

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pulmicort® Turbohaler® budesonide

Read all of this leaflet carefully before you start taking 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

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. 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.

2. Before you use Pulmicort Turbohaler

Do not use Pulmicort Turbohaler if:

- You are allergic (hypersensitive) to budesonide (the only ingredient in this medicine).

Take special care with Pulmicort Turbohaler

Before you use Pulmicort Turbohaler, tell your doctor or pharmacist if:

- You have a lung infection.
- 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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).
- HIV protease inhibitors (such as ritonavir and nelfinavir).

Pregnancy and breast-feeding

- If you are pregnant, or planning to get pregnant, talk to your doctor before using Pulmicort - 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.
- If you are breast-feeding, talk to your doctor before using Pulmicort Turbohaler.

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 Pulmicort Turbohaler exactly as your doctor, nurse or pharmacist has told you. Ask one of them for advice 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 symptoms at the time.
- 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 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 condition is not being properly controlled and you may need different or additional treatment immediately.

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.

If your doctor has told you to use your Turbohaler twice a day:

Adults and children (13 years and above)

- The usual dose is 1 or 2 inhalations, twice a day (in the morning and in the evening).
- Your doctor may increase this to a maximum of 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.

Children (5 - 12 years of age)

- The usual dose is 1 or 2 inhalations, twice a day (in the morning and in the evening).
- The doctor may increase this to a maximum of 800 micrograms a day.

If your doctor has told you to use your Turbohaler once a day:

- Only use your Turbohaler once a day if your doctor has told you to.
- Use your Turbohaler at the same time each evening.

Adults and children (13 years and above)

- The usual dose is 1 or 2 inhalations, in the evening.
- If your asthma is getting worse and you are using your 'reliever inhaler' more often or you have more symptoms:
 - double your dose immediately and talk to your doctor as soon as possible
 - double your dose by taking the same number of inhalations your doctor has told you **twice a day** (once in the morning and once in the evening).

Children (5 - 12 years of age)

- The usual dose is 1 or 2 inhalations, in the evening.
- The maximum dose is 400 micrograms a day.

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'.

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 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.



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.**



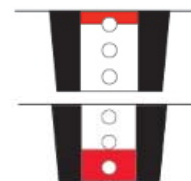
Do not try to remove or twist the mouthpiece. It is fixed to your Turbohaler and must not be taken off. Do not use your Turbohaler if it has been damaged or if the mouthpiece has come apart from your Turbohaler.

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.

If you stop using Pulmicort Turbohaler

Do not stop using this medicine even when your asthma gets better, unless your doctor tells you to.

4. Possible side effects

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

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

- Swelling of your face, particularly around your mouth (with possible swelling of the lips, tongue, eyes and ears), rash, itching, contact dermatitis (a skin problem), hives and bronchospasm (tightening of the muscles in the airways which causes wheezing). 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 (affects less than 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.

Rare (affects less than 1 in 1,000 people)

- Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children.
- Bruising of the skin.
- Loss of voice.
- Hoarse voice (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)
- a slowing of the rate of growth of children and adolescents (rare).
- 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.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pulmicort Turbohaler

- Keep out of the reach and sight of children.
- Do not store above 30°C.
- When not in use, Pulmicort Turbohaler should be stored with the cover tightened.
- Do not use Pulmicort Turbohaler after the expiry date printed on the carton or on the label of your Turbohaler. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. This will help to protect the environment.

6. Further information

What Pulmicort Turbohaler contains

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

Pulmicort Turbohaler 100 contains 200 doses (inhalations). Each metered dose contains 100 micrograms of budesonide.

Pulmicort Turbohaler 200 contains 100 doses (inhalations). Each metered dose contains 200 micrograms of budesonide.

Pulmicort Turbohaler 400 contains 50 doses (inhalations). Each metered dose contains 400 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. Each Turbohaler contains 50, 100 or 200 doses (inhalations) and has a white body with a brown base.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for Pulmicort Turbohaler are held by AstraZeneca UK Ltd, 600 Capability Green, Luton, LU1 3LU, UK.

Pulmicort Turbohaler is manufactured by AstraZeneca AB, S-151 85 Södertälje, Sweden.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference number
Pulmicort Turbohaler 100	17901/0162
Pulmicort Turbohaler 200	17901/0163
Pulmicort Turbohaler 400	17901/0164

This is a service provided by the Royal National Institute of Blind People.

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