

PATIENT INFORMATION

ENTOCORT EC (budesonide) Capsules

Read this information carefully before you begin treatment. Read the information you get whenever you get more medicine. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about ENTOCORT EC (EN-toe-cort EE-CEE), ask your health care provider. Only your provider can determine if ENTOCORT EC is right for you.

What is ENTOCORT EC?

ENTOCORT EC is a medicine to treat mild to moderate Crohn's Disease in many people. However, it does not work for everyone who takes it. ENTOCORT EC is a *nonsystemic* corticosteroid, which means it works mainly in one area of the body. The medicine in ENTOCORT EC is released in the intestine. Therefore, it controls the symptoms of Crohn's disease even though 90% of the drug does not go into the bloodstream. Because of this, it causes fewer severe side effects than other corticosteroids. (See the end of this Patient Information for information about Crohn's Disease.)

Who should not take ENTOCORT EC?

Do not take ENTOCORT EC if

- you are breast feeding. Because ENTOCORT EC is carried in human milk, it may harm the baby. Talk with your provider about whether you should stop breast feeding to take ENTOCORT EC or should use another treatment.
- you have had an allergic reaction to ENTOCORT EC or any of its ingredients.

To help your provider decide if ENTOCORT EC is right for you, tell your provider

- if you had an allergic reaction to any medicine in the past
- the names of all the prescription and nonprescription medicines you now take. Be sure to tell your provider if you take ketoconazole, which can affect processing of ENTOCORT EC by the liver, steroids such as prednisone, or any other drug that suppresses your immune system.
- if you are pregnant, think you may be pregnant, or plan to get pregnant. Your provider will talk about whether ENTOCORT EC is right for you.
- if you ever had liver problems. Liver problems affect the amount of ENTOCORT EC that stays in your system, and dosage may need to be changed.
- if you are about to have surgery for any reason. Your dosage may need to be changed.
- if you have chicken pox or measles, or any other condition that suppresses the immune system
- if you or anyone in your family has had diabetes or glaucoma
- if you ever had tuberculosis, high blood pressure, osteoporosis, ulcers, or cataracts.

How should I take ENTOCORT EC?

Take ENTOCORT EC in the morning. Swallow each ENTOCORT EC capsule whole. **Do not open, chew, or crush ENTOCORT EC capsules.** Your provider will tell you how long to take ENTOCORT EC.

What should I avoid while taking ENTOCORT EC?

Patients who take medicines that suppress the immune system, such as ENTOCORT EC, are more likely to get infections. Avoid people with infections. Also, if you never had chicken pox or measles, be careful to avoid people with these conditions. These conditions can be more serious if you get them while taking ENTOCORT EC.

While you are taking ENTOCORT EC, do not drink grapefruit juice regularly. Grapefruit juice can increase the amount of ENTOCORT EC in your blood. Other juices, like orange juice or apple juice, do not have this effect.

What are the side effects of ENTOCORT EC?

The most common side effects of ENTOCORT EC are headache, infection in your air passages (respiratory infection), nausea, and symptoms of hypercorticism (too much steroids in your body).

These symptoms include an increase in the size of the face and neck, acne, and bruising. Most symptoms of too much steroids in your body occur less often with ENTOCORT EC than with other steroids.

Call your provider right away if you notice itching, skin rash, fever, swelling of your face and neck, or trouble breathing while you are taking ENTOCORT EC. These may be signs that you are allergic to the medicine and you may need emergency medical help.

Switching from a systemic medicine, like prednisone, to a nonsystemic medicine, such as ENTOCORT EC, can cause allergies controlled by the systemic medicine to come back. These allergies may include eczema (a skin disease) or rhinitis (inflammation inside the nose).

Call your provider if

- your Crohn's disease symptoms worsen during treatment
- you notice any side effects or any other symptoms that concern you

These are not all the possible side effects of ENTOCORT EC. Ask your provider or pharmacist for a complete listing of all possible side effects of ENTOCORT EC.

What is Crohn's disease?

Crohn's disease is an inflammatory bowel disease. The inflammation caused by Crohn's disease is usually found in a part of the small intestine called the ileum and in the large intestine (colon). It may also occur in any part of the gastrointestinal tract (digestive system) from the mouth to the anus (rectum). The cause of Crohn's disease is not yet known.

There are many symptoms of Crohn's disease. These include diarrhea, crampy abdominal (stomach area) pain, fever, and sometimes bleeding from the rectum. Appetite loss followed by weight loss may occur. There may also be redness and soreness of the eyes, joint pain, and sores on the skin. These symptoms may range from mild to severe.

There is no cure yet for Crohn's disease. However, it is possible for the disease to quiet down (go into remission). During these periods of remission, there may be times when the symptoms get worse. In general, people with Crohn's disease are able to lead productive lives.

General advice about prescription medicines

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use ENTOCORT EC for a condition for which it was not prescribed. Do not give ENTOCORT EC to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about ENTOCORT EC. If you would like more information, talk with your provider. You can ask your pharmacist or provider for information about ENTOCORT EC that is written for health professionals. You can also visit the ENTOCORT EC Web site at (**web site name to come**) or call AstraZeneca toll-free (**number to come**).

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