



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

- The dose indicator tells you how many doses (inhalations) are left in your Turbohaler, starting with 60 doses when it is full.
- The dose indicator is marked in intervals of 10 doses. Therefore, it does not show every dose.
- When you first see a red mark at the edge of the indicator window, there are approximately 20 doses left. For the last 10 doses, the background of the dose indicator is red. When the ‘0’ on the red background has reached the middle of the window, you must start using your new Turbohaler.



- Note:
- The grip 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. However, the dose indicator will register all the loaded doses.

If you use more Symbicort 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 exceed your prescribed dose without seeking medical advice.

The most common symptoms that may occur if you use more Symbicort Turbohaler than you should are trembling, headache or a rapid heart beat.

If you forget to use Symbicort Turbohaler

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do **not** take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

- Like all medicines, this medicine can cause side effects, although not everybody gets them.
- If either of the following happen to you, stop using Symbicort Turbohaler and talk to your doctor immediately:**
- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty swallowing) or hives together with difficulty breathing (angioedema) and/or sudden feeling of faintness. This may mean that you are having an allergic reaction. This happens rarely, affecting less than 1 in 1,000 people.
  - Sudden acute wheezing or shortness of breath immediately after using your inhaler. **If either of these symptoms occur, stop using your Symbicort Turbohaler straightaway and use your ‘reliever’ inhaler. Contact your doctor immediately as you may need to have your treatment changed.** 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)

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use Symbicort Turbohaler.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your Symbicort Turbohaler.
- Mild sore throat, coughing and a hoarse voice.
- Headache.
- Pneumonia (infection of the lung) in COPD patients.

- Tell your doctor if you have any of the following while taking Symbicort Turbohaler, 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 restless, nervous or agitated.
- Disturbed sleep.
- Feeling dizzy.
- Nausea (feeling sick).
- Fast heart-beat.
- Bruising of the skin.
- Muscle cramps.
- Blurred vision.

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

- Rash, itching.
- Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing comes on suddenly after using Symbicort Turbohaler stop using Symbicort Turbohaler and talk to your doctor immediately.
- Low levels of potassium in your blood.
- Uneven heart-beat.

Very rare (may affect up to 1 in 10,000 people)

- Depression.
- Changes in behaviour, especially in children.
- Chest pain or tightness in the chest (angina pectoris).
- An increase in the amount of sugar (glucose) in your blood.
- Taste changes, such as an unpleasant taste in the mouth.
- Changes in your blood pressure.

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
- 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 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**Ireland**  
HPRA Pharmacovigilance.  
Website: [www.hpra.ie](http://www.hpra.ie);

5. How to store Symbicort 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 inhaler after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Keep the container tightly closed in order to protect from moisture.
- 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 protect the environment.

6. Contents of the pack and other information

What Symbicort 400/12 Turbohaler contains

The active substances are budesonide and formoterol fumarate dihydrate. Each inhaled dose contains 320 micrograms of budesonide and 9 micrograms of formoterol fumarate dihydrate, this corresponds to 400 micrograms of budesonide and 12 micrograms of formoterol fumarate dihydrate. The other ingredient is lactose monohydrate (which contains milk proteins).

What Symbicort 400/12 Turbohaler looks like and contents of the pack

Symbicort 400/12 Turbohaler is an inhaler containing your medicine. The inhalation powder is white in colour. Each Turbohaler contains 60 doses and has a white body with a red turning grip. The turning grip contains a Braille code with the number 6 for identification, to differ from other AstraZeneca inhaled products.

Symbicort 400/12 Turbohaler is available in packs of 1 Turbohaler containing 60 doses.

Parallel Product Authorisation Holder

IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufactured by

AstraZeneca AB, S-151 85 Södertälje, Sweden or AstraZeneca UK Ltd., Macclesfield, Cheshire, United Kingdom or AstraZeneca GmbH, Wedel, Germany.

Repackaged by

Cast Healthcare Ltd, Unit E The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK or IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

This medicinal product is authorised in the Member States of the EEA under the following names

| Country        | Trade name and strength                          |
|----------------|--------------------------------------------------|
| Austria        | Symbicort forte Turbohaler 320µg/9µg/inhalation  |
| Belgium        | Symbicort forte Turbohaler 320µg/9µg/inhalation  |
| Bulgaria       | Symbicort Turbuhaler 320µg/9µg/inhalation        |
| Croatia        | Symbicort Turbuhaler 320 µg/9 µg/inhalation      |
| Cyprus         | Symbicort Turbuhaler 320µg/9µg/inhalation        |
| Czech Republic | Symbicort Turbuhaler 320 µg/9 µg/inhalation      |
| Denmark        | Symbicort forte Turbuhaler 320µg/9µg/inhalation  |
| Estonia        | Symbicort Turbuhaler 320µg/9µg/inhalation        |
| Finland        | Symbicort Turbuhaler forte 320µg/9µg/inhalation  |
| France         | Symbicort Turbuhaler 400µg/12µg/inhalation       |
| Germany        | Symbicort Turbohaler 320µg/9µg/inhalation        |
| Greece         | Symbicort Turbuhaler 320µg/9µg/inhalation        |
| Hungary        | Symbicort forte Turbuhaler 320µg/9µg/inhalation  |
| Iceland        | Symbicort forte Turbuhaler 320µg/9µg/inhalation  |
| Ireland        | Symbicort Turbohaler 400µg/12µg/inhalation       |
| Italy          | Symbicort 320µg/9µg/inhalation                   |
| Latvia         | Symbicort forte Turbuhaler 320µg/9µg/inhalation  |
| Lithuania      | Symbicort Turbuhaler 320µg/9µg/inhalation        |
| Luxembourg     | Symbicort forte Turbohaler 320µg/9µg/inhalation  |
| Malta          | Symbicort Turbohaler 400µg/12µg/inhalation       |
| Netherlands    | Symbicort Turbuhaler 400µg/12µg/inhalation       |
| Norway         | Symbicort forte Turbuhaler 320µg/9µg/inhalation  |
| Poland         | Symbicort Turbuhaler 320µg/9µg/inhalation        |
| Portugal       | Symbicort Turbohaler 320µg/9µg/inhalation        |
| Romania        | Symbicort Turbuhaler 320µg/9µg/inhalation        |
| Slovakia       | Symbicort Turbuhaler forte 400µg/12µg/inhalation |
| Slovenia       | Symbicort forte Turbuhaler 320µg/9µg/inhalation  |
| Spain          | Symbicort forte Turbuhaler 320µg/9µg inhalation  |
| Sweden         | Symbicort forte Turbuhaler 320µg/9µg/inhalation  |
| United Kingdom | Symbicort Turbohaler 400µg/12µg, inhalation      |

**This leaflet was last updated in October 2021.**

Symbicort and Turbohaler are trade marks of the AstraZeneca group of companies.