

SYMBICORT RAPIHALER®

Budesonide/formoterol fumarate dihydrate (80/4.5mcg/actuation & 160/4.5mcg/actuation)

What is in this leaflet

1. What Symbicort Rapihaler is used for
2. How Symbicort Rapihaler works
3. Before you use Symbicort Rapihaler
4. How to use Symbicort Rapihaler
5. While you are using it
6. Side effects
7. Storage and Disposal of Symbicort Rapihaler
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision

What Symbicort Rapihaler is used for

Symbicort Rapihaler is an inhaler that is used to treat asthma in adults, adolescents and children aged 6 years and older. It is also used to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) in adults aged 18 years and older.

Asthma

Symbicort Rapihaler is prescribed as a daily maintenance dose and a separate 'reliever inhaler' is needed for symptom relief.

- They use Symbicort Rapihaler every day. This helps to prevent asthma symptoms from happening.
- They use their 'reliever inhaler' when they get asthma symptoms, to make it easier to breathe again.

Chronic obstructive pulmonary disease (COPD)

Symbicort Rapihaler can also be used to treat the symptoms of COPD in adults. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking.

How Symbicort Rapihaler works

Symbicort Rapihaler is an inhaler. It contains two different medicines: budesonide and formoterol fumarate dihydrate.

- Budesonide belongs to a group of medicines called 'corticosteroids'. It works by reducing and preventing swelling and inflammation in your lungs.
- Formoterol fumarate dihydrate belongs to a group of medicines called 'long-acting β_2 adrenoceptor agonists' or 'bronchodilators'. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

Before you use Symbicort Rapihaler

- When you must not use it:
Symbicort Rapihaler should not be used in cases of known hypersensitivity to the active ingredients budesonide and formoterol or to any of the excipients.

- Before you start to use it

Before you use Symbicort Rapihaler, tell your doctor or pharmacist if:

- You are diabetic.
- You have a lung infection.
- You have high blood pressure or you have ever had a heart problem (including an uneven heart beat, a very fast pulse, narrowing of the arteries or heart failure).
- You have problems with your thyroid or adrenal glands.
- You have low levels of potassium in your blood.
- You have severe liver problems.

Contact your doctor if you experience blurred vision or other visual disturbances.

- Taking other medicines

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Beta-blocker medicines (such as atenolol or propranolol for high blood pressure), including eyedrops (such as timolol for glaucoma)
- Medicines for a fast or uneven heart beat (such as quinidine)
- Medicines like digoxin, often used to treat heart failure
- Diuretics, also known as 'water tablets' (such as furosemide). These are used to treat high blood pressure.
- Steroid medicines that you take by mouth (such as prednisolone)
- Xanthine medicines (such as theophylline or aminophylline). These are often used to treat asthma
- Other bronchodilators (such as salbutamol)
- Tricyclic anti-depressants (such as amitriptyline) and the anti-depressant nefazodone
- Phenothiazine medicines (such as chlorpromazine and prochlorperazine)
- Medicines called 'HIV-protease inhibitors' (such as ritonavir) to treat HIV infection.
- Medicines to treat infections (such as ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin and telithromycin)
- Medicines for Parkinson's disease (such as leva-dopa)
- Medicines for thyroid problems (such as levo-thyroxine)

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using Symbicort Rapihaler.

Also tell your doctor or pharmacist if you are going to have a general anaesthetic for an operation or for dental work.

How to use Symbicort Rapihaler

- How much to use & when to use it

- Always use Symbicort Rapihaler exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- It is important to use Symbicort Rapihaler every day, even if you have no asthma or COPD symptoms at the time.
- If you are using Symbicort Rapihaler for asthma, your doctor will want to regularly check your symptoms.

If you have been taking steroid tablets for your asthma or COPD, your doctor may reduce the number of tablets that you take, once you start to use Symbicort Rapihaler. If you have been taking oral steroid tablets for a long time, your doctor may want you to have blood tests from time to time. When reducing oral steroid tablets, you may feel generally unwell even though your chest symptoms may be improving. You might experience symptoms such as a stuffy nose or runny nose, weakness or joint or muscle pain and rash (eczema). If any of these symptoms bother you, or if symptoms such as headache, tiredness, nausea (feeling sick) or vomiting (being sick) occur, please contact your doctor immediately. You may need to take other medication if you develop allergic or arthritic symptoms. You should speak

to your doctor if you are concerned as to whether you should continue to use Symbicort Rapihaler.

