

SYMBICORT® TURBUHALER®

Budesonide and formoterol fumarate dihydrate powder
for inhalation

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Symbicort Turbuhaler. 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 Turbuhaler 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 Turbuhaler.

You may need to read it again.

What Symbicort Turbuhaler is used for?

Symbicort Turbuhaler is inhaled into the lungs for the treatment of asthma or Chronic Obstructive Pulmonary Disease (COPD).

Symbicort Turbuhaler 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 be due to an allergy to house dust mites, smoke, air pollution or other things that irritate your lungs.

The budesonide in Symbicort Turbuhaler helps to improve your condition and to prevent asthma attacks from occurring. It is a "preventer" and needs to be taken regularly.

The formoterol in Symbicort Turbuhaler helps you breathe more easily. It should also be taken regularly to help control your symptoms.

Symbicort Turbuhaler when used regularly will help prevent asthma attacks and make it easier to breathe normally.

Symbicort Turbuhaler can also be used as a "reliever" when needed to treat your symptoms when your asthma gets worse and when used regularly will 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 Turbuhaler 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 Turbuhaler has been prescribed for you.

Your doctor may have prescribed it for another reason.

Symbicort Turbuhaler is not addictive.

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

Before you use Symbicort Turbuhaler

When you must not use it

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

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

Do not use Symbicort Turbuhaler 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 doctor should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to take regularly to control your asthma, as well as what "reliever" medicines to use when you have sudden attacks of asthma. Your doctor may have prescribed Symbicort Turbuhaler for you to use as both a "preventer" and "reliever" medicine.

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 Turbuhaler if you have, or have had, any of these conditions.

Tell your doctor if you currently have an infection.

If you take Symbicort Turbuhaler 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 Turbuhaler 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 Turbuhaler.

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 Turbuhaler 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.

These medicines may be affected by Symbicort Turbuhaler, or may affect how well it works. You may need different

amounts of your medicine, 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 Turbuhaler.

How to use Symbicort Turbuhaler

How to use your Turbuhaler

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 Turbuhaler 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 Turbuhaler, ask your doctor or pharmacist to show you how.

How much to take

ASTHMA (Adults and children 12 years and over)

Your doctor should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to take regularly to control your asthma, as well as what "reliever" medicines to use when you have a sudden attack of asthma. Your doctor may have prescribed Symbicort

Turbuhaler for you to use as both a "preventer" and "reliever" medicine.

Symbicort Turbuhaler 100/6 and 200/6

If you are using Symbicort Turbuhaler (100/6 or 200/6) as a "preventer" medicine, the usual dose is 1 - 2 inhalations twice a day.

Your doctor may also tell you to use Symbicort Turbuhaler as a "reliever", medication. This means that Symbicort Turbuhaler can be used when needed to provide relief of your asthma symptoms. If you are using Symbicort Turbuhaler (100/6 or 200/6) as both a "preventer" and "reliever" medicine, do not use more than 6 inhalations on a single occasion or more than 12 inhalations in any day. If your symptoms continue to worsen over three days, despite using additional inhalations, tell your doctor.

Symbicort Turbuhaler 400/12

This strength is recommended only for patients aged 18 years and over.

Symbicort Turbuhaler 400/12 is not recommended to be used as a "reliever" medication.

As a "preventer" medicine, the usual dose is 2 inhalations twice a day. Your doctor may also tell you to take 1 inhalation twice a day, if your asthma has been under control.

Do not take more than 2 inhalations twice a day of Symbicort Turbuhaler 400/12.

If your asthma has been under control for some time, your doctor may tell you to take less inhalations of Symbicort Turbuhaler or prescribe you a lower strength of Symbicort Turbuhaler.

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.

COPD (Adults)

The usual dose (also maximum recommended dose) is:

- 2 inhalations of Symbicort Turbuhaler 200/6 twice daily
- or
- 1 inhalation of Symbicort Turbuhaler 400/12 twice daily.

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 Turbuhaler, 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 Turbuhaler as a "reliever" medication, 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

Use Symbicort Turbuhaler every day even if you feel well.

Symbicort Turbuhaler 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 Turbuhaler.

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

You may need urgent medical attention.

If you use too much Symbicort Turbuhaler, 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 Turbuhaler

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 Turbuhaler 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 Turbuhaler (100/6 or 200/6) or another "reliever" medication.

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

If you don't you are more likely to develop thrush in your mouth. You do not have to rinse your mouth if you have to take occasional extra doses of Symbicort Turbuhaler for relief of asthma symptoms.

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

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

Patients taking Symbicort Turbuhaler 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 mucus production or change in mucus 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 Turbuhaler to anyone else, even if they have the same condition as you.

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

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

Things to be careful of

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

Symbicort Turbuhaler 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 Turbuhaler.

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 Turbuhaler 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 Turbuhaler.

- 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

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.

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 Turbuhaler

Cleaning

The Turbuhaler 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 Turbuhaler are inside each pack.

Storage

Keep your Turbuhaler in a cool dry place where the temperature stays below 30°C, with the cover firmly in place.

Do not store Symbicort Turbuhaler or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on a window sill.

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.

Disposal

Since some medicine may remain inside your Symbicort Turbuhaler you should always return it to your pharmacist for disposal including:

- **when you have taken all your doses and the dose indicator is on zero ('0' - see instructions in the pack), or**
- **it is damaged or past its expiry date, or**
- **your doctor/pharmacist have told you to stop using it.**

Product description

What it looks like

Symbicort Turbuhaler is a plastic inhaler containing the medication as a dry powder.

Symbicort Turbuhaler registered* pack sizes include:

- 100/6 - 60 (sample) or 120 inhalations
- 200/6 - 30 (sample), 60 or 120 inhalations.

- 400/12 - 60 inhalations in packs of 1 (sample) or 2 Turbuhalers.

*not all registered pack sizes might be available in Australia

Ingredients

Symbicort Turbuhaler contains budesonide and formoterol fumarate dihydrate as the active ingredients, and lactose monohydrate (which may contain milk protein residue).

The amount of lactose contained in Symbicort Turbuhaler is very small and does not normally cause problems in lactose intolerant people.

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

Sponsor

AstraZeneca Pty Ltd

ABN 54 009 682 311

66 Talavera Road

MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

This leaflet was prepared

19th December 2017

Australian Registration Numbers

100/6 - AUST R 80875

200/6 - AUST R 80876

400/12 - AUST R 80877

® Symbicort, Pulmicort, Oxis, and Turbuhaler are registered trademarks of the AstraZeneca group of companies.

© AstraZeneca, 2017

Doc ID-000378998 v6