

SYMBICORT RAPIHALER®

Budesonide and formoterol (eformoterol) fumarate dihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Symbicort Rapihaler. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using Symbicort Rapihaler against the benefits they expect it will have for you.

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

Keep this leaflet with your Symbicort Rapihaler.

You may need to read it again.

What Symbicort Rapihaler is used for?

Symbicort Rapihaler is a pressurised metered dose inhaler (pMDI) or puffer.

The medicine inside Symbicort Rapihaler is inhaled into the lungs for the treatment of asthma in adults and adolescents (12 years and over) or Chronic Obstructive Pulmonary Disease (COPD) in adults (18 years and over).

Symbicort Rapihaler contains two active ingredients in one inhaler: budesonide and formoterol (as formoterol fumarate dihydrate, which was previously known as eformoterol fumarate dihydrate).

- Budesonide belongs to a group of medicines called corticosteroids. Budesonide acts directly on your airways to reduce inflammation.
- Formoterol belongs to a group of medicines called beta-2-agonists. Formoterol opens up the airways to help you breathe more easily.

ASTHMA

Asthma is a disease where the airways of the lungs become narrow and inflamed (swollen), making it difficult to breathe. This may for example be due to exercise, or exposure to allergens (eg an allergy to house dust mites, smoke or air pollution), or other things that irritate your lungs.

The budesonide in Symbicort Rapihaler helps to improve your condition and to prevent asthma attacks from occurring.

The formoterol in Symbicort Rapihaler helps you breathe more easily.

Some people can take Symbicort Rapihaler when they need it - They use Symbicort Rapihaler as an anti-inflammatory reliever to treat their symptoms when their asthma gets worse and to help prevent asthma attacks, or to help prevent symptoms from happening (eg before exercise or exposure to other triggers such as allergens).

Some people need to take Symbicort Rapihaler every day. They use their Symbicort Rapihaler as a daily maintenance preventer to help maintain control of their asthma symptoms and help prevent asthma attacks

Chronic Obstructive Pulmonary Disease (COPD)

COPD (which includes chronic bronchitis and emphysema) is a long-term lung disease. There is often permanent narrowing and

persistent inflammation of the airways. Symptoms may include difficulty in breathing (breathlessness or wheezing), coughing and increased sputum.

Symbicort Rapihaler when used as prescribed will help to control your COPD symptoms (ie breathing difficulties).

Ask your doctor if you have any questions about why Symbicort Rapihaler has been prescribed for you.

Your doctor may have prescribed it for another reason.

Symbicort Rapihaler is not addictive.

This medicine is available only with a doctor's prescription.

Before you use Symbicort Rapihaler

When you must not use it

Do not use Symbicort Rapihaler if you have an allergy to:

- any medicine containing formoterol or budesonide
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

Do not give Symbicort Rapihaler to a child under 12 years, unless directed by the child's doctor.

Symbicort Rapihaler is not recommended for use in children under 12 years.

Do not use Symbicort Rapihaler after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

If you have asthma, ask your doctor or pharmacist if you have any questions about your Asthma Action Plan.

Your healthcare professional should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to take as a reliever when you have symptoms or sudden attacks of asthma, medicines you can take to prevent symptoms from occurring (eg prior to exercise or allergen exposure) and if you need to take daily maintenance medicines to help control your asthma. It will also provide advice on when to seek urgent medical attention such as when your asthma suddenly worsens or worsens over a period of time.

It is important that you discuss with your doctor both your exposure to triggers and how often you exercise, as these could impact how your doctor prescribes your Symbicort Rapihaler.

Your doctor may prescribe Symbicort Rapihaler for you to use as:

- an anti-inflammatory reliever medicine only,

- both an anti-inflammatory reliever and daily maintenance preventer medicine or,
- as a daily maintenance preventer only, where another medicine is used as a reliever.

Ask your doctor if you have any questions about how you should be using your Symbicort Rapihaler.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- thyroid problems
- diabetes
- heart problems
- liver problems
- tuberculosis (TB)
- low levels of potassium in the blood

It may not be safe for you to take Symbicort Rapihaler if you have, or have had, any of these conditions.

Tell your doctor if you currently have an infection.

