

# IMPORTANT INFORMATION ABOUT SYMBICORT

Please read this summary carefully and then ask your doctor about SYMBICORT.

No advertisement can provide all the information needed to determine if a drug is right for you or take the place of careful discussions with your health care professional. **Only your health care professional has the training to weigh the risks and benefits of a prescription drug.**

## WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT SYMBICORT?

- In patients with asthma, long-acting beta<sub>2</sub>-agonist (LABA) medicines, such as formoterol (one of the medicines in SYMBICORT), may increase the chance of death from asthma problems. In a large asthma study, more patients who used another LABA medicine died from asthma problems, compared with patients who did not use that LABA medicine. Talk with your health care professional about this risk and the benefits of treating your asthma with SYMBICORT.
- SYMBICORT does not relieve sudden symptoms, so you should always have a fast-acting inhaler (short-acting beta<sub>2</sub>-agonist medicine) with you. If you do not have this type of inhaler, talk with your health care professional to have one prescribed for you.
- Get emergency medical care if your breathing problems worsen quickly and your fast-acting inhaler does not relieve them.
- Do not stop using SYMBICORT unless your health care professional tells you to stop because your symptoms might get worse.

## WHAT IS SYMBICORT?

SYMBICORT is an inhaled prescription medicine for long-term maintenance treatment, taken twice a day, every day, to control asthma in patients 12 years and older. It will not replace your fast-acting inhaler for relief of sudden asthma symptoms.

SYMBICORT contains two medicines:

- Budesonide (the same medicine found in PULMICORT TURBUHALER® [budesonide inhalation powder], PULMICORT FLEXHALER™ [budesonide inhalation powder]), an inhaled corticosteroid medicine, or ICS. ICS medicines help to decrease inflammation in the lungs. Inflammation in the lungs can lead to asthma symptoms.
- Formoterol (the same medicine found in Foradil® Aerolizer®) is a long-acting beta<sub>2</sub>-agonist medicine, or LABA. LABA medicines help the muscles in the airways of the lungs stay relaxed to prevent asthma symptoms, such as wheezing and shortness of breath. These symptoms can happen when the muscles in the airways tighten, which, in severe cases, can cause breathing to stop completely if not treated right away.

## WHO SHOULD NOT TAKE SYMBICORT?

You should NOT take SYMBICORT if your health care professional:

- decides that your asthma is well controlled using another asthma-controller medicine
- you only use a fast-acting inhaler less than twice a week

## WHAT SHOULD I TELL MY HEALTH CARE PROFESSIONAL BEFORE USING SYMBICORT?

Tell your health care professional about all of your health conditions, including if you

- have heart problems
- have high blood pressure
- have seizures
- have thyroid problems
- have diabetes
- have liver problems
- have been on an oral steroid, like prednisone
- have osteoporosis
- have an immune system problem or have been exposed to chicken pox or measles
- have tuberculosis or other infections
- are pregnant or planning to become pregnant because it is not known if SYMBICORT may harm your unborn baby
- are breast-feeding because it is not known if SYMBICORT passes into your milk and if it can harm your baby

Tell your health care professional about ALL the medicines you are taking, including all your prescription and nonprescription medicines, vitamins, and herbal supplements.

SYMBICORT and certain other medicines may interact with each other and can cause serious side effects. So be sure to keep track of ALL the medication you take. You might want to make a list and show it to your health care professional, including your pharmacist, each time you get any new medicine, just to ensure there are no potential drug interactions.

## HOW DO I USE SYMBICORT?

Do not use SYMBICORT unless your health care professional has carefully demonstrated how to do so. If you have any questions concerning the use of SYMBICORT, ask your health care professional.

SYMBICORT should be taken twice every day as prescribed by your health care professional.

SYMBICORT comes in two strengths. Your health care professional will prescribe the strength that is best for you.

### When you use SYMBICORT, make sure you

- use SYMBICORT exactly as prescribed
- take two puffs of SYMBICORT in the morning and two puffs in the evening every day. If you miss a dose of SYMBICORT, you should take your next dose at the same time you normally do
- do not take SYMBICORT more often or use more puffs than you have been prescribed
- rinse your mouth with water after each dose (two puffs) of SYMBICORT without swallowing
- do not change or stop any of the medicines you use to control or treat your breathing problems. Your health care professional will adjust your medicines as needed
- always have a fast-acting inhaler with you. Use it if you have breathing problems between doses of SYMBICORT

### Seek emergency medical care if

- your breathing problems worsen quickly and your fast-acting inhaler does not relieve your breathing problems
- you experience any symptoms of a serious allergic reaction to SYMBICORT, such as a rash; hives; swelling of the face, mouth, tongue; and breathing problems

### Contact your health care professional if

- you need to use your fast-acting inhaler more often than usual
- your fast-acting inhaler does not work as well for you at relieving symptoms
- you need to use four or more inhalations of your fast-acting inhaler for 2 or more days in a row
- you use up your entire fast-acting inhaler canister within 8 weeks
- your peak-flow meter results decrease. Your health care professional will tell you the numbers that are right for you
- your asthma symptoms do not improve after using SYMBICORT regularly for 1 week

## WHAT MEDICATIONS SHOULD I NOT TAKE WHEN USING SYMBICORT?

While you are using SYMBICORT, do NOT use other medicines that contain a long-acting beta<sub>2</sub>-agonist (LABA) for any reason, such as

- Serevent® Diskus® (salmeterol xinafoate inhalation powder)
- Advair Diskus® or Advair® HFA (fluticasone propionate and salmeterol)
- Foradil® Aerolizer® (formoterol fumarate inhalation powder)

## WHAT ARE OTHER IMPORTANT SAFETY CONSIDERATIONS WITH SYMBICORT?

- Cardiovascular and central nervous system effects of LABAs, such as chest pain, increased blood pressure, fast or irregular heartbeat, tremor, or nervousness
- Immune system effects and a higher chance for infections
- Osteoporosis. People at risk for increased bone loss may have a greater risk with SYMBICORT
- Slowed growth in children. As a result, growth should be carefully monitored
- Eye problems, such as glaucoma and cataracts. Regular eye exams should be considered while using SYMBICORT

## WHAT ARE OTHER POSSIBLE SIDE EFFECTS WITH SYMBICORT?

- Nose and throat irritation
- Headache
- Upper respiratory tract infection
- Sore throat
- Sinusitis
- Stomach discomfort
- Oral thrush

Tell your health care professional about any side effect that bothers you or that does not go away. These are not all the side effects with SYMBICORT. Ask your health care professional for more information.

**NOTE: This summary provides important information about SYMBICORT. For more information, please ask your doctor or health care professional about the full Prescribing Information and discuss it with him or her.**

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