

PACKAGE LEAFLET

Package leaflet: Information for the user

Symbicort 80 micrograms/2.25 micrograms/actuation pressurised inhalation, suspension Budesonide/Formoterol fumarate dihydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Symbicort is and what it is used for
2. What you need to know before you use Symbicort
3. How to use Symbicort
4. Possible side effects
5. How to store Symbicort
6. Contents of the pack and other information

1. What Symbicort is and what it is used for

What Symbicort is

Symbicort is an inhaler that is used to treat asthma in adults and adolescents aged 12-17 years. It contains two different medicines: budesonide and formoterol fumarate dihydrate.

- Budesonide belongs to a group of medicines called ‘corticosteroids’.
- Formoterol fumarate dihydrate belongs to a group of medicines called ‘long-acting beta₂ adrenoceptor agonists’ or ‘bronchodilators’.

What Symbicort is used to treat

Symbicort is used to treat asthma, and can be prescribed alone or with a separate reliever inhaler:

Some people are prescribed two asthma inhalers: Symbicort inhaler and a separate ‘reliever inhaler’

- They use Symbicort every day. This helps to prevent signs of asthma.
- They use their ‘reliever inhaler’ when they get signs of asthma, to make it easier to breathe again.

Some people are prescribed Symbicort as their only asthma inhaler

- They use Symbicort every day. This helps to prevent signs of asthma.
- They also use Symbicort when they need extra doses for relief from signs of asthma, to make it easier to breathe again and if agreed with the doctor also to prevent asthma symptoms from happening (for example, when exercising or on exposure to allergens). They do not need a separate inhaler for this.

How Symbicort works

- Budesonide works by reducing and preventing swelling and inflammation in your lungs.
- Formoterol fumarate dihydrate works by relaxing the muscles in your airways – this helps you to breathe more easily.

2. What you need to know before you use Symbicort

Do not use Symbicort:

- if you are allergic to budesonide, formoterol or any of the other ingredient of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Symbicort 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 heartbeat, 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.

Talk to your doctor while using Symbicort if you have blurred vision or other visual disturbances.

Children

Do not use this medicine in children under 12 years.

Other medicines and Symbicort

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 for high blood pressure – such as atenolol or propranolol.
- Eye drops – such as timolol for glaucoma.
- Medicines for a fast or uneven heartbeat – such as quinidine.
- Medicines like digoxin – often used to treat heart failure.
- Water tablets (diuretics) for high blood pressure – such as furosemide.
- 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.
- Anti-depressants – such as amitriptyline and nefazodone.
- Phenothiazine medicines – such as chlorpromazine and prochlorperazine.
- Medicines to treat HIV infection – such as ritonavir.
- 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.

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

Pregnancy and breast-feeding

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

Driving and using machines

Symbicort has no or very little effect on your ability to drive or to use tools or machines.

3. How to use Symbicort

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- It is important to use Symbicort every day, even if you have no signs of asthma at the time.
- Your doctor will want to regularly check your asthma symptoms.
- Your doctor may consider adding steroid tablets to your usual treatment during periods of stress (such as if you have a chest infection or before an operation).

Symbicort can be prescribed for asthma alone or with a separate reliever inhaler. You need to take two puffs (actuations) of Symbicort to get a full dose. The amount of Symbicort to use and when to use it depends on how it has been prescribed for you.

- a) If you have been prescribed Symbicort and a separate reliever inhaler, read the section called 'a) Using Symbicort and a separate reliever inhaler'.
- b) If you have been prescribed Symbicort as your only inhaler, read the section called 'b) Using Symbicort as your only asthma inhaler'.

a) Using Symbicort and a separate 'reliever inhaler'

Use Symbicort every day. This helps to prevent signs of asthma.

Adults (18 years and above)

- The usual dose is 2-4 puffs, twice a day.
- Your doctor may increase this to 8 puffs, twice a day.
- If your signs of asthma are well controlled, your doctor may ask you to take your medicine once a day.

