

## PART III: CONSUMER INFORMATION

**Pr** SYMBICORT® TURBUHALER®  
budesonide/formoterol fumarate dihydrate powder for  
inhalation

This leaflet is part III of a three-part "Product Monograph" published when SYMBICORT TURBUHALER was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SYMBICORT TURBUHALER. Contact your doctor or pharmacist if you have any questions about the drug.

### ABOUT THIS MEDICATION

#### WHAT THE MEDICATION IS USED FOR:

SYMBICORT TURBUHALER contains a mixture of the medicines budesonide and formoterol to treat asthma in adults and children (i.e. 12 years and older) and Chronic Obstructive Pulmonary Disease (COPD) in adults (i.e. 18 years and older).

#### Asthma

Asthma is a chronic disease of the lungs caused by inflammation which causes narrowing of the airways and increased mucus production. Symptoms such as chest tightness, wheezing, coughing and difficulty in breathing are common. These symptoms become more pronounced during periods of disease worsening or an asthma attack due to the narrowing of the airways.

SYMBICORT TURBUHALER should only be used when your doctor decides that other asthma medications (i.e. inhaled glucocorticosteroids along with an as needed relief medication) are not helping you enough, or that you need two maintenance medications to control your asthma. SYMBICORT TURBUHALER should not be the first medication you use, unless advised by your doctor.

#### COPD

Chronic Obstructive Pulmonary Disease (COPD) is also referred to as chronic bronchitis and emphysema. COPD is a chronic lung disease largely caused by cigarette smoking. COPD leads to a narrowing and persistent inflammation of the airways, increased mucous production and damage to the lungs. This results in breathing difficulties and a feeling of breathlessness. Symptoms such as coughing, breathlessness, mucous production and coughing and wheezing can become intense during periods of disease worsening.

#### WHAT IT DOES:

Budesonide is a corticosteroid that reduces and prevents this airway inflammation. Formoterol widens your airways by relaxing the airway muscles, making it easier for you to breathe. This effect starts within 1-3 minutes after you have inhaled the medicine and lasts for up to 12 hours. When you breathe in through the

mouthpiece of the inhaler, the medicine follows your breath to your lungs.

Regular use of SYMBICORT TURBUHALER gives 24-hour relief or prevention of symptoms such as shortness of breath in patients with asthma, COPD and other similar conditions (see PROPER USE OF THIS MEDICATION).

#### WHEN IT SHOULD NOT BE USED:

If you are allergic to budesonide, formoterol or inhaled lactose.

#### WHAT THE MEDICINAL INGREDIENT IS:

SYMBICORT TURBUHALER is a dry powder inhalation device that contains formoterol fumarate dihydrate and budesonide.

#### WHAT THE NONMEDICINAL INGREDIENTS ARE:

Lactose (may contain milk protein).

#### WHAT DOSAGE FORMS IT COMES IN:

SYMBICORT TURBUHALER is supplied in two strengths:

SYMBICORT **100** TURBUHALER (100/6 µg budesonide/formoterol fumarate dihydrate per dose) and

SYMBICORT **200** TURBUHALER (200/6 µg budesonide/formoterol fumarate dihydrate per dose).

SYMBICORT **100** TURBUHALER and SYMBICORT **200** TURBUHALER are available in 60 or 120 dose pack sizes.

### WARNINGS AND PRECAUTIONS

#### Patients with asthma

- A large US clinical trial showed an increased risk of asthma related death and serious respiratory-related outcomes in patients who used salmeterol (a long-acting bronchodilator) in addition to their usual asthma therapy, in comparison with those who used placebo in addition to their usual asthma therapy. One of the medications in SYMBICORT TURBUHALER is formoterol fumarate dihydrate (also known as OXEZE®), which is a different long-acting bronchodilator. Although similar findings have not been seen with formoterol fumarate dihydrate, the risks associated with salmeterol may also apply to other long-acting bronchodilator drugs including formoterol fumarate dihydrate.
- SYMBICORT TURBUHALER should only be used when your doctor decides that other asthma medications (i.e. inhaled glucocorticosteroids along with an as needed relief medication) are not helping you enough, or that you need two maintenance medications to control your asthma. SYMBICORT TURBUHALER should not be the first medication you use, unless advised by your doctor.

