Entocort® CR 3 mg Capsules

(budesonide)

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

This medicine is available using the above name but will be referred to as Entocort Capsules throughout the leaflet.

What is in this leaflet
1. What Entocort Capsules are and what they are used for
2. What you need to know before you take Entocort Capsules
3. How to take Entocort Capsules
4. Possible side effects
5. How to store Entocort Capsules
6. Contents of the pack and other information

1. WHAT ENTOCORT CAPSULES ARE AND WHAT THEY ARE USED FOR

Entocort Capsules contain the active substance budesonide. This belongs to a group of medicines called ‘corticosteroids’. These are used to reduce inflammation.

Entocort Capsules are used to treat an inflammation of the small bowel and the first part of the large bowel. This is known as Crohn's disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ENTOCORT CAPSULES

Do not take Entocort Capsules:
- If you are allergic to budesonide or any of the other ingredients of this medicine (listed in Section 6).
- If you have an infection.
- Do not take Entocort Capsules if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Entocort Capsules.

Warnings and precautions
- Talk to your doctor or pharmacist before taking Entocort Capsules if:
  - You have ever had tuberculosis (TB).
  - You have ever had high blood pressure.
  - You have diabetes.
  - You have ever had brittle bones.
  - You have ever had stomach ulcers.
  - You have ever had glaucoma (increased pressure in the eye) or cataracts.
  - A member of your family has ever had diabetes or glaucoma.
  - You have ever had liver problems.
  - You or a member of your family has ever had mental health problems.
  - If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Entocort Capsules.

Other medicines and Entocort Capsules
- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Entocort Capsules can affect the way some medicines work and some medicines can have an effect on Entocort Capsules.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Steroid medicines, such as prednisolone or dexamethasone.
- Colestyramine, used to reduce cholesterol levels or reduce itching caused by liver problems.
- Ketoconazole or itraconazole, used to treat infections caused by a fungus.
- Medicines that contain oestrogen, such as hormone replacement therapy (HRT) and some oral contraceptives.
- HIV protease inhibitors (such as ritonavir and nelfinavir).
- Carbamazepine (used to treat epilepsy and fits).

Entocort Capsules with food and drink
- Do not drink grapefruit juice while you are taking Entocort Capsules. It can affect the way the medicine works.

Pregnancy, breast-feeding and fertility
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
- Entocort Capsules are not likely to affect you being able to drive or use any machines.

Entocort Capsules contain sucrose
- Entocort Capsules contain sucrose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ENTOCORT CAPSULES

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Your doctor will tell you how many capsules to take and when to take them.
- Swallow the capsules whole with a glass of water.
- The recommended dose for an attack of Crohn's disease is 3 capsules in the morning before breakfast.
- Normally, you will take this number of capsules for up to 8 weeks. Your doctor will then gradually reduce the dose.
- The medicine will usually have its full effect within 2 to 4 weeks. Continue to take Entocort Capsules as your doctor has told you, even if you start feeling better.

Use in children
- Entocort Capsules are not recommended for children.

Additional information about taking Entocort Capsules
- If you are about to have an operation or during times of stress, please tell the doctor that you take Entocort Capsules. The doctor may ask you to take steroid tablets as well, particularly if you have been taking a high dose of Entocort Capsules, or a similar medicine, for a long time.
- Try to avoid people who have chicken pox or measles while you are taking Entocort Capsules. Talk to your doctor if you think you may have caught chicken pox or measles while taking this medicine.

If you take more Entocort Capsules than you should
- If you take more Entocort Capsules than you should, talk to a doctor or pharmacist straight away.

If you forget to take Entocort Capsules
- If you forget to take a dose of Entocort Capsules, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Entocort Capsules
- Do not stop taking Entocort Capsules without talking to your doctor first. If you stop taking your capsules suddenly it may make you ill.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you have an allergic reaction, see a doctor straight away. The signs may include raised lumps on your skin (wells), or swelling of your face, lips, mouth, tongue or throat. This may make it difficult to breathe.

The following side effects may happen with this medicine:

Common (may affect up to 1 in 10 people)
- Heartburn.
- Muscle cramps.
- Pounding heart beat (palpitations).
- Blurred eyesight.
- Rash or itchy skin.
- Heavy or irregular periods in women.
- Low levels of potassium in the blood which may cause muscle weakness, thirst or 'pins and needles'.
- Cushingoid features such as a rounded face, acne, weight gain and bruising more easily.
- Behavioural changes such as feeling nervous, difficulty sleeping and mood swings.

Uncommon (may affect up to 1 in 100 people)
- Shaking.

Very Rare (may affect up to 1 in 10,000 people)
- A severe allergic reaction (called anaphylaxis) which may cause difficulty in breathing or shock.
- A slowing of the rate of growth in children and adolescents.

Other side effects may include:
- Glaucoma (increased pressure in the eye).
Medicines like Entocort Capsules (corticosteroids) can affect the normal production of steroid hormones in your body. The effects include:
- Changes in bone mineral density (thinning of the bones).
- Glaucoma (increased pressure in the eye).
- A slowing of the rate of growth of children and adolescents.
- An effect on the adrenal gland (a small gland near the kidney).

Mental health problems can happen while taking steroids like Entocort Capsules. Talk to a doctor if you (or someone taking this medicine), show any signs of mental health problems. This is particularly important if you are depressed, or might be thinking about suicide. Very rarely mental health problems have happened when high doses have been taken for a long time.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. **HOW TO STORE ENTOCORT CAPSULES**
Keep out of the sight and reach of children.
Do not use your capsules after the expiry date stated on the bottle. The expiry date refers to the last day of that month.
Do not store this medicine above 30°C.
Store in original container and keep it tightly closed.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

6. **CONTENTS OF THE PACK AND OTHER INFORMATION**
**What Entocort capsules contain**
The active ingredient is budesonide. Each modified release capsule contains 3 mg of budesonide.
The other ingredients are ethyl cellulose, acetyltributyl citrate, methacrylic acid copolymer type C, triethyl citrate, antifoam, polysorbate, talc, sugar pellets (sucrose and corn starch), gelatin, sodium lauryl sulphate, colloidal silicon dioxide, printing ink, edible oil, titanium dioxide (E 171) and red iron oxide (E 172), black iron oxide (E 172), yellow iron oxide (E 172).

**What Entocort Capsules look like and contents of the pack**
Entocort CR 3 mg Capsules are hard gelatin capsules with an opaque, light grey body and opaque, pink cap marked "CIR 3 mg" in black radial print.

There are 100 capsules in each container.

**MANUFACTURER AND PRODUCT LICENCE HOLDER**
Entocort Capsules is manufactured by Astrazeneca AB, S-151 85 Sodertalje, Sweden and is procured from the EU by Product Licence holder: Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharm Ltd.

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