If you take Symbicort Rapihaler while you have an infection, the medicine may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is not serious.

Tell your doctor if you are pregnant or intend to become pregnant or breastfeeding.

Your doctor will discuss the possible risks and benefits of using Symbicort Rapihaler during pregnancy and while breastfeeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Symbicort Rapihaler.

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Symbicort Rapihaler may interfere with each other. These include:

- medicines used to treat heart problems or high blood pressure such as beta-blockers, diuretics and antiarrhythmics (disopyramide, procainamide and quinidine)
- medicines used to treat glaucoma such as beta-blockers
- medicines used to treat depression or other mood/mental disorders such as tricyclic antidepressants, monoamine oxidase inhibitors and phenothiazines
- medicines used to treat hayfever, coughs, colds and runny nose such as antihistamines
- medicines used to treat fungal infections (eg ketoconazole)
- xanthine derivatives (eg theophylline) which are a class of medicines used to treat asthma and COPD.
- medicines used to treat Addison's disease (when there is inadequate production of a natural steroid hormone

by the adrenal gland) or another condition where there is too much salt lost in the urine (eg fludrocortisone)

These medicines may be affected by Symbicort Rapihaler or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Symbicort Rapihaler.

How to use Symbicort Rapihaler

How to use your Rapihaler

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

If you are not sure how to use the Rapihaler, ask your doctor or pharmacist to show you how.

How much to take

ASTHMA (Adults and children 12 years and over)

Your healthcare professional should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to take as a reliever when you have symptoms or sudden attacks of asthma, medicines you can take prevent symptoms from occurring (eg prior to exercise or allergen exposure) and if you need to take daily maintenance medicines to help control your asthma.

It is important that you discuss with your doctor both your exposure to triggers and how often you exercise, as these could impact how your doctor prescribes your Symbicort Rapihaler.

Your doctor may prescribe Symbicort Rapihaler for you to use as:

- an anti-inflammatory reliever medicine only,
- both an anti-inflammatory reliever and daily maintenance preventer medicine or,
- as a daily maintenance preventer only, where another medicine is used as a reliever.

Ask your doctor if you have any questions about how you should be using your Symbicort Rapihaler.

If your asthma has been under control for some time, your doctor may tell you to take less inhalations of Symbicort Rapihaler, prescribe you a lower strength of Symbicort Rapihaler or recommend that you use Symbicort Rapihaler in a different way.

If you are using more inhalations of your reliever medicine or you are wheezing or breathless more than usual tell your doctor as your asthma may be getting worse.

Anti-inflammatory reliever only (Symbicort Rapihaler 100/3)

For patients aged 12 years and over, Symbicort Rapihaler 100/3 can be used to treat asthma symptoms when they happen and to help stop asthma symptoms from

happening (eg just before exercise or before you get exposed to other triggers).

If you get asthma symptoms, take 2 inhalations and wait a few minutes. If you do not feel better, take 2 more inhalations.

Your doctor will tell you how many inhalations to take before exercising or exposure to other triggers to help stop symptoms from happening.

Do not use more than 12 inhalations on a single occasion or more than 24 inhalations in any day. If your symptoms continue to worsen over 3 days, despite using additional inhalations, tell your doctor.

Have your Symbicort Rapihaler reliever with you at all times.

Anti-inflammatory reliever plus maintenance therapy (Symbicort Rapihaler 50/3 and 100/3)

For patients aged 12 years and over, Symbicort Rapihaler 50/3 and 100/3 can be used to treat asthma symptoms when they happen. Symbicort Rapihaler 100/3 can also be used to help stop asthma symptoms from happening (eg just before exercise or before you get exposed to other triggers).

If you get asthma symptoms, take 2 inhalations of Symbicort Rapihaler 50/3 or 100/3 and wait a few minutes. If you do not feel better, take 2 more inhalations.

Your doctor will tell you how many inhalations of Symbicort Rapihaler 100/3 to take before exercising or exposure to other triggers to help stop symptoms from happening.

Have your Symbicort Rapihaler 50/3 or 100/3 reliever with you at all times.