**BEFORE you use SYMBICORT TURBUHALER talk to your doctor or pharmacist if:**

- you have health problems now or have had in the past, especially if you have any problems with your heart, high blood sugar (diabetes), low blood potassium or any problems with your thyroid gland, or if you suffer from seizures (epilepsy).
- you suffer from severe liver problems (e.g. cirrhosis).
- you take other medicines, including those you have bought without a prescription. Certain types of medicines, for example beta-blockers, [some medicines for heart conditions (propranolol), high blood pressure (atenolol) or eye drops (timolol)] may reduce or block the effect of SYMBICORT TURBUHALER when taken at the same time. As well, some medicines used to treat fungal infections (ketoconazole, itraconazole) or ritonavir (medication used to treat HIV infection or AIDS) may alter the effect of SYMBICORT TURBUHALER.
- you take, or have taken steroid medicines within the past several months.
- you have ever had a bad, unusual or allergic reaction to budesonide, formoterol or lactose or to other medicines for breathing problems.
- you are pregnant, plan to become pregnant or are breast feeding.

**INTERACTIONS WITH THIS MEDICATION**

**Drugs that may interact with SYMBICORT TURBUHALER include: beta-blockers (propranolol, atenolol, timolol), ketoconazole, itraconazole and ritonavir.**

**PROPER USE OF THIS MEDICATION**

**The dosage of SYMBICORT TURBUHALER is individual. It should be taken regularly (every day), even when you have no symptoms.**

Follow your doctor's instructions carefully. Asthma and COPD therapy will differ from person to person and therefore your prescribed treatment may be different from the information contained in this leaflet.

**Patients with Asthma**

Treatment with SYMBICORT should not be initiated to treat an asthma attack.

**For the treatment of asthma**, your doctor will instruct you to use SYMBICORT TURBUHALER in one of two ways, as SYMBICORT maintenance therapy or as SYMBICORT maintenance and reliever therapy. Each of these treatment plans is described below.

**SYMBICORT Maintenance Therapy for asthma**

You take a regular daily dose from SYMBICORT TURBUHALER. In addition, you use a separate inhaler, containing a fast-acting bronchodilator (airway-widening medicine) for relief of asthma symptoms. This means that you need two separate inhalers.

**Adults and adolescents (12 years and older)**

1 - 2 inhalations SYMBICORT **100** TURBUHALER once or twice daily. The maximum recommended daily maintenance dose is 4 inhalations.

or

1 - 2 inhalations SYMBICORT **200** TURBUHALER once or twice daily. The maximum recommended daily maintenance dose is 4 inhalations.

**Always carry your fast-acting bronchodilator (rescue medication) with you for relief of symptoms.**

During periods of worsening asthma, the dose may temporarily be increased up to a maximum of 4 inhalations of SYMBICORT **100** TURBUHALER or SYMBICORT **200** TURBUHALER twice daily.

**Do NOT exceed the dose prescribed by your doctor.**

**SYMBICORT Maintenance and Reliever Therapy (Symbicort SMART) for asthma**

You take a regular daily maintenance dose of SYMBICORT TURBUHALER, and also use SYMBICORT TURBUHALER if you need extra doses for relief of asthma symptoms. **This means that you always have SYMBICORT TURBUHALER available for symptom relief.**

**Adults and adolescents (12 years and older)**

1 - 2 inhalations SYMBICORT **100** TURBUHALER twice daily or 2 inhalations once daily. You should take 1 additional inhalation as-needed if you feel symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. Not more than 6 inhalations should be taken on any single occasion. The maximum recommended daily dose is 8 inhalations.

or

1 - 2 inhalations SYMBICORT **200** TURBUHALER twice daily or 2 inhalations once daily. You should take 1 additional inhalation as-needed if you feel symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. Not more than 6 inhalations should be taken on any single occasion. The maximum recommended daily dose is 8 inhalations.

**Always carry SYMBICORT TURBUHALER with you. You should use extra doses as needed to relieve your asthma symptoms, including periods when your asthma gets worse.**

**Do not exceed the maximum total number of daily inhalations (8 inhalations/day). If you exceed 8 inhalations/day please seek medical attention.**

**Patients with COPD**

**For the maintenance treatment of COPD**, your doctor will instruct you to use SYMBICORT TURBUHALER as follows:

**Adults (18 years and older)**

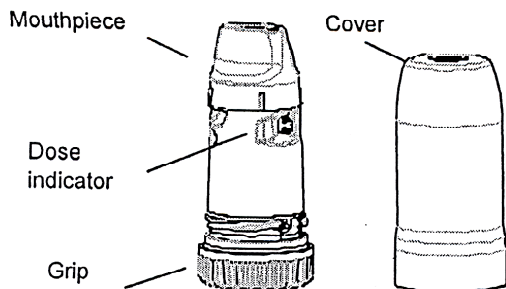
2 inhalations SYMBICORT 200 TURBUHALER twice daily. The maximum recommended daily dose is 4 inhalations.

