

MEDICATION GUIDE

SYMBICORT 80/4.5

(budesonide 80 mcg and formoterol fumarate dihydrate 4.5 mcg) Inhalation Aerosol

SYMBICORT 160/4.5

(budesonide 160 mcg and formoterol fumarate dihydrate 4.5 mcg) Inhalation Aerosol

Read the Medication Guide that comes with SYMBICORT before you start using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about SYMBICORT?

- SYMBICORT contains 2 medicines:
 - Budesonide (the same medicine found in PULMICORT TURBUHALER[®]), an inhaled corticosteroid medicine. Inhaled corticosteroids help to decrease inflammation in the lungs. Inflammation in the lungs can lead to asthma symptoms.
 - Formoterol (the same medicine found in FORADIL[®] AEROLIZER[®]), a long-acting beta₂-agonist medicine or LABA. LABA medicines are used in patients with asthma. LABA medicines help the muscles around the airways in your lungs stay relaxed to prevent asthma symptoms, such as wheezing and shortness of breath. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe. In severe cases, wheezing can stop your breathing and may lead to death if not treated right away.
- **In patients with asthma, 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 healthcare provider about this risk and the benefits of treating your asthma with SYMBICORT.
- **SYMBICORT does not relieve sudden symptoms. Always have an inhaled short-acting beta₂-agonist medicine with you to treat sudden symptoms. If you do not have this type of medicine, contact your healthcare provider to have one prescribed for you.**
- **Do not stop using SYMBICORT unless told to do so by your healthcare provider because your symptoms might get worse.**
- **SYMBICORT should be used only if your healthcare provider decides that another asthma-controller medicine alone does not control your asthma or that you need two asthma-controller medicines.**
- **Call your healthcare provider if breathing problems worsen over time while using SYMBICORT. You may need different treatment.**
- **Get emergency medical care if:**
 - **Breathing problems worsen quickly, and**

- **You use your short-acting beta₂-agonist medicine, but it does not relieve your breathing problems.**

What is SYMBICORT?

SYMBICORT combines an inhaled corticosteroid medicine, budesonide (the same medicine found in PULMICORT TURBUHALER), and a long-acting beta₂-agonist medicine (LABA), formoterol (the same medicine found in FORADIL AEROLIZER).

SYMBICORT is used long-term, twice a day, everyday to control symptoms of asthma, and prevent symptoms such as wheezing in patients 12 years of age and older.

SYMBICORT contains formoterol (the same medicine found in FORADIL AEROLIZER). Because LABA medicines such as formoterol may increase the chance of death from asthma problems, SYMBICORT is not for patients with asthma who:

- are well controlled with another asthma-controller medicine such as a low to medium dose of an inhaled corticosteroid medicine
- only need short-acting beta₂-agonist medicines once in awhile

What should I tell my healthcare provider before using SYMBICORT?

Tell your healthcare provider 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 osteoporosis**
- **have an immune system problem**
- **are pregnant or planning to become pregnant.** It is not known if SYMBICORT may harm your unborn baby.
- **are breastfeeding.** It is not known if SYMBICORT passes into your milk and if it can harm your baby.
- **are allergic to SYMBICORT or any other medicines**
- **are exposed to chicken pox or measles**

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. SYMBICORT and certain other medicines may interact with each other. This may cause serious side effects.

Know all the medicines you take. Keep a list and show it to your healthcare provider and pharmacist each time you get a new medicine.

How do I use SYMBICORT?

See the step-by-step instructions for using SYMBICORT at the end of this Medication Guide. Do not use SYMBICORT unless your healthcare provider has taught you and you understand everything. Ask your healthcare provider or pharmacist if you have any questions.

- Use SYMBICORT exactly as prescribed. **Do not use SYMBICORT more often than prescribed.** SYMBICORT comes in two strengths. Your healthcare provider has prescribed the strength that is best for you. **Note the differences between SYMBICORT and your other inhaled medications, including the differences in prescribed use and physical appearance.**
- SYMBICORT should be taken as two puffs 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.
- **While you are using SYMBICORT twice a day, do not use other medicines that contain a long-acting beta₂-agonist (LABA) for any reason, such as SEREVENT DISKUS (salmeterol xinafoate inhalation powder), ADVAIR DISKUS or ADVAIR HFA (fluticasone propionate and salmeterol), or FORADIL AEROLIZER (formoterol fumarate inhalation powder).**
- Do not change or stop any of your medicines used to control or treat your breathing problems. Your healthcare provider will adjust your medicines as needed.
- Make sure you always have a short-acting beta₂-agonist medicine with you. Use your short-acting beta₂-agonist medicine if you have breathing problems between doses of SYMBICORT.
- **Call your healthcare provider or get medical care right away if:**
 - your breathing problems worsen with SYMBICORT
 - you need to use your short-acting beta₂-agonist medicine more often than usual
 - your short-acting beta₂-agonist medicine does not work as well for you at relieving symptoms
 - you need to use four or more inhalations of your short-acting beta₂-agonist medicine for 2 or more days in a row
 - you use one whole canister of your short-acting beta₂-agonist medicine in 8 weeks' time
 - your peak flow meter results decrease. Your healthcare provider will tell you the numbers that are right for you.
 - your asthma symptoms do not improve after using SYMBICORT regularly for 1 week.