You also need to take your Symbicort Rapihaler (50/3 and 100/3) daily as your maintenance preventer. The usual maintenance dose is 4 inhalations per day (given either as 2 inhalations in the morning and evening or as 4 inhalations in either the morning or evening). Your doctor may prescribe a maintenance dose of Symbicort Rapihaler 100/3 4 inhalations twice a day.

Do not use more than 12 inhalations on a single occasion or more than 24 inhalations of Symbicort Rapihaler (as needed and daily dose) in any day. If your symptoms continue to worsen over 3 days, despite using additional inhalations, tell your doctor.

NOTE: Symbicort Rapihaler 200/6 is not recommended to be used as an anti-inflammatory reliever medicine.

Daily fixed dose maintenance therapy (Symbicort Rapihaler 50/3, 100/3 and 200/6)

For patients aged 12 years and over, Symbicort Rapihaler 50/3, 100/3 and 200/6 can be used as a daily fixed-dose maintenance preventer.

The usual dose of Symbicort Rapihaler 50/3 and 100/3 is 2 or 4 inhalations twice a day. Do not take more than 8 inhalations a day.

The usual dose of Symbicort Rapihaler 200/6 is 2 inhalations twice a day. Do not take more than 4 inhalations per day.

Symbicort Rapihaler 200/6 can also be given as a higher dose in patients aged 18 years and over. The usual dose is 4 inhalations twice a day. Do not take more than 8 inhalations per day.

Have your separate reliever with you at all times.

COPD (Adults)

The usual dose (also maximum recommended dose) is 2 puffs of Symbicort Rapihaler 200/6 twice a day.

Your doctor should tell you the best way to manage your symptoms and any flare ups. This may include additional medicines (such as reliever medicines) to use when you have sudden attacks of breathlessness.

If you are using more inhalations of your reliever medicine or you are wheezing or breathless more than usual tell your doctor.

If your COPD gets worse, your doctor may give you some additional medicines (such as oral corticosteroids or antibiotics).

If you forget to use it

If you miss a dose of Symbicort Rapihaler, take your dose as soon as you remember.

Do not use a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are using Symbicort Rapihaler as a reliever medicine, consult your doctor on the correct use of the product.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

How long to use it

If your doctor has told you to take Symbicort Rapihaler daily, it is important that you use it every day even if you feel well.

Symbicort Rapihaler helps control your asthma or COPD but does not cure it.

Keep using it for as long as your doctor tells you to. Do not stop using it unless your doctor tells you to.

If you take too much (overdose)

Telephone your doctor, pharmacist or the Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too much Symbicort Rapihaler.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you use too much Symbicort Rapihaler, you may feel sick or vomit, have a fast or irregular heartbeat, a headache, tremble, feel shaky, agitated, anxious, tense, restless, excited or be unable to sleep.

While you are using Symbicort Rapihaler

Things you must do

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

Keep using Symbicort Rapihaler for as long as your doctor tells you to, even if you are feeling well.

See your doctor regularly to make sure that your asthma or COPD is not getting worse.

Have your reliever medicine available at all times.

As advised by your doctor, this may be your Symbicort Rapihaler (50/3 or 100/3) or another reliever medicine.

Rinse your mouth out with water after taking your daily morning and/or evening dose of Symbicort Rapihaler and spit this out.

If you don't rinse your mouth you are more likely to develop thrush in your mouth. You do not have to rinse your mouth if you have to take occasional puffs of Symbicort Rapihaler for relief of asthma symptoms (ie as an anti-inflammatory reliever).

Tell any other doctors, dentists and pharmacists who are treating you that you are using Symbicort Rapihaler.

If you become pregnant while using Symbicort Rapihaler, tell your doctor.

Patients taking Symbicort Rapihaler for COPD should tell their doctor or pharmacist immediately if they notice any signs of pneumonia (infection of the lung).

Signs include fever or chills, increased phlegm/sputum production or change in colour, increased cough or increased breathing difficulties. Pneumonia is a serious medical condition and will require urgent medical attention.

Things you must not do

Do not take any other medicines for your asthma or COPD without checking with your doctor.

Do not give Symbicort Rapihaler to anyone else, even if they have the same condition as you.

Do not use Symbicort Rapihaler to treat any other complaints unless your doctor tells you to.

