Package leaflet: Information for the user

Symbicort® Turbohaler® 100/6, inhalation powder

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

1. What Symbicort Turbohaler is and what it is used for

Symbicort Turbohaler is an inhaler that is used to treat asthma in adults, adolescents and children aged 6 years and older. 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 $beta_2$ adrenoceptor agonists' or 'bronchodilators'. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

Symbicort Turbohaler can be prescribed for asthma in two different ways.

Some people are prescribed with Symbicort Turbohaler and a separate reliever inhaler.
a) Symbicort Turbohaler every day and a separate reliever inhaler when required
- You take a fixed dose of Symbicort Turbohaler every day. This helps to prevent asthma symptoms from happening.
- You use a separate reliever inhaler when you get asthma symptoms, to make it easier to breathe again.

Some people are prescribed Symbicort Turbohaler as their only asthma inhaler.
b) Symbicort Turbohaler every day and also when required (Symbicort maintenance and reliever therapy).
- You take Symbicort Turbohaler every day. This helps to prevent asthma symptoms from happening.

- You also take Symbicort Turbohaler when you need extra doses for relief of asthma symptoms, to make it easier to breathe again. You do not need a separate inhaler for this.

2. What you need to know before you use Symbicort Turbohaler

Do not use Symbicort Turbohaler:
- if you are allergic to budesonide, formoterol or the other ingredient of this medicine (listed in section 6), which is lactose (which contains small amounts of milk protein).

Warnings and precautions
Talk to your healthcare practitioner before using Symbicort Turbohaler 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.

Other medicines and Symbicort Turbohaler
Tell your healthcare practitioner 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 Turbohaler.

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

Pregnancy, breast-feeding and fertility

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

Driving and using machines

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

Symbicort Turbohaler contains lactose

Symbicort Turbohaler contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this medicine. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant.
The excipient lactose contains small amounts of milk proteins, which may cause an allergic reaction.

3. How to use Symbicort Turbohaler

- Always use this medicine exactly as your doctor has told you. Check with your healthcare practitioner if you are not sure.
- If you have been prescribed a daily dose of Symbicort Turbohaler, it is important to use your inhaler every day, even if you have no asthma symptoms at the time.
- Your doctor will want to regularly check your asthma 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 Turbohaler. 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 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 Turbohaler.

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 symptoms

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

Asthma

Symbicort Turbohaler can be prescribed for asthma in two different ways. The amount of Symbicort Turbohaler to use and when to use it depends on how it has been prescribed for you.

a) If you have been prescribed a fixed dose of Symbicort Turbohaler and a separate reliever inhaler, read the below section called 'a) Using Symbicort Turbohaler and a separate reliever inhaler'.
b) If you have been prescribed Symbicort Turbohaler as your only inhaler, read the below section called 'b) Using Symbicort Turbohaler as your only asthma inhaler every day and also when required (Symbicort maintenance and reliever therapy) '.

a) Using Symbicort Turbohaler and a separate reliever inhaler

Take your fixed dose Symbicort Turbohaler every day. This helps to prevent asthma symptoms from happening.

Adults (18 years and above)

- The usual dose is 1 or 2 inhalations, twice a day.
- Your doctor may increase this to 4 inhalations, twice a day.
- If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

Adolescents (12 to 17 years)

- The usual dose is 1 or 2 inhalations, twice a day.
- If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

Children (6 to 11 years)

- The usual dose is 1-2 inhalations, twice a day.

Symbicort Turbohaler is not recommended to be used in children who are younger than 6 years.

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 the dose without talking to your doctor (or asthma nurse) first.

Use a 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 Turbohaler to treat asthma symptoms - use your reliever inhaler.

b) Using Symbicort Turbohaler every day and also when required (Symbicort maintenance and reliever therapy)

Only use Symbicort Turbohaler in this way if your doctor has told you to and if you are aged 6 or above.

Use your Symbicort Turbohaler every day. This helps to prevent asthma symptoms from happening.

Adults and adolescents (12 years and above)

You can take:

1 inhalation in the morning **and** 1 inhalation in the evening
or
2 inhalations in the morning
or
2 inhalations in the evening.

Children (6 to 11 years)

You can take:

1 inhalation in the morning
or
1 inhalation in the evening
or
Your doctor may increase this to 1 inhalation in the morning and 1 inhalation in the evening.

Tell your healthcare practitioner if you recently turned or will be shortly turning 12 years old for assessment of your Symbicort dosing.
Also use Symbicort Turbohaler as your reliever inhaler to treat asthma symptoms when they happen.

- If you get asthma symptoms, take 1 inhalation and wait a few minutes.
- If you do not feel better, take another inhalation.
- Do not take more than 6 inhalations (for adults and adolescents) or 4 inhalations (for children 6 to 11 years) at a single time.

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

Seek urgent medical advice if Symbicort Turbohaler does not relieve your asthma symptoms or if your asthma symptoms worsen despite treatment with Symbicort.

A total daily dose of more than 8 inhalations (for adults and adolescents) or 4 inhalations (for children 6 to 11 years) is not normally needed. However, your doctor may allow you to take up to 12 inhalations (for adults and adolescents) or 8 inhalations (for children 6 to 11 years) a day for a limited period.

If you regularly need to use 8 or more inhalations a day (for adults and adolescents) or 4 or more inhalations per day (for children 6 to 11 years), make an appointment to see your doctor or nurse as soon as possible. They may need to change your treatment.

Do not use more than 12 inhalations (for adults and adolescents) or 8 inhalations (for children 6 to 11 years) in total in 24 hours.

