

Symbicort Turbuhaler[®]

Budesonide/eformoterol

100/6, 200/6 or 400/12 micrograms per inhalation

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Symbicort Turbuhaler**. It does not contain all the information that is known about **Symbicort Turbuhaler**. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Symbicort Turbuhaler** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Symbicort Turbuhaler is used for

Symbicort Turbuhaler is used to treat the inflammation caused by your airway disease (asthma or chronic obstructive pulmonary disease (COPD)). It also widens the airways so that you find it easier to breathe. To get the best effect, you should use **Symbicort Turbuhaler** as prescribed by your doctor, even when you have no symptoms.

Symbicort Turbuhaler contains both the medicines budesonide and eformoterol, which have different ways of treating your airway disease (asthma or chronic obstructive pulmonary disease). Your airway disease is caused by an inflammation in the airways. Budesonide reduces and prevents this inflammation.

Eformoterol works by widening your airways, making it easier for you to breathe. This effect starts within 1-3 minutes after inhaling the medicine and lasts for up to 12 hours. When you breathe in through the mouthpiece of the inhaler, your breath carries the medicine to your lungs. See the instructions on "**How to use Turbuhaler**" in the pack.

Symbicort Turbuhaler is not addictive.

Symbicort Turbuhaler is only available with a doctor's prescription.

Before you use Symbicort Turbuhaler

When you must not use it

Do not use Symbicort Turbuhaler if you are pregnant or breast feeding unless your doctor says to do so. Ask your doctor about the risks and benefits involved.

Do not use Symbicort Turbuhaler after the use by (expiry) date printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use Symbicort Turbuhaler if the packaging is torn or shows signs of tampering.

Symbicort Turbuhaler has been prescribed for your airway disease (asthma or chronic obstructive pulmonary disease). Do not use it to treat any other complaints unless your doctor tells you to. Do not lend your Turbuhaler to anyone else even if their symptoms seem similar to yours.

You must tell your doctor if:

1. you have any allergies to

- Eformoterol, budesonide or lactose
- any other substances

If you have an allergic reaction, you may get a skin rash, hay fever or an asthma attack.

2. you have any of these medical conditions

- thyroid problems
- diabetes
- any heart problems
- tuberculosis
- problems with your potassium levels

You should tell your doctor if you have any of the following symptoms, which could be signs of chest infection: fever or chills, increased mucus production or change in mucus colour, increased cough or increased breathing difficulties.

It may not be safe for you to take **Symbicort Turbuhaler** if you have any of these conditions.

Taking other medicines

You must tell your doctor if you are taking any other medicines, including

- medicines used to treat heart problems or high blood pressure
- medicines for glaucoma, including eye drops
- medicines used to treat fungal infections
- any other medicine that you buy at the chemist, supermarket or health food shop.

These medicines may be affected by **Symbicort Turbuhaler**, or may affect how well it works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell him/her before you take any Symbicort Turbuhaler.

Special warnings

You must contact your doctor as soon as possible if you need to use your rescue medicine inhaler more often than usual to control your airway disease. **Do not increase the dose of Symbicort Turbuhaler without talking to your doctor.** Always carry your rescue medicine with you.

If you experience an immediate increase in wheezing or shortness of breath after taking **Symbicort Turbuhaler** contact a doctor immediately.

You should always be very careful with the use of medicines if you are pregnant or breastfeeding. If you do become pregnant while using **Symbicort Turbuhaler** you should contact your doctor as soon as possible.

Using Symbicort Turbuhaler

Your doctor will have explained why you are being treated with **Symbicort Turbuhaler** and told you what dose to take. **Follow all directions given to you by your doctor carefully.** They may differ from the information contained in this leaflet.

If you have asthma your doctor will instruct you to use **Symbicort Turbuhaler** in either of the following ways:

- A. Symbicort maintenance and reliever therapy for asthma (Symbicort SMART)

B. Symbicort maintenance therapy for asthma

If you have COPD your doctor will instruct you to use Symbicort Turbuhaler only as maintenance therapy:

C. Symbicort maintenance therapy for COPD.

The dosage of **Symbicort Turbuhaler** is individual and the maintenance dose should be taken even when you have no symptoms.

If you are instructed by your doctor to discontinue treatment with **Symbicort Turbuhaler**, follow any directions on dose reduction carefully.