Adolescents (12 to 17 years)

- The usual dose is 2-4 puffs, twice a day.
- If your signs of asthma are well controlled, your doctor may ask you to take your medicine once a day.

Your doctor (or asthma nurse) will help you to manage your asthma. They will adjust the dose of this medicine to the lowest dose that controls your asthma. However, do not adjust or stop the dose without talking to your doctor (or asthma nurse) first.

Use your separate 'reliever inhaler' to treat asthma symptoms when they happen.

- Always keep your 'reliever inhaler' with you to use when you need it.
- Do not use Symbicort to treat signs of asthma – use your reliever inhaler.

b) Using Symbicort as your only asthma inhaler

Only use Symbicort in this way if your doctor has told you to and if you are aged 12 or above.

Use your Symbicort every day. This helps to prevent signs of asthma. You can take either:

- 2 puffs in the morning and 2 puffs in the evening
- 4 puffs in the morning
- 4 puffs in the evening

Your doctor may increase this to 4 puffs twice a day.

Also use Symbicort as a 'reliever inhaler' to treat asthma symptoms when they happen and to prevent asthma symptoms from happening (for example, when exercising or on exposure to allergens).

- If you get signs of asthma, take 2 puffs and wait a few minutes.
- If you do not feel better, take another 2 puffs.
- Do not take more than 12 puffs at a single time.

Always keep your Symbicort inhaler with you, so you can use it when you need it.

A total daily dose of more than 16 puffs is not normally needed. However, your doctor may allow you to take up to 24 puffs a day for a limited period.

If you regularly need to use 16 or more puffs a day, make an appointment to see your doctor or nurse. They may need to change your treatment.

Do not use more than 24 puffs in 24 hours.

If you are doing exercise and you get signs of asthma, use Symbicort as described here. It is important that you discuss with your doctor the use of Symbicort to prevent asthma symptoms from happening; how often you exercise or how often you are exposed to allergens could impact the treatment that it is prescribed to you.

Symbicort and Steroid tablets

If you have been taking steroid tablets for your asthma, your doctor may reduce the number of tablets that you take, once you start to use Symbicort. 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. Signs may include:

- a stuffy or runny nose
- weakness
- joint or muscle pain
- rash (eczema).

Talk to your doctor immediately if you have signs such as:

- headache
- tiredness
- feeling sick (nausea)
- being sick (vomiting).

If you get any of the signs above, talk to your doctor immediately- you may need to take other medication. Talk to your doctor if you are concerned as to whether you should continue to use Symbicort.

Use in children

Other forms of this medicine are suitable for children; ask your doctor or pharmacist.

Important information about your asthma symptoms

If you feel you are getting breathless or wheezy while using Symbicort, you should continue to use Symbicort but go to see your doctor as soon as possible, as you may need additional treatment.

Talk to 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 is not being properly controlled and you may need different or additional treatment immediately.

Information about your Symbicort

- Before starting to use your Symbicort, remove it from the foil wrapper. Throw away the wrapper as well as the drying agent which is inside the wrapper. If the drying agent has leaked out of its packet, do not use the inhaler.
- After you have taken the inhaler out of its foil wrapper, you should use it within 3 months. Write the use by date (3 months from opening the wrapper) in the blank space provided on the inhaler label to remind you when to stop using the inhaler.
- The parts of your inhaler are shown in the picture. The inhaler will already be assembled when you first receive it. If the canister becomes loose, put it back in the inhaler and keep using the inhaler.



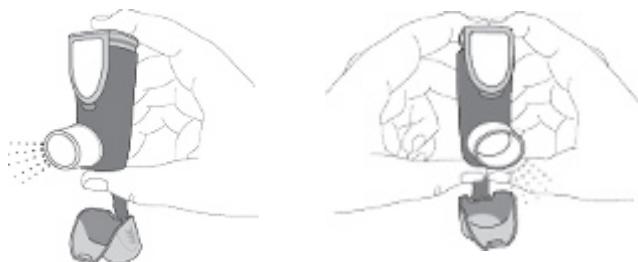
Preparing your Symbicort

You need to prepare your inhaler for use in the following situations:

- If you are using your new Symbicort for the first time.
- If you have not used it for more than 7 days.
- If it has been dropped.

