

Symbicort® Turbuhaler® (powder inhaler)

ASTRAZENECA

AMZV

What is Symbicort Turbuhaler and when is it used?

Symbicort contains the two active substances budesonide and formoterol, which affect your respiratory disease in different ways.

(e.g., asthma or other inflammatory respiratory diseases). The cause of your disease is inflammation of the airways. Budesonide reduces and prevents this inflammation. Formoterol widens your airways, relieves bronchial muscle spasms, and helps you breathe better. You will notice this effect within 1–3 minutes after inhaling Symbicort.

By inhalation, the active substances reach the lungs directly and exert their effect there.

Symbicort should only be used on prescription and under constant supervision of a doctor.

The doctor will prescribe either Symbicort as the only inhaler (for maintenance and as-needed therapy) or Symbicort for maintenance therapy and a second inhaler for as-needed therapy. You must always carry your inhaler for as-needed therapy (emergency medication for sudden bronchial muscle spasms) with you.

What should be considered?

Special note for smokers

You can support the effectiveness of Symbicort by refraining from smoking! This is especially true for patients who already suffer from emphysema.

When should Symbicort Turbuhaler not be used?

Symbicort should not be used in case of known hypersensitivity to the active substances budesonide and formoterol or to the excipient lactose.

Similarly, Symbicort should not be used in certain severe heart diseases (irregular heartbeat and in the so-called heart block).

When should caution be exercised when using Symbicort Turbuhaler?

In case of rapidly worsening shortness of breath, or if additional inhalations do not lead to sufficient improvement quickly, the doctor or the nearest hospital should be consulted immediately. If you have to wheeze or become breathless, you must continue to use Symbicort, but contact your doctor as soon as possible.

The use of active substances of the corticosteroid type (active substance budesonide in Symbicort) reduces the body's defense against infectious diseases. The risk of an infectious disease is lower with the inhalative use of Symbicort Turbuhaler than with oral treatment with other corticosteroids (e.g., tablets). Nevertheless, you should take care to avoid possible sources of infection during treatment with Symbicort.

In infectious lung diseases, including pulmonary tuberculosis and fungal infections of the lungs (pulmonary mycosis), Symbicort should only be used if a targeted antibiotic treatment is carried out at the same time, or if medications against fungal infections are administered.

Inform your doctor immediately if an infectious disease occurs during treatment with Symbicort. Especially with chickenpox and measles, a severe form can occur, which must be treated by the doctor accordingly.

In case of excessive use or long-term application in children, the possibility of growth delay cannot be excluded. Therefore, the doctor will carefully monitor the growth development of children who are treated with Symbicort over a longer period.

Caution is advised when taking certain medications over a long period for the treatment of fungal infections (ketoconazole) and in cases of liver cirrhosis. Caution is also advised when taking antidepressants and cardiovascular preparations simultaneously.

The simultaneous intake of grapefruit juice should be avoided.

In cases of specific heart or heart muscle diseases, severe hypertension (high blood pressure), epilepsy, diabetes, or an overactive thyroid, Symbicort should only be used on the explicit instructions of a doctor.

Symbicort Turbuhaler contains less than 1 mg of lactose per inhalation. Normally, this amount does not cause problems for patients with lactose intolerance.

Inform your doctor or pharmacist if you suffer from other illnesses, have allergies, or are taking other medications (including those purchased yourself!).

Can Symbicort Turbuhaler be used during pregnancy or breastfeeding?

If you are pregnant or wish to become pregnant, and during breastfeeding, you should not use Symbicort Turbuhaler unless explicitly prescribed by a doctor.

How do you use Symbicort Turbuhaler?

The doctor will determine the appropriate dosage for you based on regular examinations and will tell you how to use the Turbuhaler: as regular maintenance therapy or as maintenance and reliever therapy.

A. Maintenance and reliever therapy

Every day, you administer a regular dose with the Symbicort Turbuhaler. If there is an additional need, use the Symbicort Turbuhaler for further administration to relieve asthma symptoms. You only use the Symbicort Turbuhaler as an inhaler for both regular daily dose administration and emergencies. You do not need another inhalation device to relieve symptoms.

B. Regular maintenance therapy

Every day, you administer a regular dose with the Symbicort Turbuhaler. In addition, you use another inhalation device that contains a fast-acting bronchodilator (a medication that expands the airways) to relieve asthma symptoms. So you use two different inhalation devices.

A. Maintenance and reliever therapy

Asthma

Children from 6 years

Symbicort 100/6: 1–2× daily 1 inhalation of 100/6 µg. Additional doses can be inhaled as needed for asthma symptoms. However, a maximum of 8 doses may be inhaled daily.

Adults, elderly patients, and adolescents aged 12 years and older

Symbicort 100/6: 2× daily 1–2 inhalations of 100/6 µg or 1× daily 2 inhalations of 100/6 µg in the evening.

Symbicort 200/6: 2× daily 1 inhalation of 200/6 µg or 1× daily 1–2 inhalations of 200/6 µg in the evening.

In exceptional situations, the maintenance therapy dosage can be increased by the doctor.

In case of asthma symptoms, additional doses of Symbicort 100/6 or 200/6 can be inhaled as needed. However, a total daily dose of 12 puffs should never be exceeded.

This maximum dose of 12 puffs should only be used temporarily and in exceptional situations. If you find the treatment ineffective or if the number of inhalations needs to be constantly increased within 2 weeks, you should contact your doctor. They will review the appropriateness of your therapy.