Each pack of **Symbicort Turbuhaler** contains an instruction leaflet that tells you the correct way to use it. Please read this carefully.

Be sure to rinse your mouth out with water after using Symbicort Turbuhaler each time. This is to help reduce the chance of developing thrush in your mouth.

A. Symbicort Maintenance and Reliever Therapy for Asthma (Symbicort SMART)

You take a maintenance dose of **Symbicort Turbuhaler** every day. You also use **Symbicort Turbuhaler** if you need extra doses for relief of asthma symptoms. This means that you use Symbicort Turbuhaler as your only inhaler both for regular daily use and as rescue medication. You will not need a separate inhaler for relief of symptoms.

Always carry **Symbicort Turbuhaler** with you for relief of symptoms. It is important that you contact your doctor if you find the treatment ineffective or if you exceed the highest recommended dose.

Symbicort 100/6 Turbuhaler**Usual doses for adults and adolescents 12 years and older:**

- 2 inhalations per day, given either as one inhalation in the morning and evening or as 2 inhalations in either the morning or evening.
- If you experience symptoms, take 1 additional inhalation and wait a few minutes. If you don't feel better, take another inhalation. You must not use more than 6 inhalations each time.

Usual doses for children (4 years and older)

- 1 inhalation once daily.
- If you experience symptoms, take 1 additional inhalation and wait a few minutes. If you don't feel better, take another inhalation. You must not use more than 4 inhalations each time.

Contact your doctor:

- If you need to take an increasing number of inhalations for symptom relief without getting better asthma control within 2 weeks, or
- If you regularly use more than 8 inhalations (4 inhalations for children) per day.

Never take more than 12 inhalations in total (8 inhalations for children) per day.

Symbicort 200/6 Turbuhaler**Usual doses for adults and adolescents 12 years and older:**

- 2 inhalations per day, given either as one inhalation in the morning and evening or as 2 inhalations in either the morning or evening. Your doctor may prescribe a maintenance dose of 2 inhalations twice daily.
- If you experience symptoms, take 1 additional inhalation and wait a few minutes. If you don't feel better, take another inhalation. You must not use more than 6 inhalations each time.

Contact your doctor:

- If you need to take an increasing number of inhalations for symptom relief without getting better asthma control within 2 weeks, or
- If you regularly use more than 8 inhalations (4 inhalations for children) per day.

Never take more than 12 inhalations in total (8 inhalations for children) per day.

B. Symbicort Maintenance Therapy for Asthma

You take a maintenance dose of **Symbicort Turbuhaler** every day. In addition, you use a separate inhaler, containing only a rapid-acting bronchodilator (airway widening medicine) for relief of asthma symptoms. This means that you use two separate inhalers.

Always carry your rescue medication with you for relief of symptoms. It is important that you contact your doctor if you find the treatment ineffective or if you exceed the highest recommended dose.

Symbicort 100/6 Turbuhaler

Usual doses for adults and adolescents 12 years and older:

- 1-2 inhalations once or twice daily.
- Maximum daily maintenance dose: 4 inhalations.
- Maximum dose during worsening asthma: 4 inhalations twice daily.

Usual doses for children (4 years and older)

- 1-2 inhalations twice daily
- Maximum daily dose: 4 inhalations

Symbicort 200/6 Turbuhaler

Usual doses for adults and adolescents 12 years and older:

- 1-2 inhalations once or twice daily
- Maximum daily maintenance dose: 4 inhalations.
- Maximum dose during worsening asthma: 4 inhalations twice daily.

Usual doses for children (4 years and older)

- 1 inhalation twice daily
- Maximum daily dose: 2 inhalations

Symbicort 400/12 Turbuhaler

Usual doses for adults and adolescents 12 years and older:

- 1 inhalation once or twice daily
- Maximum daily maintenance dose: 2 inhalations.
- Maximum dose during worsening asthma: 2 inhalations twice daily.

Usual doses for children (4 years and older)

- Not recommended for use in children.

If you have an Asthma Action Plan that you have agreed with your doctor, follow it closely at all times.