Parents and caregivers of a child using Symbicort Turbohaler should ensure that the child understands the maximum number of inhalations allowed each day.

If you are doing exercise and you get asthma symptoms, use Symbicort Turbohaler as described here. However, do not use Symbicort Turbohaler just before exercise to stop asthma symptoms from happening.

Preparing your new Symbicort Turbohaler
Before using your **new** Symbicort Turbohaler **for the first time**, you need to prepare it for use as follows:



- Unscrew the cover and lift it off. You may hear a rattling sound.
- Hold your Symbicort Turbohaler upright with the red grip at the bottom.
- Turn the red grip as far as it will go in one direction. Then turn it as far as it will go in the other direction (it does not matter which way you turn it first). You should hear a click sound. It does not matter whether the click comes on the first or the second twist.



- Do this again, turning the red grip in both directions.
- Your Symbicort Turbohaler is now loaded and ready for use.

How to take an inhalation
Every time you need to take an inhalation, follow the instructions below.

1. Unscrew the cover and lift it off. You may hear a rattling sound.
2. **Hold your Symbicort Turbohaler upright** with the red grip at the bottom.
3. Do not hold the mouthpiece when you load your Symbicort Turbohaler. To load your Symbicort Turbohaler with a dose, turn the red grip as far as it will go in one direction. Then turn it as far as it will go in the other direction (it does not matter which way you turn it first). You should hear a click sound. It does not matter whether the click comes on the first or the second twist. Your Symbicort Turbohaler is now loaded and ready to use. Only load your Turbohaler when you need to use it.
4. Hold your Symbicort Turbohaler away from your mouth. Breathe out gently (as far as is comfortable). Do not breathe out through your Turbohaler.



5. Place the mouthpiece gently between your teeth. Close your lips. Breathe in as deeply and as hard as you can through your mouth. Do not chew or bite on the mouthpiece.
6. **Remove your Symbicort Turbohaler from your mouth. Then breathe out gently.** The amount of medicine that is inhaled is very small. This means you may not be able to taste it after inhalation. If you have followed the instructions, you can still be confident that you have inhaled the dose and the medicine is now in your lungs.



7. If you are to take a second inhalation, repeat steps 2 to 6.
8. Replace the cover tightly after use.
9. Rinse your mouth with water after your daily morning and/or evening doses, and spit it out.

Do not try to remove or twist the mouthpiece. It is fixed to your Symbicort Turbohaler and must not be taken off. Do not use your Symbicort Turbohaler if it has been damaged or if the mouthpiece has come apart from your Symbicort Turbohaler.

As with all inhalers, caregivers should ensure that children prescribed Symbicort Turbohaler use correct inhalation technique, as described above.

Cleaning your Symbicort Turbohaler
Wipe the outside of the mouthpiece once a week with a dry tissue. Do not use water or liquids.

When to start using a new inhaler



- The dose indicator tells you how many doses (inhalations) are left in your Symbicort Turbohaler, starting with either 60 or 120 doses when it is full.
- The dose indicator is marked in intervals of 10 doses. Therefore, it does not show every dose.
- When you first see a red mark at the edge of the indicator window, there are approximately 20 doses left. For the last 10 doses, the background of the dose indicator is red. When the '0' on the red background has reached the middle of the window, you must start using your new Symbicort Turbohaler.

Note:
- The grip will still twist and 'click' even when your Symbicort Turbohaler is empty.
- The sound that you hear as you shake your Symbicort Turbohaler is produced by a drying agent and not the medicine. Therefore, the sound does not tell you how much medicine is left in your Symbicort Turbohaler.
- If you load your Symbicort Turbohaler more than once by mistake before taking your dose, you will still only receive one dose. However, the dose indicator will register all the loaded doses.

If you use more Symbicort Turbohaler 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 exceed your prescribed dose without seeking medical advice.

The most common symptoms that may occur if you use more Symbicort Turbohaler than you should are trembling, headache or a rapid heart beat.

If you forget to use Symbicort Turbohaler
- 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 product, 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 happen to you, stop using Symbicort Turbohaler and talk to your doctor immediately:

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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Symbicort Turbohaler

- 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 carton or on the label of your inhaler after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- 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.

6. Contents of the pack and other information

What Symbicort Turbohaler 100/6 contains
The active substances are budesonide and formoterol fumarate dihydrate. Each inhaled dose contains 80 micrograms of budesonide and 4.5 micrograms of formoterol fumarate dihydrate, this corresponds to a metered dose of 100 micrograms of budesonide and 6 micrograms of formoterol fumarate dihydrate.
The other ingredient is lactose monohydrate (which contains milk proteins).

What Symbicort Turbohaler 100/6 looks like and contents of the pack
Symbicort Turbohaler 100/6 is an inhaler containing your medicine. The inhalation powder is white in colour. Each Turbohaler contains either 60 or 120 doses and has a white body with a red turning grip. The turning grip contains a Braille code with the number 6 for identification, to differ from other AstraZeneca inhaled products.

Symbicort Turbohaler 100/6 is available in packs of 1, 2, 3, 10 or 18 Turbohalers containing 60 or 120 doses.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation for Symbicort Turbohaler 100/6 is held by AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge, CB2 0AA, UK.

Symbicort Turbohaler 100/6 is manufactured by AstraZeneca AB, Forskargatan 18, SE-151 36 Södertälje, Sweden.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name **Symbicort Turbohaler 100/6**
Reference number 17901/0091

This is a service provided by the Royal National Institute of Blind People.

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