains**

The active substance is budesonide. There are three different strengths of Turbohaler.

**Pulmicort Turbohaler 100 contains 200 inhalations.** Each metered dose contains 100 micrograms of budesonide.

**Pulmicort Turbohaler 200 contains 100 inhalations.** Each metered dose contains 200 micrograms of budesonide.

There are no other ingredients.

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

Pulmicort Turbohaler is an inhaler containing your medicine. The inhalation powder contains white to off-white round granules which break into a fine powder on inhalation. Each Turbohaler contains 100 or 200 inhalations and has a white body with a brown base.

**Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:**

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

**Manufacturer**

Pulmicort Turbohalers are manufactured by AstraZeneca AB, S- 151 85 Sodertalje, Sweden or AstraZeneca Dunkerque Production (AZDP), France or Pharma-stern GmbH, 22876 Wedel, Germany or Minakem Dunkerque S.A.S 224 Avenue de la Dordogne 59640 Dunkerque France

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**Parallel Product Authorisation Number**

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