

IMPORTANT: PLEASE READ

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 rapidly open 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.

SYMBICORT TURBUHALER can be used for rapid relief of asthma symptoms. Asthma symptoms can lead to worsening asthma or an asthma "attack". Daily 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 NON-MEDICINAL 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

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 TURBUHALER 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.

Patients with Asthma:

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When LABA medicines are used alone without an ICS, they increase the risk of hospitalization and death from asthma problems. SYMBICORT TURBUHALER contains both an ICS and LABA. Studies showed that when an ICS and LABA are used together, there is not a significant increased risk in hospitalizations and death from asthma problems.

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.

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;
- Diuretics or “water pills” used to lower blood pressure;
- Antidepressants, monoamine oxidase inhibitors used to treat depression.

PROPER USE OF THIS MEDICATION

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.

DOSING

Patients with Asthma:

Treatment with only SYMBICORT TURBUHALER is not enough to treat an asthma attack.

For the treatment of asthma, your doctor may instruct you to use SYMBICORT TURBUHALER in one of three ways:

- A) SYMBICORT TURBUHALER as reliever
- B) SYMBICORT TURBUHALER as reliever plus daily maintenance
- C) SYMBICORT TURBUHALER as daily maintenance

Each of these treatment plans is described below.

A) SYMBICORT TURBUHALER as Reliever: Anti-inflammatory Reliever Therapy

Only SYMBICORT **200** TURBUHALER is used for anti-inflammatory reliever therapy.

Using SYMBICORT **200** TURBUHALER for anti-inflammatory reliever therapy means:

- i. you take SYMBICORT **200** TURBUHALER anti-inflammatory reliever as needed for rapid relief of asthma symptoms.

This means that you use one inhaler (SYMBICORT **200 TURBUHALER) for rapid symptom relief. You will not need a separate inhaler for rapid relief of symptoms.**

Adults and adolescents (12 years and older)

- 1 inhalation of SYMBICORT **200** TURBUHALER if you experience symptoms. Wait a few minutes. If you don't feel better, take another inhalation. Not more than 6 inhalations should be taken on any single occasion. The maximum recommended daily dose is 8 inhalations.

Always carry SYMBICORT **200 TURBUHALER with you for rapid relief of symptoms.**

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

B) SYMBICORT TURBUHALER as Reliever plus Daily Maintenance:

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Anti-inflammatory Reliever plus Maintenance Therapy (SYMBICORT SMART®)

Using SYMBICORT TURBUHALER for anti-inflammatory reliever plus maintenance therapy means:

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

This means that you use one inhaler (SYMBICORT TURBUHALER) for both a regular daily dose and for rapid symptom relief. You will not need a separate inhaler for rapid relief of symptoms.

Adults and adolescents (12 years and older)

- 1 or 2 inhalations of SYMBICORT **100** TURBUHALER or SYMBICORT **200** TURBUHALER twice daily or 2 inhalations once daily. You should take 1 additional inhalation of SYMBICORT **100** TURBUHALER or SYMBICORT **200** TURBUHALER 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 for rapid relief of symptoms. 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.

Your doctor will adjust your maintenance medicine to the lowest dose that controls your asthma.

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

C) SYMBICORT TURBUHALER as Maintenance

Using SYMBICORT TURBUHALER for daily maintenance therapy means:

- i. you take a daily maintenance dose of SYMBICORT TURBUHALER (fixed dose), AND
- ii. you use a separate inhaler, containing a short-acting bronchodilator (airway-widening medicine) for rapid relief of asthma symptoms.

This means that you use two separate inhalers.

Adults and adolescents (12 years and older)

- 1 or 2 inhalations of SYMBICORT **100** TURBUHALER or SYMBICORT **200** TURBUHALER once or twice daily. The maximum recommended daily maintenance dose is 4 inhalations.
- or
- 1 inhalation of SYMBICORT **FORTE** TURBUHALER once or twice daily. The maximum recommended daily maintenance dose is 4 inhalations.

Always carry your short-acting bronchodilator (reliever medication) with you for rapid 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.

Your doctor will adjust your maintenance medicine to the lowest dose that controls your asthma.

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

Patients with COPD

Adults (18 years and older)

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

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

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

MISSED DOSE:

If you miss a maintenance dose, take it as soon as you remember and then go back to your regular schedule. Never take a double

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dose to make up for missed maintenance 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

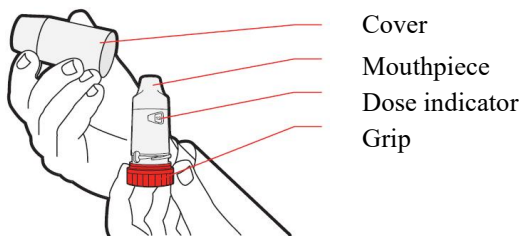
Before you start using SYMBICORT TURBUHALER for the first time it is important that you read the instructions below and follow them carefully. Your doctor, nurse or pharmacist should instruct you in the correct use of your inhaler.

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



If you are unsure about how to use your inhaler, ask your doctor, nurse or pharmacist.

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.

Figure 1



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.

Figure 2



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.

Figure 1



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

Figure 2

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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.

Figure 3



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

- **Inhale as deeply and 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.

Figure 4



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

Figure 5



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.

Uncommon side effects are:

- Nausea;

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- 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 SYMBICORT TURBUHALER as a reliever, or your fast-acting reliever medication without getting better asthma control within 2 weeks;
- 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:

- **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% 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.**

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	
Common	Pneumonia (<i>an infection of the lungs</i>): Fever, chills, increase in sputum production, change in sputum colour, increased cough or an increase in breathing difficulties.		✓	
Rare	Bronchospasm: Increased wheezing or tightness in the chest or difficulty in breathing immediately after inhalation of SYMBICORT TURBUHALER.			✓
	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 (<i>hypercorticism</i>): 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	Eosinophilic granulomatosis with polyangiitis (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.		✓	

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

	Glaucoma: Increased pressure in your eyes, and/or eye pain.		✓	
	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.		✓	

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 SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

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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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