

# SYMBICORT® TURBUHALER®

Budesonide and formoterol (eformoterol) 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?

The medicine inside Symbicort Turbuhaler 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 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 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 Turbuhaler helps to improve your condition and to prevent asthma attacks from occurring.

The formoterol in Symbicort Turbuhaler helps you breathe more easily.

Some people can take Symbicort Turbuhaler when they need it – they use Symbicort Turbuhaler 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 Turbuhaler every day – they use their Symbicort Turbuhaler 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 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.

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### 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 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 your exercise, as these could impact how your doctor prescribes your Symbicort Turbuhaler.

Your doctor may prescribe Symbicort Turbuhaler 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 Turbuhaler.**

**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.

- 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 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.

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## How to use Symbicort Turbuhaler

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### *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 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 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 Turbuhaler.

Your doctor may have prescribed Symbicort Turbuhaler for you to use as:

- an anti-inflammatory reliever medicine only,
- both an anti-inflammatory reliever and a 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 Turbuhaler.**

If your asthma has been under control for some time, your doctor may tell you to take less inhalations of Symbicort Turbuhaler, prescribe you a lower strength of Symbicort Turbuhaler or recommended that you use Symbicort Turbuhaler 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 Turbuhaler 200/6)**

For patients aged 12 years and over, Symbicort Turbuhaler 200/6 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 1 inhalation and wait a few minutes. If you do not feel better, take another inhalation.

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 6 inhalations on a single occasion or more than 12 inhalations in any day. If your symptoms continue to worsen over 3 days, despite using additional inhalations, tell your doctor.**

Have your Symbicort Turbuhaler reliever with you at all times.

#### **Anti-inflammatory reliever plus maintenance therapy (Symbicort Turbuhaler 100/6 and 200/6)**

For patients aged 12 years and over, Symbicort Turbuhaler 100/6 and 200/6 can be used to treat asthma symptoms when they happen. Symbicort Turbuhaler 200/6 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 1 inhalation of Symbicort Turbuhaler 100/6 or 200/6 and wait a few minutes. If you do not feel better, take another inhalation.

Your doctor will tell you how many inhalations of Symbicort Turbuhaler 200/6 to take before exercising or exposure to other triggers to help stop symptoms from happening.

Have your Symbicort Turbuhaler 100/6 or 200/6 reliever with you at all times.

You also need to take your Symbicort Turbuhaler (100/6 or 200/6) daily as your maintenance preventer. The usual maintenance dose is 2 inhalations per day (given either as 1 inhalation in the morning and evening or as 2 inhalations in either the morning or evening). Your doctor may prescribe a maintenance dose of Symbicort Turbuhaler 200/6, 2 inhalations twice a day.

**Do not use more than 6 inhalations on a single occasion or more than 12 inhalations of Symbicort Turbuhaler (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 Turbuhaler 400/12 is not recommended to be used as anti-inflammatory reliever medicine.

#### **Daily fixed dose maintenance therapy (Symbicort Turbuhaler 100/6, 200/6 and 400/12)**

For patients aged 12 years and over, Symbicort Turbuhaler 100/6 and 200/6 can be used as a daily fixed-dose maintenance preventer. The usual dose is 1-2 inhalations twice a day.

Symbicort Turbuhaler 400/12 is recommended only for patients aged 18 years and over who need a higher daily dose.

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 100/6, 200/6 or 400/12.

Have your separate reliever with you at all times.

#### **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 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 Turbuhaler daily, it is important that you use it 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.

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## While you are using Symbicort Turbuhaler

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### *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 medicine.

**Rinse your mouth out with water after taking your daily morning and/or evening dose of Symbicort Turbuhaler 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 doses of Symbicort Turbuhaler 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 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 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 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.

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## 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
- 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.

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## 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.

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## Product description

### *What it looks like*

Symbicort Turbuhaler is a plastic inhaler containing the medicine 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 (eformoterol) 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*

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