

PART III: CONSUMER INFORMATION

Pr SYMBICORT® TURBUHALER®

budesonide/formoterol fumarate dihydrate dry powder for oral 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

This medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

WHAT THE MEDICATION IS USED FOR:

SYMBICORT TURBUHALER is used 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).

WHAT IT DOES:

SYMBICORT TURBUHALER contains the medicines budesonide and formoterol.

- Budesonide is an inhaled corticosteroid (ICS). It reduces and prevents inflammation in the airways;
- Formoterol is a long-acting beta₂-agonist (LABA). It helps to widen and relax the muscles in your airways. This makes 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.

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.
- **Asthma:** if you are under 12 years old.
- **COPD:** if you are under 18 years old.

WHAT THE MEDICINAL INGREDIENTS ARE:

Budesonide and formoterol fumarate dihydrate.

WHAT THE NONMEDICINAL INGREDIENTS ARE:

Lactose (may contain milk protein).

WHAT DOSAGE FORMS IT COMES IN:

Dry powder for oral inhalation:

- SYMBICORT **100** TURBUHALER (100 mcg/6 mcg);
- SYMBICORT **200** TURBUHALER (200 mcg/6 mcg);
- SYMBICORT **FORTE** TURBUHALER (400 mcg/12 mcg).

Your inhaler can contain either 60 or 120 doses.

WARNINGS AND PRECAUTIONS

Serious Warnings for Asthma Patients

Formoterol, one of the medicines in SYMBICORT TURBUHALER, may increase the risk of asthma-related death. It may increase the risk of asthma-related hospitalizations in pediatric and adolescent patients. Therefore,

- Your doctor will assess your asthma control at regular intervals. SYMBICORT TURBUHALER should only be used when your doctor decides that other asthma medications (e.g. 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.

For any concerns regarding the use of SYMBICORT TURBUHALER, consult 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
- Have heart problems;
- Have high blood sugar (diabetes);
- Have low blood potassium or any problems with your thyroid gland;
- Have seizures (epilepsy);
- Have severe liver problems (e.g. cirrhosis);
- Take, or have taken steroid medicines within the past several months;
- Have ever had a bad, unusual or allergic reaction to budesonide, formoterol or lactose or to other medicines for breathing problems;
- Are pregnant or planning to become pregnant;
- Are breast feeding;
- Have weak bones (osteoporosis).

Drugs like SYMBICORT can cause eye disorders:

- Cataracts: clouding of the lens in the eye, blurry vision, eye pain
- Glaucoma: an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss;

You should therefore have regular eye exams.

You should avoid coming into contact with people who have measles or chicken pox while taking SYMBICORT TURBUHALER. If you are exposed, tell your doctor right away.

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Special attention should be paid if you are an adolescent with asthma. Your growth should be monitored regularly by a doctor when being treated with corticosteroids. Studies have also shown that children whose asthma is not controlled do not grow as quickly as other children.

Patients with COPD:

Patients with COPD have a higher chance of getting pneumonia (a lung infection). Drugs like SYMBICORT TURBUHALER may increase the chance of getting pneumonia. It is very important that you tell your doctor immediately if you suspect an infection as even mild chest infections should be treated right away.

You should avoid close contact with people who have colds or the flu (influenza). Your doctor may also recommend that you receive a flu shot each year.

If you are using SYMBICORT TURBUHALER for COPD, tell your doctor if you have any of the following symptoms:

- Fever or chills;
- Increased mucus production or change in mucus colour;
- Increased cough;
- Increased breathing difficulties.

These all may be signs of pneumonia.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

Drugs that may interact with SYMBICORT TURBUHALER are:

- Beta-blockers used to lower blood pressure (propranolol) or for other heart or eye problems (e.g. atenolol, timolol);
- Ketoconazole, itraconazole used to treat fungal infections;
- Ritonavir used to treat HIV or AIDS.

PROPER USE OF THIS MEDICATION

SYMBICORT TURBUHALER should be taken regularly (every day), even when you have no symptoms. Follow your doctor's instructions carefully. Asthma and COPD treatment will differ from person to person. Your prescribed treatment may be different from the information in this leaflet.

Do not stop taking SYMBICORT TURBUHALER without talking to your doctor. It is important that you do not suddenly stop taking SYMBICORT TURBUHALER as it may cause unwanted side effects.