What are the possible side effects with SYMBICORT?

SYMBICORT contains formoterol. In patients with asthma, LABA medicines such as formoterol may increase the chance of death from asthma problems. See “What is the most important information I should know about SYMBICORT?”

Other possible side effects with SYMBICORT include:

- **serious allergic reactions including rash, hives, swelling of the face, mouth, and tongue, and breathing problems.** Call your healthcare provider or get emergency medical care if you get any symptoms of a serious allergic reaction.
- **chest pain**
- **increased blood pressure**
- **a fast and irregular heartbeat**
- **headache**
- **tremor**
- **nervousness**
- **immune system effects and a higher chance for infections**
- **eye problems including glaucoma and cataracts.** Regular eye exams should be considered while using SYMBICORT.
- **lower bone mineral density.** This may be a problem for people who already have a higher chance for low bone mineral density (osteoporosis).
- **slowed growth in children.** A child's growth should be checked often.
- **throat irritation.**

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the side effects with SYMBICORT. Ask your healthcare provider or pharmacist for more information.

How do I store SYMBICORT?

- Store SYMBICORT at room temperature 68°F to 77°F (20°C to 25°C). Store with the mouthpiece down.
- The contents of your SYMBICORT canister are under pressure. Do not puncture or throw the canister into a fire or incinerator. Do not use or store it near heat or open flame. Storage above 120°F may cause the canister to burst.
- **Keep SYMBICORT and all medicines out of the reach of children.**

General Information about SYMBICORT

Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not use SYMBICORT for a condition for which it was not prescribed. Do not give your SYMBICORT to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about SYMBICORT. If you would like more information, talk with your healthcare provider or pharmacist. You can ask your healthcare provider or pharmacist for information about SYMBICORT that was written for healthcare professionals. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You can also contact the company that makes SYMBICORT (toll free) at 1-800-236-9933 or visit our web site at www.MySymbicort.com.

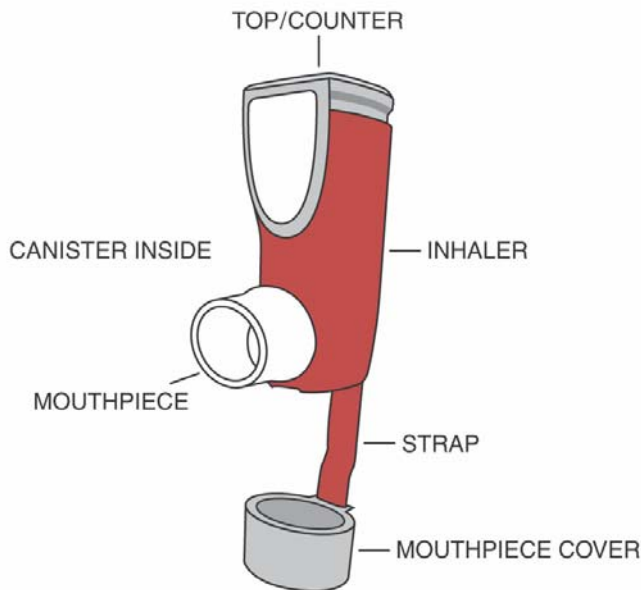


Figure 1

HOW TO USE SYMBICORT

Follow the instructions below for using SYMBICORT. You will breathe-in (inhale) the medicine. If you have any questions, ask your doctor or pharmacist.