B. Regular maintenance therapy dosage for asthma

Children from 6 years

Symbicort 100/6: 2× daily 1–2 inhalations of 100/6 µg.

Symbicort 200/6: 2× daily 1 inhalation of 200/6 µg.

Symbicort 400/12: Symbicort 400/12 µg is not suitable for children under 12 years.

Adults, elderly patients, and adolescents aged 12 years and older

Symbicort 100/6: 2× daily 1–2 inhalations of 100/6 µg or 1× daily 2 inhalations of 100/6 µg in the evening.

Symbicort 200/6: 2× daily 1–2 inhalations of 200/6 µg or 1× daily 1–2 inhalations of 200/6 µg in the evening.

Symbicort 400/12: 2× daily 1 inhalation of 400/12 µg. During the course of treatment, the doctor may adjust the dosage.

In the case of nocturnal asthma symptoms, Symbicort Turbuhaler can be prescribed by the doctor as a single administration at night.

Dosage for chronic obstructive pulmonary disease (COPD)

Adults

Symbicort 200/6: 2× daily 2 inhalations.

Do not change the prescribed dosage on your own. If you think the medicine is too weak or too strong, talk to your doctor or pharmacist.

After using Symbicort, teeth should be brushed or the mouth rinsed.

Preparation of the new Symbicort Turbuhaler before the first inhalation

Before first use, the new Turbuhaler must be specially prepared. This process does not need to be repeated, even if the Turbuhaler is not used regularly:

1. Unscrew the protective cap. Turning causes a rattling noise.

2. Hold the inhaler upright.
3. Turn the red dosage wheel to the stop and back to the starting position. It does not matter which side is turned first. This process must be performed twice. Do not hold the mouthpiece.
4. Continue at point 2 of the following instructions for the 'Method of use'.

After preparing the new Turbuhaler:

Method of use after preparing the new Turbuhaler

1. Unscrew the protective cap. Turning causes a rattling noise.
2. Hold the inhaler upright.
3. Turn the red dosage wheel to the stop and back to the starting position. Do not hold the mouthpiece. The device is now ready for inhalation.
4. Exhale. Do not exhale through the mouthpiece.
5. Gently enclose the mouthpiece with your teeth and lips and inhale deeply and forcefully. Do not chew or bite the mouthpiece.
6. Remove the device from the mouth and hold your breath for a few seconds. Exhale slowly.
7. Screw on the protective cap.
8. Rinse the mouth with water. Do not swallow the water.

If more than 1 inhalation per application is needed, the steps 3/4/5/6 must be repeated accordingly.

After each use, the Symbicort Turbuhaler should be closed again with the protective cap.

Regular care of the mouthpiece

The mouthpiece should be wiped externally with a dry cloth daily. Water should never be used to clean the mouthpiece.

When is the Symbicort Turbuhaler used up?

In the 'window' located under the mouthpiece, the remaining available doses are displayed. The Turbuhaler contains no more doses when the number zero on the red background reaches the middle of the window.

The noise that occurs when shaking the Turbuhaler is caused by the drying agent. It can still be heard even when all doses are used up.

It is possible that you may not feel or taste the active ingredients during inhalation, as very little active ingredient is released.

What side effects can Symbicort Turbuhaler have?

Commonly, headaches, palpitations, tremors, local fungal infections on the oral and pharyngeal mucosa (thrush), mild irritation of the pharyngeal mucosa with swallowing difficulties, cough, and hoarseness may occur.

Occasionally, agitation, restlessness, nervousness, nausea, dizziness, sleep disturbances, an increase in heart rate, muscle cramps, and muscle pain are observed.

Rarely, allergic skin reactions, itching, irregular heartbeat, spasms in the airways (bronchospasms), and severe allergic reactions may occur.

In very rare cases, depression, behavioral disorders, facial swelling, increased blood sugar levels, and chest pain have been observed.

If you notice side effects not described here, you should inform your doctor or pharmacist.

What else should be considered?

Symbicort should be stored below 30 °C and out of reach of children. The medication should only be used until the date marked 'EXP' on the container.

If you are in possession of expired medications, return them to the pharmacy for disposal.

Further information can be provided by your doctor or pharmacist. These individuals have the detailed professional information.

What is contained in Symbicort Turbuhaler?

1 inhalation dose of Symbicort Turbuhaler 100/6 contains 100 µg (micrograms) of budesonide and 6 µg of formoterol as active ingredients, and lactose as an excipient.

1 inhalation dose of Symbicort Turbuhaler 200/6 contains 200 µg of budesonide and 6 µg of formoterol as active ingredients, and lactose as an excipient.

1 inhalation dose of Symbicort Turbuhaler 400/12 contains 400 µg of budesonide and 12 µg of formoterol as active ingredients, and lactose as an excipient.

The lactose used as an excipient may contain trace amounts of milk protein.

Authorization number
55568 (Swissmedic).

Where can you obtain Symbicort Turbuhaler? Which packages are available?
Symbicort Turbuhaler is available in pharmacies only with a doctor's prescription.

Packages with 60 or 120 single doses of 100/6 µg or 200/6 µg respectively.

Packages with 60 single doses of 400/12 µg.

Marketing authorization holder
AstraZeneca AG, 6301 Zug.

This package leaflet was last reviewed by the medicines authority (Swissmedic) in April 2008.

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