To prepare your inhaler for use, follow the instructions below:

1. Shake the inhaler well for at least 5 seconds to mix the contents of the aerosol canister.
2. Remove the mouthpiece cover by pressing lightly on the bumps on the side. The strap on the mouthpiece cover will stay attached to the inhaler.
3. Hold the inhaler upright. Then press the counter (on the top of the inhaler) to release a puff into the air. You can use one or both hands, as shown in the pictures.



4. Release your finger(s) from the counter.
5. Wait for 10 seconds, shake well and then repeat steps 3 and 4.
6. Your inhaler is now ready for use.

How to take an inhalation

Each time you need to take an inhalation, follow the instructions below:

1. Shake the inhaler well for at least 5 seconds to mix the contents of the aerosol canister.
2. Remove the mouthpiece cover by pressing lightly on the bumps on the side. Check that the mouthpiece is not blocked.
3. Hold your inhaler upright (using one or both hands). Breathe out gently.
4. Place the mouthpiece gently between your teeth. Close your lips.
5. Start to breathe in slowly and deeply through your mouth. Press the counter (on the top of the inhaler) firmly to release a puff. Keep breathing in for a short while after pressing the counter. Breathing in at the same time as pressing the counter ensures that the medicine reaches your lungs.
6. Hold your breath for 10 seconds, or for as long as it is comfortable.
7. Before you breathe out, release your finger from the counter and remove the inhaler from your mouth. Keep the inhaler upright.
8. Then breathe out slowly. To take another inhalation, shake the inhaler well for at least 5 seconds and repeat steps 3 to 7.
9. Replace the mouthpiece cover.
10. Rinse your mouth with water after your daily morning and evening doses and spit it out.



Using a spacer device

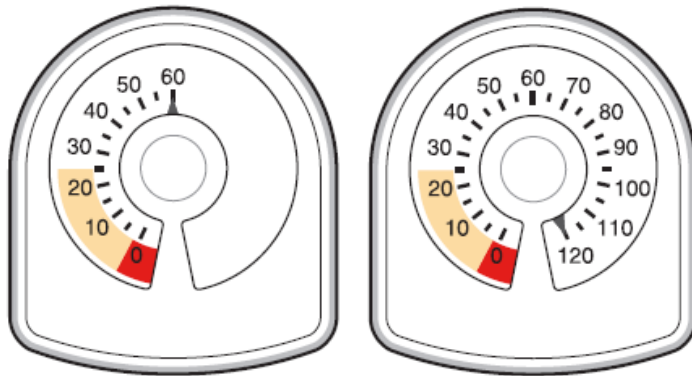
Your doctor, nurse or pharmacist may suggest that you use a spacer device (e.g. **AeroChamber Plus Flow Vu** or **AeroChamber Plus**). Follow the instructions in the leaflet that is packed with the spacer device.

Cleaning your Symbicort

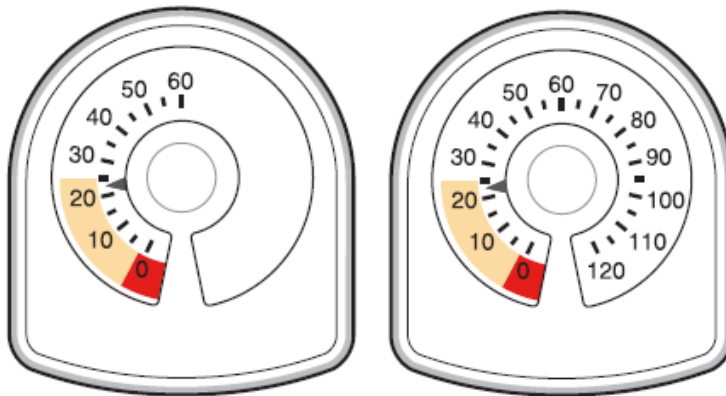
- Wipe the inside and outside of the mouthpiece at least once a week with a dry tissue.
- Do not use water or liquids
- Do not remove the canister from the inhaler.