DOSING

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:

- 1) SYMBICORT maintenance therapy; or
- 2) SYMBICORT maintenance and reliever therapy.

Each of these treatment plans is described below.

1) SYMBICORT Maintenance Therapy for Asthma

Using SYMBICORT TURBUHALER for maintenance therapy means:

- i. you take a regular daily dose of SYMBICORT TURBUHALER, AND
- ii. 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.
or
- 1 inhalation SYMBICORT **FORTE** 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 or 2 inhalations of SYMBICORT **FORTE** TURBUHALER twice daily.

Do NOT exceed the dose prescribed by your doctor.

2) SYMBICORT Maintenance and Reliever Therapy (SYMBICORT SMART[®]) for Asthma

Using SYMBICORT TURBUHALER for maintenance and reliever therapy means:

- i. you take a regular daily maintenance dose of SYMBICORT TURBUHALER, AND
- ii. you use SYMBICORT TURBUHALER if you need extra doses for relief of asthma symptoms.

This means that you use one inhaler (SYMBICORT TURBUHALER) for both daily maintenance and 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

Adults (18 years and older)

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

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

MISSED DOSE:

If you miss a dose, take it as soon as you remember and then go back to your regular schedule. Never take a double dose to make up for missed doses. If you are still unsure, check with your doctor or pharmacist to see what you should do.

OVERDOSE:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

The most common signs and symptoms of an overdose are:

- trembling
- headache
- rapid heartbeat.

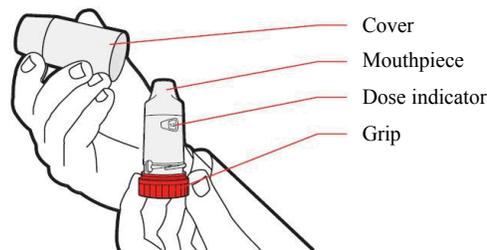
HOW TO USE YOUR SYMBICORT TURBUHALER INHALER

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

Watch our video to make sure you use SYMBICORT TURBUHALER correctly.



TURBUHALER is a multidose inhaler from which very small amounts of powder are administered. When you breathe in through the TURBUHALER, powder is delivered to the lungs. It is therefore important that you **inhale as deeply and strongly** as you can through the mouthpiece.



Before you use a **NEW** inhaler for the first time you must prepare the inhaler for use. Follow the steps under “**A. How to prepare a NEW inhaler for use:**”.

For regular use of your inhaler follow the steps under “**B. How to take a dose:**”.

A. How to prepare a NEW inhaler for use:

You only need to prepare your **NEW** inhaler for use **once**. You do not need to repeat these steps even if your inhaler is not used regularly.

STEP 1 Unscrew and lift off the cover (Figure 1). You will hear a rattling sound when you unscrew the cover. This is normal.



STEP 2 Hold the inhaler upright. Do not hold the inhaler by the mouthpiece.

- Turn the **red grip** as far as it will go in one direction (clockwise or counter-clockwise, it does not matter)



- which way you turn it first).
- Then turn the red grip as far as it will go in the opposite direction (Figure 2).
- At some point when you are turning the grip, **you will hear a “click”**. This is part of the preparation process.

STEP 3 Repeat STEP 2 one more time. Then follow the steps under “**B. How to take a dose:**”, starting at **STEP 2**.

B. How to take a dose:

To properly take a dose, follow these 4 steps:

STEP 1 Unscrew and lift off the cover (Figure 1). You will hear a rattling sound when you unscrew the cover. This is normal.



STEP 2 Hold the inhaler upright. Do not hold the inhaler by the mouthpiece.

- Turn the **red grip** as far as it will go in one direction (clockwise or counter-clockwise, it does not matter which way you turn it first).
- Then turn the red grip as far as it will go in the opposite direction (Figure 2).



A dose has now been loaded.

- At some point when you are turning the grip, **you will hear a “click”**. This is part of the loading process.

NOTE: If you accidentally **drop, shake** or **breathe out** into SYMBICORT TURBUHALER after the dose has been loaded, you will lose your dose. If this happens, repeat STEP 2 to load a new dose.

STEP 3 Breathe out, with your mouth away from the mouthpiece (Figure 3). Then, place the mouthpiece gently between your teeth.



STEP 4 Now close your lips over the mouthpiece. Do not bite or chew the mouthpiece.