Treatment with SYMBICORT should not be initiated to treat a COPD attack.

**A. How to prepare a new inhaler for use**

Before you start using SYMBICORT TURBUHALER for the first time it is important that you read the instructions below and follow them carefully.

TURBUHALER is an inhaler from which very small amounts of powder are administered. When you breathe in through TURBUHALER the powder is delivered to the lungs. It is therefore important that you **inhale forcefully and deeply** through the mouthpiece.



SYMBICORT TURBUHALER is **very** easy to use.

**If you follow the instructions below, you will receive the medication.**

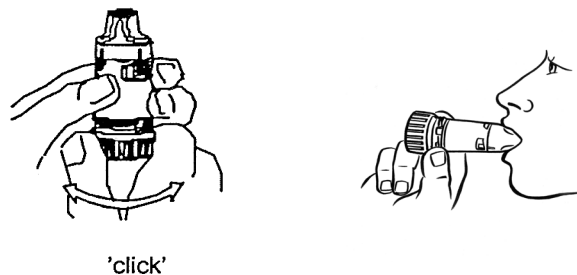
**Preparation before first use of new inhaler:**

Before using your inhaler for the first time you need to prepare the inhaler for use. The preparation does not need to be repeated even if your inhaler is not used regularly.

1. Unscrew and lift off the cover. You may hear a rattling sound. This is normal.
2. Hold the inhaler upright with the red grip downwards (Fig.1). Turn the red grip as far as it will go in one direction and then turn it back as far as it will go in the opposite direction. Perform this procedure twice.

Figure 1

Figure 2



**B. Using the inhaler**

To administer a dose, simply follow the instructions below.

Unscrew and lift off the cover. A rattling sound may be heard. This is normal.

**TURN** **Hold the inhaler upright** with the red grip downwards (Fig. 1). Do not hold the mouthpiece when turning the grip. To load the inhaler with a dose **turn the grip as far as it will go in one direction and then turn it back again as far as it will go in the opposite direction.**

You will hear a 'click' some time during this procedure. The inhaler is now ready to use. **Breathe out.** Do **not** breathe out through the mouthpiece.

**INHALE** Place the mouthpiece gently between your teeth. Close your lips and **breathe in forcefully and deeply** through your mouth (Fig. 2). You may not taste or feel any medication when inhaling. This is common. Do not chew or bite on the mouthpiece.

**Remove the inhaler from your mouth before breathing out again.**

If more than one dose has been prescribed, repeat the steps above.

Replace the cover.

If you accidentally drop, shake or breathe out into SYMBICORT TURBUHALER after it is loaded, you will lose your dose. If this happens, you should load a new dose and inhale it.

**Note: Never breathe out through the mouthpiece. Always replace the cover properly after use. Do not try to remove the mouthpiece or to twist it unnecessarily; it is fixed to the inhaler and must not be taken off.**

As the amount of powder dispensed is very small, you may not be able to taste or feel it after inhalation. However, you can still be

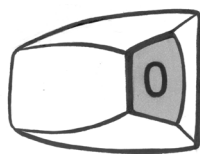
confident that the dose has been inhaled if you have followed the instructions.

### **Stopping SYMBICORT TURBUHALER**

Talk to your doctor about how to gradually stop your medication if necessary. It is important that you do not suddenly stop taking SYMBICORT TURBUHALER as it may cause unwanted side effects.

**Cleaning:** Clean the outside of the mouthpiece once a week with a dry tissue. Never use water or any other fluid when cleaning the mouthpiece. If fluid enters the inhaler it may not work properly.

**When to start a new inhaler:** SYMBICORT TURBUHALER has a dose indicator. The dose indicator tells you how many doses are left in the inhaler. The dose indicator moves slowly each time you load a dose. Every 20th dose is marked with a number and every 10th dose is marked with a dash. When the "0" on the red background has reached the middle of the window you should discard your inhaler. The sound you hear when you shake the inhaler is produced by a drying agent, not the medication. SYMBICORT TURBUHALER cannot be re-filled with drug and should be discarded.