Your doctor may consider adding steroid tablets to your usual treatment during periods of stress (for example, when you have a chest infection or before an operation).

Important information about your asthma or COPD symptoms

If you feel you are getting breathless or wheezy while using Symbicort Rapihaler, you should continue to use Symbicort Rapihaler 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 asthma or COPD is not properly controlled and you may need different or additional treatment immediately.

Usually, the following dosage guidelines apply

Dosage for asthma

Children over 6 years of age

Symbicort Rapihaler 80/4.5: 2 puffs of 80/4.5 µg twice daily, a maximum of 4 puffs per day.

Adults and adolescents over 12 years of age

Symbicort Rapihaler 80/4.5: 2 puffs of 80/4.5 µg one to two times daily. Your doctor may prescribe you a maximum of up to 4 puffs twice daily.
Symbicort Rapihaler 160/4.5: 2 puffs one to two times daily. Your doctor may prescribe you a maximum of up to 4 puffs twice daily.

Dosage for Chronic Obstructive Pulmonary Disease (COPD)

Adults

Symbicort Rapihaler 160/4.5: 2 inhalations twice daily.

- How long to use it

- Always use Symbicort Rapihaler exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- It is important to use Symbicort Rapihaler every day, even if you have no asthma or COPD symptoms at the time.
- If you are using Symbicort Rapihaler for asthma, your doctor will want to regularly check your symptoms.

- If you forget to use it

- 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.

- If you use too much (overdose)

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 after if you use more Symbicort Rapihaler than you should are trembling, headache or a rapid heart beat.

While you are using Symbicort Rapihaler **- Things you must do**

Use Symbicort Rapihaler as directed by your doctor.

- Things you must not do

Do not stop using Symbicort Rapihaler unless advised by your doctor.

- Things to be careful of

Pregnancy and breast-feeding

- If you are pregnant, or planning to get pregnant, talk to your doctor before using Symbicort Rapihaler - do not use Symbicort Rapihaler unless your doctor tells you to.
- If you get pregnant while using Symbicort Rapihaler, do not stop using Symbicort Rapihaler but talk to your doctor immediately.
- If you are breast-feeding, talk to your doctor before using Symbicort Rapihaler.

Driving and using machines

Symbicort Rapihaler has no or negligible effect on your ability to drive or to use tools or machines.

Side effects

Like all medicines, Symbicort Rapihaler can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

If either of the following happens to you, stop using Symbicort Rapihaler and talk to your doctor immediately:

- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty to swallow) or hives together with difficulties to breath (angoioedema) and or sudden feeling if 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 Rapihaler 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 Rapihaler.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your Symbicort Rapihaler.
- 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 Rapihaler, 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 Rapihaler stop using Symbicort Rapihaler 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.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Symbicort Rapihaler

- Storage

- Symbicort Rapihaler should not be stored above 30 °C and it should be kept out of the reach of children. The drug may only be used up to the date indicated on the package under “EXP”.
- After removing the foil, the metered dose inhaler may only be used for 3 months. Store the metered dose inhaler with the mouthpiece facing down and the counter facing up.
- The container of Symbicort Rapihaler metered dose inhaler is pressurized. It must not be exposed to temperatures above 50 °C and should not be damaged, forcibly opened or burned

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Packages of 120 single doses of 80/4.5 µg and 160/4.5 µg.

- Ingredients

- *Active Ingredients*
 - 1 puff of Symbicort Rapihaler metered dose inhaler 80/4.5 contains 80 µg budesonide and 4.5 µg formoterol fumarate dihydrate.
 - 1 puff of Symbicort Rapihaler metered dose inhaler 160/4.5 contains 160 µg budesonide and 4.5 µg formoterol fumarate dihydrate.
- *Inactive Ingredients*
 - Apaflurane, Povidone K25 and Macrogol 1000.

MAL numbers:

80/4.5 mcg/actuation:
MAL20026050AZ

160/4.5 mcg/actuation:
MAL20026051AZ

Manufacturer

AstraZeneca Dunkerque
Production,
Dunkerque,
France.

Product Registration Holder

AstraZeneca Sdn. Bhd.
Level 11 & 12, The
Bousteador, No. 10, Jalan PJU
7/6, Mutiara Damansara,
47800 Petaling Jaya, Selangor,
Malaysia.

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