PREPARING YOUR INHALER FOR USE

1. Take your SYMBICORT inhaler out of the moisture-protective foil pouch before you use it for the first time and throw the foil away. Write the date that you open the foil pouch on the box.
2. A counter is attached to the top of the metal canister. The counter will count down towards zero (“0”). Each time you release a puff from the inhaler, the number will count down by 1. The arrow points to the number of inhalations (puffs) remaining in the canister. The counter will stop counting at zero (“0”). You should discard the inhaler when the counter reaches zero (“0”), indicating that the labeled number of inhalations have been used or within 3 months of opening the foil pouch.
3. Use the SYMBICORT canister only with the red SYMBICORT inhaler supplied with the product. Parts of the SYMBICORT inhaler should not be used with parts from any other inhalation drug product.
4. SHAKE THE INHALER WELL for 5 seconds right before each use. Remove the mouthpiece cover. Check the mouthpiece for foreign objects prior to use.

5. SYMBICORT should be primed before using it for the first time and also when the inhaler has not been used for more than 7 days or when it has been dropped. Prime the inhaler by shaking the inhaler well for 5 seconds and then releasing a test spray. Then shake the inhaler again and release a second test spray. Your inhaler is now primed and ready for use. After you have primed the inhaler for the first time, the counter will read either 120 or 60, depending on whether you have a filled prescription (120) or an institutional or sample pack (60).

Do not spray the medicine in your eyes during priming or use.

WAYS TO HOLD THE INHALER FOR USE

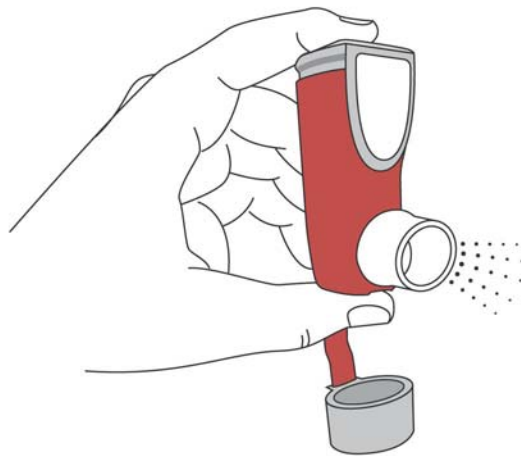


Figure 2

OR



Figure 3

USING YOUR SYMBICORT INHALER

6. SHAKE THE INHALER WELL for 5 seconds. Remove the mouthpiece cover. Check the mouthpiece for foreign objects.

7. Breathe out fully (exhale). Raise the inhaler up to your mouth. Place the white mouthpiece fully into your mouth and close your lips around it. Make sure that the inhaler is upright and that the opening of the mouthpiece is pointing towards the back of your throat (see Figure 4).



Figure 4

8. While breathing in deeply and slowly through your mouth, press down firmly and fully on the top of the counter on the inhaler to release the medicine (see Figures 2 and 3).
9. Continue to breathe in and hold your breath for about 10 seconds, or for as long as is comfortable. Before breathing out, release your finger from the top of the counter and remove the inhaler from your mouth while keeping the inhaler upright.
10. Shake the inhaler again for 5 seconds and repeat steps 7 through 9.

AFTER USING YOUR SYMBICORT INHALER

11. Replace the mouthpiece cover after use.
12. After you finish taking this medicine (two puffs), rinse your mouth with water. Spit out the water. Do not swallow it.

READING THE COUNTER

- The arrow on the counter on the top of the inhaler points to the number of inhalations (puffs) remaining in your inhaler.



- The counter will count down toward zero (“0”) each time you release a puff of medicine (either when preparing your inhaler for use or when taking the medicine).
- When the arrow on the counter approaches 20, you will notice the beginning of a yellow colored zone, indicating that it is time to call for a refill.



- It is very important that you note the number of inhalations (puffs) remaining in your SYMBICORT inhaler by reading the counter. Discard SYMBICORT after the counter reaches zero (“0”), indicating that you have used the number of inhalations on the product label and box. Your inhaler may not feel empty and it may continue to operate, but you will not get the right amount of medicine if you keep using it.

OTHER IMPORTANT INFORMATION ABOUT YOUR SYMBICORT INHALER

SYMBICORT should be discarded within 3 months after it is taken out of its foil pouch.

- For best results, use and store at room temperature. Avoid exposing product to extreme heat and cold. Store with the mouthpiece down.

HOW TO CLEAN YOUR SYMBICORT INHALER

Clean the white mouthpiece of the inhaler every 7 days. To clean the mouthpiece:

- Remove the grey mouthpiece cover
- Wipe the inside and outside of the white mouthpiece opening with a clean, dry cloth
- Replace the mouthpiece cover
- **Do not put the inhaler into water**
- Do not try to take the inhaler apart

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