Dose indicator shows that it is time to start a new inhaler

### **OVERDOSE:**

**Call your doctor, pharmacist or regional poison control centre right away in case of an overdose.**

The most common signs and symptoms that may occur after overdosage are trembling, headache and rapid heartbeat.

### **MISSED DOSE:**

If you miss a dose of SYMBICORT TURBUHALER, take it as soon as you remember and then go back to your regular schedule.

Never take a double dose of SYMBICORT TURBUHALER to make up for missed doses. If you are still unsure, check with your doctor or pharmacist to see what you should do.

## **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, SYMBICORT may cause unwanted reactions, so-called side effects. Most patients do not experience side effects from SYMBICORT.

The most commonly reported side effects of SYMBICORT are: headache, sensation of heart beat, cough, irritation of mouth and/or throat and hoarseness.

Less commonly reported side effects of SYMBICORT include: nausea, sleep difficulties, restlessness or nervousness, dizziness and muscle cramps.

If any of these side effects concern you, do not stop treatment, but tell your doctor about them.

Additional side effects including skin rash and bruising, itching, facial swelling, increase in chest tightness, chest pain, depression or behavioural disturbances and high blood sugar levels were also reported rarely.

Tell your doctor if you are exposed to chicken pox or measles while using this medication, as you may be more prone to infection.

If you had been taking oral corticosteroids to treat your asthma and you suddenly have a severe asthma attack when starting SYMBICORT TURBUHALER, contact your doctor immediately.

### **In patients with asthma, you should TELL YOUR DOCTOR if:**

- the relief of your asthma is not as good as usual or does not last as long as usual. A change from "usual" includes more wheezing, coughing, tightness or shortness of breath.
- you exceed the maximum total number of daily inhalations (8 inhalations/day).
- there is a persistent increase in your use of fast-acting reliever medication.
- your symptoms are waking you up at night.
- measurement from your peak flow meter indicates a value between 60% and 80% of predicted or personal best.

These may be signs that your asthma is getting worse. Your doctor may adjust your treatment.

### **You should TELL YOU DOCTOR RIGHT AWAY or go to the nearest hospital if you notice the following warning signs:**

- a sudden worsening of your shortness of breath and wheezing shortly after using your fast-acting medication.
- You do not feel relief from additional doses of your fast-acting reliever medication.
- Measurement from your peak flow meter indicates a value less than 60 percent of predicted or personal best.
- You are breathless at rest.
- Your pulse is more than 120 beats per minute.

**In patients with COPD, you should TELL YOUR DOCTOR RIGHT AWAY if you notice the following warning signs, which indicate your condition is worsening:**

- unusual increase in the severity of the breathlessness, cough, tiredness or wheeze

- **unusual colour, level, consistency or stickiness of phlegm**
- **symptoms of a chest cold and/or chest tightness (e.g. indicating a chest infections)**
- **unexplained swelling**
- **unexplained fever.**

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

	Symptom / effect	Talk with you doctor or pharmacist		Stop taking drug and seek emergency medical attention
		Only if severe	In all cases	
Rare	Increased wheezing or tightness in the chest or difficulty in breathing (sign of bronchospasm) immediately after inhalation of SYMBICORT			√
	<i>Hypersensitivity reactions</i> Skin rash, skin eruption or other effect on the skin or eyes, itching or fever			√
	<i>Allergic reactions</i> Swelling of the lips, face or neck, accompanied by difficulty in breathing, speaking or swallowing (signs of angioedema) and anaphylactic reaction.			√
	Fast or irregular heart beat		√	

***This is not a complete list of side effects. For any unexpected effects while taking SYMBICORT TURBUHALER, contact your doctor or pharmacist.***

**HOW TO STORE IT**

Remember to keep SYMBICORT TURBUHALER out of the reach of children.

Always replace the cover after using SYMBICORT TURBUHALER. Store the inhaler at room temperature (15-30°C).

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)  
Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or
- Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701C  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing.

The Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: [www.astrazeneca.ca](http://www.astrazeneca.ca)  
or by contacting the sponsor, AstraZeneca Canada Inc. at:  
Customer Inquiries – 1 (800) 668-6000  
Renseignements – 1 (800) 461-3787.

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