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Budesonide and formoterol: Patient drug information

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(For additional information see "Budesonide and formoterol: Drug information" and see "Budesonide and formoterol: Pediatric drug information")

Brand Names: US

Symbicort

Brand Names: Canada

Symbicort 100 Turbuhaler; Symbicort 200 Turbuhaler; Symbicort Forte Turbuhaler

What is this drug used for?

- It is used to treat COPD (chronic obstructive pulmonary disease).
- It is used to treat asthma.
- This drug is not to be used to treat intense flare-ups of shortness of breath. Use a rescue inhaler. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to budesonide, formoterol, or any other part of this drug.
- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.

• If you are using another drug like this one. If you are not sure, ask your doctor or pharmacist.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

For all uses of this drug:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- If you have high blood sugar (diabetes), talk with your doctor. This drug may raise blood sugar.
- It may take 2 weeks to see the full effect.
- Call your doctor right away if your breathing problems get worse, if your rescue inhaler does not work as well, or if you need to use your rescue inhaler more often.
- Do not take more of this drug or use it more often than you have been told. Deaths have happened when too much of this type of drug has been taken. Talk with your doctor.
- When changing from an oral steroid to another form of a steroid, there may be very bad and sometimes deadly side effects. Signs like weakness, feeling tired, dizziness, upset stomach, throwing up, not thinking clearly, or low blood sugar may happen. Call your doctor right away if you have any of these signs. If you have a bad injury, have surgery, or any type of infection, you may need extra doses of oral steroids. These extra steroids will help your body deal with these stresses. Carry a warning card saying that there may be times when you may need extra steroids.
- Long-term use may raise the chance of cataracts or glaucoma. Talk with the doctor.
- Have an eye exam as you have been told by your doctor.
- This drug may cause weak bones (osteoporosis) with long-term use. Talk with your doctor to see if you have a higher chance of weak bones or if you have any questions.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- Chickenpox and measles can be very bad or even deadly in some people taking steroid drugs like this drug. Avoid being near anyone with chickenpox or measles if you have not

had these health problems before. If you have been exposed to chickenpox or measles, talk with your doctor.

- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may affect growth in children and teens in some cases. They may need regular growth checks. Talk with the doctor.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

COPD:

• The chance of getting pneumonia is higher in people with COPD. This drug may raise the chance of getting pneumonia. Talk with the doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Signs of low potassium levels like muscle pain or weakness, muscle cramps, or a heartbeat that does not feel normal.
- Signs of a weak adrenal gland like a very bad upset stomach or throwing up, very bad dizziness or passing out, muscle weakness, feeling very tired, mood changes, not hungry, or weight loss.
- Signs of high or low blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Chest pain or pressure.
- Fast or abnormal heartbeat.

- · Shakiness.
- Feeling nervous and excitable.
- Bone pain.
- · Dizziness or passing out.
- · Seizures.
- Very upset stomach or throwing up.
- Feeling very tired or weak.
- Trouble sleeping.
- A burning, numbness, or tingling feeling that is not normal.
- Flu-like signs.
- · Sinus pain.
- Change in eyesight, eye pain, or very bad eye irritation.
- Redness or white patches in mouth or throat.
- · Mouth irritation or mouth sores.
- This drug can cause very bad breathing problems right after you take a dose. Sometimes, this may be life-threatening. If you have trouble breathing, breathing that is worse, wheezing, or coughing after using this drug, use a rescue inhaler and get medical help right away.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- · Stomach pain.
- · Nose or throat irritation.
- Signs of a common cold.
- · Back pain.
- Throwing up.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- For breathing in only.
- Keep using this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Prepare the inhaler before first use, when the inhaler has not been used for more than 7 days, or if it has been dropped. Spray 2 test sprays into the air. Shake well before each test spray.
- Shake well before use.
- Rinse out mouth after each use. Do not swallow the rinse water. Spit it out.
- Put the cap back on after you are done using your dose.
- This inhaler has a dose counter to keep track of how many doses are left. Throw away the inhaler when you have been told after opening or when the dose counter reaches "0", whichever comes first.
- Never wash the inhaler. Keep it dry.
- If you are using more than 1 inhaled drug, ask the doctor which drug to use first.
- If you get this drug in your eyes, wash right away with water. If you have eye irritation that lasts or a change in eyesight, call your doctor.

What do I do if I miss a dose?

- Skip the missed dose and go back to your normal time.
- Do not use 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature. Throw away any part not used 3 months after taking out of foil package.
- Protect from heat or open flame. Do not puncture or burn even if it seems empty.
- Store in a dry place. Do not store in a bathroom.
- Store with the mouthpiece down.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.

• Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- · If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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