How will I know when to replace my Symbicort

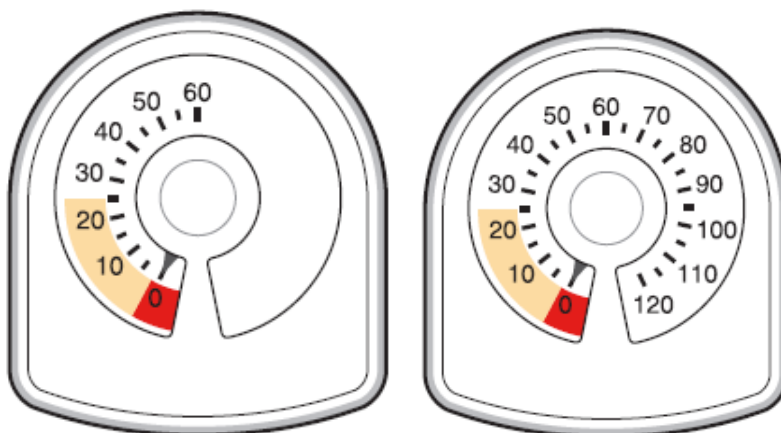
- The counter on the top of your inhaler tells you how many puffs (actuations) are left in your Symbicort. It starts with 60 or 120 puffs when it is full.



- Each time you take an inhalation, or release a puff into the air, the arrow counts down towards zero ('0').
- When the arrow first enters the yellow area, this means that there are about 20 puffs left.



- When the arrow reaches '0', you must stop using your Symbicort. Your inhaler may not feel empty and it may seem as though it still works. However, you will not get the right amount of medicine if you keep using it.



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

If you use more Symbicort than you should, talk to your doctor or pharmacist for advice. The following effects may happen: trembling, headache or a rapid heartbeat.

If you forget to use Symbicort

- 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 stop using Symbicort

Before you stop using Symbicort, you should talk to your doctor or your pharmacist. If you stop using Symbicort the signs of asthma may worsen.

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 happens to you, stop using Symbicort and talk to your doctor immediately:

- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty to swallow), rash or hives together with difficulties to breathe (angioedema) and/or suddenly feeling faint. 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 Symbicort inhaler. If either of these symptoms occur, stop using your Symbicort straightaway and use your separate 'reliever' inhaler if available. Talk to 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.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after your daily morning and evening doses of Symbicort.
- Mild sore throat, coughing and a hoarse voice.
- Headache.

Uncommon (may affect up to 1 in 100 people)

- Feeling restless, nervous or agitated.
- Disturbed sleep.
- Feeling dizzy.
- Nausea (feeling sick).
- Fast heartbeat.
- 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, stop using Symbicort and talk to your doctor immediately.
- Low levels of potassium in your blood.
- Uneven heartbeat.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Symbicort

- 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 canister label, carton and foil wrapper after 'EXP'. The expiry date refers to the last day of that month.
- After you have taken the inhaler out of its foil wrapper, you should use it within 3 months. Write the use by date (3 months from opening the wrapper) in the blank space provided on the inhaler label to remind you when to stop using the inhaler.
- As with most inhaled medicines in pressurised canisters, the effect of this medicine may decrease when the canister is cold. For best results, this medicine should be kept at room temperature before use.
- Do not refrigerate or freeze. Protect from frost and direct sunlight.
- Always replace the mouthpiece cover firmly and snap into position after using your inhaler.
- 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.

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

6. Contents of the pack and other information**What Symbicort contains**

The active substances are budesonide and formoterol fumarate dihydrate. Each puff contains 80 micrograms of budesonide and 2.25 micrograms of formoterol fumarate dihydrate.

The other ingredients are apafurane (HFA 227), povidone and macrogol. This is a CFC-free inhaler.

This medicine contains fluorinated greenhouse gases. Each inhaler contains 10.8 g of apafurane (HFC-227ea) corresponding to 0.035 tonne CO₂ equivalent (global warming potential GWP= 3,220).

