

Package leaflet: Information for the user

Entocort[®] CR 3 mg Gastro-resistant Capsule, Hard

budesonide

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.

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.

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

Microscopic colitis: Entocort Capsules are used to treat microscopic colitis (a disease with chronic inflammation of the large bowel which is typically with chronic watery diarrhoea): Entocort Capsules can be used to treat both active illness as well as in severe cases to prevent recurring problems (maintenance treatment).

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, including viral, bacterial or fungal infections.

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).
- If you have ever had high blood pressure.
- If you have diabetes.
- If you have ever had brittle bones.
- If you have ever had stomach ulcers.
- If you have ever had glaucoma (increased pressure in the eye) or cataracts.
- If a member of your family has ever had diabetes or glaucoma.
- If you have ever had liver problems.
- If 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.

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.

Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Entocort Capsules

Tell your doctor or pharmacist if you are taking, haven 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, some medicines can have an effect on Entocort Capsules and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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, cobicistat and nelfinavir).
- Carbamazepine (used to treat epilepsy and fits).

Diagnostic tests for pituitary glands activity may show false low values due to suppression of the adrenal function.

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 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.

Entocort Capsules contain sodium:

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially sodium-free.

3. How to take Entocort Capsules

Always take Entocort Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Entocort Capsules are not recommended for children.

Your doctor will tell you how many capsules to take and when to take them.

Swallow the capsules whole with a glass of water.

Crohn's disease:

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.

Microscopic colitis:

For treatment of active disease: Take 3 capsules once daily in the morning for up to 8 weeks. When treatment is to be discontinued, the dose should normally be reduced for the last 2 to 4 weeks of therapy.

For maintenance of remission: Take 2 capsules once daily in the morning. Your doctor may reduce your once daily dose as required.

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. 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).
- 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, mood swings and depression.

Uncommon (may affect up to 1 in 100 people)

- Shaking
- Unintentional movements or extreme restlessness possibly accompanied by muscle spasms or twitching.
- Anxiety.

Rare (may affect up to 1 in 1000 people)

- Aggression.
- Clouding of the eye's natural lens including the back of the lens.
- Skin discoloration resulting from bleeding beneath the skin.
- Glaucoma (increased pressure in the eye)
- Blurred vision.

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.

Not known (frequency cannot be estimated from the available data)

allergic reaction which can cause swelling of the face, particularly eyelids, lips, tongue or throat (angioedema).

Medicines like Entocort Capsules (corticosteroids) can affect the normal production of steroid hormones in your body particularly if you take high doses for a long time. 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).

Most of the side effects mentioned in this list can also be expected with other glucocorticoids treatment.

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 HPRAs Pharmacovigilance Website: www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Entocort Capsules

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and bottle after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 30°C. Store in the original package. Keep the container tightly closed.
- Replace the cap firmly after use.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Entocort Capsules contain

The active ingredient is budesonide. Each capsule contains 3 mg of budesonide.

The other ingredients in the product imported from Greece are ethyl cellulose, tributyl acetyl citrate, Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent, triethyl citrate, Simethicone (Antifoam M), polysorbate 80, talc, sucrose (consisting of sucrose and maize starch). Capsule: Black iron oxide (E172), titanium dioxide (E 171), Gelatine, Red iron oxide (E172), Yellow iron oxide (E172).

The other ingredients in the product imported from Belgium are ethylcellulose, tributyl acetyl citrate, methacrylic acid copolymer type C, triethyl citrate, Antifoam M, polysorbate 80, talc, sucrose spheres. Capsule: black iron oxide (E172), titanium dioxide (E171), gelatin, sodium lauril sulfate, colloidal anhydrous silica, red iron oxide (E172), yellow iron oxide (E172), ink (der. 41/370-42/1015).

What Entocort Capsules look like and contents of the pack

Hard gelatin capsules with an opaque, light grey body and opaque, pink cap marked 'CIR 3 mg' in black radial print. They come in a white polyethylene container fitted with a cap containing a desiccant.

For the product imported from Greece there are 50 capsules in each container and 2 containers in each carton.

For the product imported from Belgium there is 100 capsules in the container.

Manufacturer

Entocort CR 3 mg Capsules are manufactured by Recipharm Fontaine SAS or Astrea Fontaine SAS, Rue des Près Potets, 21121 Fontaine-les-Dijon, France or Tillotts Pharma GmbH, Warmbacher Strasse 80, 79618, Rheinfelden, Baden, Germany.

Product procured from within the EU, repackaged and distributed by the PPA Holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

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Entocort is a registered trademark of Tillotts Pharma AG.

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