- **Inhale as deeply and**

Figure 4

strongly as you can (Figure 4).

- You may not feel or taste the medication when inhaling. This is common.
- Before you exhale, remember to remove the inhaler from your mouth.



Repeat STEPS 2-4 if more than one dose has been prescribed. When you have taken the prescribed amount of doses, **replace the cover of the inhaler by screwing it back on.** Rinse your mouth with water, and do not swallow.

Note: Do not try to take off the mouthpiece or to twist it unnecessarily. The mouthpiece can be rotated but it is fixed to the inhaler and must not be taken off. Do not use the TURBUHALER if it has been damaged.

I cannot remember how many times I turned the red grip. What should I do?

The TURBUHALER is designed to load only one dose at a time. If you can't remember how many times you have turned the red grip, you can start the process again. Follow the steps below. You will not end up loading two doses.

If you are using a **NEW** inhaler for the first time, start at the beginning of STEP 2 under the section “**A. How to prepare a NEW inhaler for use:**”.

If you are already regularly using your inhaler, start at the beginning of STEP 2 under the section “**B. How to take a dose:**”.

How do I know my dose has been loaded?

By turning the red grip all the way in BOTH directions, you will properly load a dose of your medication. At some point when you are turning the grip you will hear a “click”. This is part of the loading process. If you are not sure you heard the “click”, repeat from the beginning of STEP 2 under the section “**B. How to take a dose:**”. This will not result in two doses being loaded. The TURBUHALER is designed to load only one dose at a time.

How do I clean my inhaler?

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

How do I know when to start a new inhaler?

SYMBICORT TURBUHALER has a dose indicator. The dose indicator tells you around 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 (Figure 5). When the “0” on the red background has reached the middle of the window, you should throw out your inhaler and start a new inhaler. The sound you hear if you shake the inhaler is made by a drying agent, not the

IMPORTANT: PLEASE READ

medication. SYMBICORT TURBUHALER cannot be refilled with drug and should be thrown away.

Figure 5



- 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 infection);
- Unexplained swelling;
- Unexplained fever.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Common side effects are:

- Headache;
- Trembling;
- Sensation of heart beat;
- Cough;
- Irritation of mouth and/or throat;
- Hoarseness.

Less common side effects are:

- Nausea;
- Sleep difficulties;
- Agitation;
- Restlessness or nervousness;
- Dizziness;
- Muscle cramps.

Rare side effects are:

- Skin bruising;
- Depression or behavioural disturbances.

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

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 right away.

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 constant 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 YOUR DOCTOR RIGHT AWAY or go to the nearest hospital if you notice the following warning signs:

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

	Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek emergency medical attention
		Only if severe	In all cases	
Rare	Bronchospasm: Increased wheezing or tightness in the chest or difficulty in breathing immediately after inhalation of SYMBICORT.			√
	Hypersensitivity reactions: Skin rash, skin eruption or other effect on the skin or eyes, itching or fever.			√

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SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
	Allergic reactions: Swelling of the lips, face or neck, accompanied by difficulty in breathing, speaking or swallowing (angioedema) and anaphylactic reaction.			√
	Fast or irregular heartbeat.		√	
Very Rare	Cushing's Syndrome (hypercorticism): Rapid weight gain especially around the body and face; round "moon" face, excess sweating; thinning of the skin with easy bruising and dryness; muscle and bone weakness.		√	
	Increased blood sugar: Frequent urination, thirst and hunger.			√
Unknown	Churg-Strauss syndrome: A flu-like illness, rash, pins and needles or numbness of arms or legs, severe sinusitis and worsening lung or breathing problems.		√	
	Glaucoma: Increased pressure in your eyes, and/or eye pain.		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
	Cataract: Clouding of the lens in the eye, blurry vision, and/or eye pain.		√	
	Bone Fractures or Osteoporosis: In situations where healthy people would not normally break a bone you may have sudden pain in any location and especially in the wrist, spine or hip. This may be a fracture.		√	
	Pneumonia (an infection of the lungs): Fever, chills, increase in sputum production, change in sputum colour, increased cough or an increase in breathing difficulties.		√	

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 and sight 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
- 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 1908C
Ottawa, ON K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Forms and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at 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 CONSUMER INFORMATION 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

or by contacting the sponsor, AstraZeneca Canada Inc. at: 1-800-668-6000.

This leaflet was prepared by
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