C. Symbicort Maintenance Therapy for Chronic Obstructive Pulmonary Disease (COPD)

Symbicort 200/6 Turbuhaler

Usual dose for adults (40 years and older)

- 2 inhalations twice daily
- Maximum daily maintenance dose: 4 inhalations

Symbicort 400/12 Turbuhaler

Usual dose for adults (40 years and older)

- 1 inhalation twice daily
- Maximum daily maintenance dose: 2 inhalations

If you forget to take it

If you miss a dose, it is not necessary to make up for the dose you have missed. Just take it when the next dose is due. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Overdose

Use only the number of inhalations your doctor has prescribed. Using more will increase the risk of side effects.

The most common symptoms and signs that may occur after overdosage are:

- trembling
- headache
- rapid heartbeat

If you use too much **Symbicort Turbuhaler** over a longer period (months) it is possible that you may get side effects related to budesonide.

If you think this may have happened to you or if any of the above mentioned symptoms bother you, please discuss it with your doctor or pharmacist.

Please telephone your doctor or the National Poisons Information Centre Ph: 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Symbicort Turbuhaler, even if there are no signs of discomfort or poisoning.

While you are using Symbicort Turbuhaler

Things you must do

Take your **Symbicort Turbuhaler** regularly for your airway disease, even if you feel well. See your doctor regularly to make sure that your airway disease is not getting worse. Your **Symbicort Turbuhaler** dose will be changed (up or down) by your doctor depending on your condition.

Note:

- Do not try to remove the mouthpiece since it is fixed to the inhaler. The mouthpiece can be rotated, but do not twist it unnecessarily.
- As the amount of powder dispensed is very small, you may not be able to taste it after inhalation. However, you can still be confident that you have inhaled the dose if you have followed the instructions.
- If you by mistake perform the loading procedure more than once before taking your dose, you will still only receive one dose. The dose indicator will, however, register all the loaded doses.
- The sound heard if you shake the inhaler is not produced by the medication but by a drying agent.

Things you must not do

Do not stop taking Symbicort Turbuhaler unless you have discussed it with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Symbicort Turbuhaler. Ask them to answer any questions you may have.

Usually you do not feel any side effects when you use **Symbicort Turbuhaler**. However, be sure to tell your doctor if any of the following side effects bother you or if any other unusual effects bother you:

Common side effects

- mild irritation in the throat
- coughing
- hoarseness
- thrush (fungal infection in mouth and throat)
- headache
- trembling
- rapid or irregular heartbeat

Less common side effects

- sleep difficulties
- restlessness, nervousness and anxiety
- dizziness
- vomiting / nausea / diarrhoea
- taste disturbance, thirst
- muscle cramps
- weight gain

Rare side effects

- skin rash and bruising
- itching
- facial swelling
- spasm in the airways
- high blood sugar levels
- depression
- chest pain
- behavioural symptoms
- severe allergic reaction

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Symbicort Turbuhaler**.

Tell your doctor if you notice anything else that is making you feel unwell or bothering you.

After using it**Cleaning**

The Turbuhaler must be wiped with a clean dry tissue and must never get wet. Full instructions on the right way to use and clean the Turbuhaler are inside each pack.

Storage

Symbicort Turbuhaler should be kept below 30°C. Always replace the cover after using Symbicort Turbuhaler. **Do not store Symbicort Turbuhaler or any other medicine in the bathroom or near a sink.** Heat and dampness can destroy some medicines.

Keep Symbicort Turbuhaler where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave Symbicort Turbuhaler in the car on hot days.

Disposal

Ask your pharmacist what to do with any Symbicort Turbuhaler you have left over if your doctor tells you to stop taking it, or you find that the expiry date has passed.

Product description

Symbicort Turbuhaler contains an inhalation powder which is a mixture of the active ingredients, budesonide and eformoterol. The other ingredient is lactose. **Symbicort Turbuhaler** contains very small amounts of lactose, which may contain milk protein residue. It is unlikely that these will cause any problems in patients who are intolerant to lactose.

Symbicort Turbuhaler contains 60 or 120 doses.

Symbicort 100/6 Turbuhaler: One inhalation contains budesonide equivalent to 100 micrograms metered dose and eformoterol equivalent to 6 micrograms metered dose.

Symbicort 200/6 Turbuhaler: One inhalation contains budesonide equivalent to 200 micrograms metered dose and eformoterol equivalent to 6 micrograms metered dose.

Symbicort 400/12 Turbuhaler: One inhalation contains budesonide equivalent to 400 micrograms metered dose and eformoterol equivalent to 12 micrograms metered dose.

The inhaler is made of plastic parts.

Marketed by:

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