What Symbicort looks like and contents of the pack

Symbicort is an inhaler containing your medicine. The medicine, a white suspension for inhalation, is contained in a pressurised canister with attached dose indicator. The canister is fitted into a red plastic actuator with a white plastic mouthpiece and an integrated grey plastic dust cap. Each inhaler contains 60 or 120 puffs after it has been prepared for use. Each inhaler is individually packed in a foil wrapper containing a drying agent.

Symbicort 80 micrograms/2.25 micrograms/actuation pressurised inhalation, suspension (Budesonide/Formoterol fumarate dihydrate) is available in packs of one inhaler. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

Austria: Symbicort 80 Mikrogramm/2,25 Mikrogramm/Inhalation Druckgasinhalation, Suspension;
Belgium: Symbicort 80 microgram/2,25 microgram/inhalatie, aërosol, suspensie; Symbicort 80 microgrammes/2,25 microgrammes/inhalation, suspension pour inhalation en flacon pressurisé;
Bulgaria: Симбикорт 80 микрограма/2,25 микрограма/впръскване Суспензия под налягане за инхалация;
Croatia: Symbicort 80 mikrograma/2,25 mikrograma po potisku, stlačeni inhalat, suspenzija;
Cyprus: Symbicort 80 μικρογραμμάρια/2,25 μικρογραμμάρια/ψεκασμός; **Czech Republic:** Symbicort 80 micrograms/2,25 micrograms/inhalation, suspension in pMDI; **Denmark:** Symbicort 80 mikrogram/2.25 mikrogram/inhalation; **Estonia:** Symbicort; **Finland:** Symbicort 80 mikrog/2.25 mikrog/inhalaatio; **France:** Symbicort 100/3 microgrammes par inhalation, suspension pour inhalation en flacon préssurisé; **Greece:** Symbicort 80 μικρογραμμάρια/2,25 μικρογραμμάρια/ψεκασμός; **Hungary:** Symbicort 2,25 mikrogramm/80 mikrogramm/ adag túlnyomásos inhalációs szuszpenzió; **Iceland:** Symbicort 80 míkrogrömm/2,25 míkrogrömm/ inhalation; **Italy:** Symbicort; **Latvia:** Symbicort 80 mikrogrami/2.25 mikrogrami/ inhalācijā, izsmidzinājuma, aerosols inhalācijām zem spiediena; **Lithuania:** Symbicort 80 mikrogramų/2,25 mikrogramo/išpurškime suslėgtoji įkvepiamoji suspensija; **Luxembourg:** Symbicort 80 microgrammes/2,25 microgrammes/inhalation, suspension pour inhalation en flacon pressurisé;
Malta: Symbicort 100 micrograms/3 micrograms/inhalation, pressurised inhalation, suspension;
Netherlands: Symbicort aërosol 100/3, 100 microgram/3 microgram per dosis, aërosol, suspensie;
Norway: Symbicort 80 mikrogram/2.25 mikrogram/ inhalasjon; **Poland:** Symbicort; **Portugal:** Symbicort 80 microgramas/2,25 microgramas/inalação Suspensão pressurizada para inalação;
Romania: Symbicort 80 micrograme/2,25 micrograme/inhalație, suspensie de inhalat presurizată;
Slovakia: Symbicort 80 mikrogramov/2,25 mikrogramov/inhalačná dávka, inhalačná suspenzia v tlakovom obale; **Slovenia:** Symbicort 80 mikrogramov/2,25 mikrograma na vdih, inhalacijska suspenzija pod tlakom; **Spain:** Symbicort 80 microgramos/2,25 microgramos/inhalación suspensión para inhalación en envase a presión; **Sweden:** Symbicort 80 mikrogram/2.25 mikrogram/inhalation;
United Kingdom: Symbicort 100 micrograms/3 micrograms actuation pressurised inhalation, suspension

This leaflet was last revised in MM/YYYY

2024-11-22[To be completed nationally]