

INFORMATION TO THE CONSUMER

IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT

 ENTOCORT[®] Capsules

(budesonide)

Read this leaflet carefully. It has been prepared by the makers of ENTOCORT Capsules to help you get the most benefit from this medicine. It contains general points about ENTOCORT Capsules and should add to more specific advice from your doctor or pharmacist.

This Leaflet Should Not Replace Your Doctor's or Pharmacist's Advice. Because of your health condition, they may have given you different instructions. If so, be sure to follow their advice. Also, if you have any questions or concerns after reading this leaflet, talk to your doctor or pharmacist.

WHAT IS ENTOCORT?

ENTOCORT is a brand name for a drug called budesonide. It is an anti-inflammatory drug which belongs to the steroid family of drugs.

WHAT IS IN ENTOCORT CAPSULES?

ENTOCORT Capsules are filled with a large number of small grains and contain 3 mg of the medicine budesonide. When swallowed, the medicine passes through the stomach intact, and is gradually released in the small bowel.

Most medicines contain more than just the active drug. These are needed to keep medicines in a form you can use. Check with your doctor if you think you might be allergic to any of these items: ethylcellulose, acetyltributyl citrate, methacrylic acid copolymer, triethylcitrate, dimethicone, polysorbate 80, talc, sugar spheres (sucrose and maize starch), gelatin, sodium lauryl sulphate, titanium dioxide and iron oxide.

HOW DO ENTOCORT CAPSULES WORK?

ENTOCORT Capsules are used in the treatment of Crohn's disease in the small bowel and/or in the first part of the large bowel.

Crohn's disease is an inflammatory bowel disease, which causes symptoms such as stomach pain, diarrhoea and fever. ENTOCORT capsules reduce the inflammation and improve the symptoms.

WHAT SHOULD I DO BEFORE STARTING ENTOCORT CAPSULES?

Be sure you've told your doctor:

- about **all** health problems you have now or have had in the past, especially tuberculosis and any other recent infection, liver disease, brittle bones (osteoporosis), stomach ulcer, high blood pressure, cataracts or any other eye diseases, diabetes or a family history of diabetes or glaucoma;
- about **all** other medicines you take, particularly if you take medicines against fungal infections, including ones you can buy without a prescription;
- about **any** operation you are about to have or plan to have;
- regular ingestion of grapefruit or its juice should be avoided during treatment with ENTOCORT capsules, since intake of grapefruit can increase the amount of budesonide that is absorbed from the gut (other fruits such as orange or apple do not influence the uptake of budesonide);
- if you take, or have taken steroid medicines within the past several months;
- if you are pregnant, plan to become pregnant or are breastfeeding;
- if you have ever had an allergic, bad or unusual reaction to ENTOCORT Capsules or the medicine budesonide;
- if you are allergic to "non-medicinal" substances like food products, preservatives, or dyes, which may be present in ENTOCORT Capsules (See 'What is in ENTOCORT Capsules').

HOW DO I TAKE ENTOCORT CAPSULES PROPERLY?

Take all doses of ENTOCORT Capsules, as recommended by your doctor, even if you feel better. The full effect of ENTOCORT Capsules is usually achieved within 2-4 weeks. Do not miss doses, or take extra doses, unless your doctor tells you. If you miss a dose, just take the next dose on time. Never take a double dose of ENTOCORT capsules to make up for missed doses.

Tell your doctor if you get an infection. Avoid exposure to chicken pox and measles.

ENTOCORT Capsules should be swallowed whole with water. The capsules must not be broken or chewed. ENTOCORT Capsules should be taken before meals.

Acute Treatment

The usual dose for treatment of acute symptoms is 9 mg per day, for up to 8 weeks. The dose can be given once daily as three 3 mg capsules in the morning.

Long Term Treatment

The usual starting dose for long-term treatment is 6 mg per day. Take two 3 mg capsules in the morning, before breakfast. Your doctor may want to change the dose, depending on the activity of your disease.

Continue taking ENTOCORT Capsules until your doctor tells you to stop. Your doctor may want to slowly reduce the dose.

Note: If your medication has been changed from “cortisone” tablets (such as prednisone, prednisolone or methylprednisolone) to ENTOCORT capsules you may temporarily experience symptoms, that may have bothered you when you first started taking “cortisone”, e.g. rash, pain in muscles and joints. If any of these symptoms bothers you, or symptoms such as headache, tiredness, nausea or vomiting occur, please contact your doctor.

Overdose

Telephone your doctor, regional poison control centre or go to your nearest hospital immediately if you think that you or anyone else may have taken too many ENTOCORT Capsules even if there are no signs of discomfort or poisoning.

ARE THERE ANY SIDE EFFECTS?

ENTOCORT Capsules, like any medication, may cause side effects in some people. These may not be caused by ENTOCORT Capsules in your case, but only a doctor can assess this.

Side effects that do occur are usually mild to moderate. However, be sure to tell your doctor if any of the following side effects bother you: swelling of the face; indigestion; menstrual problems; behavioural changes such as insomnia, mood swings and nervousness; muscle cramps; trembling; rapid or irregular heart beats; blurred vision, itching and skin rash. Allergic reactions with symptoms such as rash, swelling of tissues, and difficulty in breathing may also occur, as well as low potassium levels in the blood.

Other unwanted effects which cannot be predicted may occur in rare cases. If you have any bothersome or unusual effects while using ENTOCORT Capsules, check with your doctor or pharmacist right away.

Medicines affect different people in different ways. Just because side effects have occurred in other patients does not mean you will get them.

Do not stop taking ENTOCORT Capsules on your own. Your doctor may want to slowly reduce your dose, especially if you have been using ENTOCORT Capsules for a long time. Although rare, symptoms of steroid withdrawal i.e. fatigue, muscle or joint aches may occur if ENTOCORT Capsules are stopped too quickly.

WHERE SHOULD I KEEP ENTOCORT CAPSULES?

Remember to **keep ENTOCORT Capsules well out of the reach of children.**

ENTOCORT Capsules come in a container with a drying agent. Always keep ENTOCORT Capsules in the container. If you don't, moisture from the air may damage the capsules.

Store ENTOCORT Capsules at room temperature (15-30°C) and in a dry place. Do not keep them in the bathroom medicine cabinet or other warm, moist places.

Do not use ENTOCORT Capsules after the expiry date marked on the package.

Note:

This leaflet alerts you to some of the times you should call your doctor. Other situations which cannot be predicted may arise. Nothing about this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using ENTOCORT Capsules.

This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing. Please refer to the Consumer Information Leaflet located at www.astrazeneca.ca, to see if more up-to-date information has been posted.

Customer Inquiries: 1 800 668-6000

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