Do not stop using Symbicort Rapihaler without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Symbicort Rapihaler affects you.

Symbicort Rapihaler may cause dizziness, light-headedness, tiredness or drowsiness in some people when they first start using it.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Symbicort Rapihaler.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If you get any side effects, do not stop using Symbicort Rapihaler without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- sore, yellowish, raised patches in the mouth (thrush)
- hoarse voice
- irritation of the tongue and mouth
- coughing

These are less likely to happen if you rinse your mouth out after every time you use your usual morning and/or evening dose of Symbicort Rapihaler.

- Trembling or shakiness
- Feeling anxious, nervous, restless or upset
- Fast or irregular heart rate or pounding heart
- Chest pain
- Headache
- Feeling light-headed or dizzy
- Thirsty
- Unpleasant taste in your mouth
- Nausea (feeling sick)
- Diarrhoea
- Difficulty sleeping
- Muscle twitching or cramps
- Skin rash
- Tiredness
- Weight gain
- Skin bruising

These side effects are usually mild.

Tell your doctor or pharmacist immediately if you notice any of the following:

- Difficulty breathing or worsening of your breathing problems
- Swelling of the face, lips, tongue or other parts of the body
- Severe rash
- Mood changes
- fever or chills, increased phlegm/sputum production or a change in colour, increased cough or difficulties breathing – these maybe a sign of pneumonia (a lung infection)

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

Other side effects not listed above may occur in some patients.

Some of these side effects (for example, changes in blood sugars) can only be found when your doctor does tests from time to time to check your progress.

Tell your doctor if you notice any issues with your eyes such as blurred vision or other problems with your eyesight.

Your doctor may need to send you to an ophthalmologist (eye doctor) to check that you don't have eye problems such as cataracts (clouding of the eye lens), glaucoma (increased pressure in your eyeballs) or other rare eye conditions reported with corticosteroid use.

Corticosteroids taken into the lungs for long periods (eg 12 months) may affect how children/adolescents grow. In rare cases, some children/adolescents may be sensitive to the growth effects of corticosteroids, so the doctor may monitor a child's/adolescent's height.

After using Symbicort Rapihaler

Cleaning

The Rapihaler mouthpiece must be wiped with a clean dry cloth/tissue and must never get wet.

Full instructions on the right way to use and clean Symbicort Rapihaler are inside each pack.

Storage

Keep your Symbicort Rapihaler in a cool dry place where the temperature stays below 30°C.

Always replace the mouthpiece cover after using Symbicort Rapihaler.

Discard Symbicort Rapihaler within 3 months after removal from the foil pouch.

Do not store Symbicort Rapihaler or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days or on a windowsill.

Heat and dampness can destroy some medicines.

Keep it 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.

WARNING:

The canister in Symbicort Rapihaler contains a pressurised liquid. Do not expose to temperatures high than 50°C. Do not pierce the canister. The canister should not be broken, punctured or burnt, even when it seems empty.

Disposal

Your Symbicort Rapihaler should always be returned to your pharmacist for disposal including:

- **when you have taken all your doses and the dose counter reaches zero ('0' - see instructions in the pack), or**
- **3 months after removal from the foil pouch, or**
- **it is damaged or past its expiry date, or**
- **your doctor/pharmacist has told you to stop using it.**

Product description

What it looks like

Symbicort Rapihaler is a pressurised metered dose inhaler with a dose counter. The inhaler is comprised of a pressurised aluminium canister with an attached dose counter, a red plastic casing body with a white mouthpiece and attached grey mouthpiece cover. Each inhaler is individually wrapped in a foil laminate pouch (containing a sachet of drying agent).

Symbicort Rapihaler contains 120 puffs (inhalations) and is available in three strengths: 50/3, 100/3 and 200/6. Each pack contains 1 inhaler. Symbicort Rapihaler 200/6 also has a 60 puff (inhalation) pack size (sample).

Ingredients

Symbicort Rapihaler contains budesonide and formoterol (eformoterol) fumarate dihydrate as the active ingredients. The other ingredients are apafurane (HFA-227), macrogol 1000 and povidone.

Symbicort Rapihaler does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

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