

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

ENTOCORD® 3 mg, modified-release hard capsules

Budesonide

Contains sugar (sucrose 320 mg)

Read all of this leaflet carefully before you start taking ENTOCORD 3 mg capsules.

- Keep this leaflet. You may need to read it again.
- If you have further questions please ask your doctor, pharmacist, nurse, or other healthcare provider.
- ENTOCORD 3 mg capsules have been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

Throughout this leaflet ENTOCORD 3 mg Capsules is referred to as ENTOCORD Capsules.

What is in this leaflet

1. What ENTOCORD Capsules is and what it is used for
2. What you need to know before you take ENTOCORD Capsules
3. How to take ENTOCORD Capsules
4. Possible side effects
5. How to store ENTOCORD Capsules
6. Contents of the pack and other information

1. What ENTOCORD 3 mg is and what it is used for

ENTOCORD Capsules belongs to a group of medicines called glucocorticosteroids (a type of cortisone), which is used to reduce inflammation.

ENTOCORD Capsules are used in the treatment of Crohn's disease in the small intestine and/or in the first part of the large intestine in adults and children 11 years and older.

Active Crohn's disease is an inflammatory bowel disease, which causes symptoms like stomach pain, diarrhoea and fever. ENTOCORD Capsules reduces the inflammation and improves the symptoms.

ENTOCORD Capsules reduce inflammation in the small intestine and the first part of the large intestine.

2. What you need to know before you take ENTOCORD

Do not take ENTOCORD Capsules:

- If you are hypersensitive (allergic) to budesonide or any of the other ingredients of ENTOCORD Capsules (listed in section 6).
- In children under the age of 11 years.

Warnings and precautions

Take special care with ENTOCORD Capsules:

Before taking ENTOCORD Capsules tell your doctor, pharmacist or other healthcare provider:

- If you have had any unusual reaction to budesonide or any of the other ingredients in ENTOCORD Capsules, or to other medicines.
- If you have or have had any infection including tuberculosis, or diabetes (including family history of diabetes), liver disease, brittle bones (osteoporosis), stomach ulcer, high blood pressure or any eye diseases (including family history of glaucoma).
- If you have not previously been infected with chicken pox or measles, or if you develop chicken pox or measles while taking ENTOCORD Capsules.
- If you or a member of your family has ever had mental health problems.

Regular intake of large volumes of grapefruit or grapefruit juice should be avoided during treatment with ENTOCORD 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 absorption of budesonide).

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

ENTOCORD Capsules have been specifically prescribed for your current condition. Do not take it for other problems unless your doctor, pharmacist or other health care professional tells you to do so.

Other medicines and ENTOCORD Capsules

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

- Colestyramine, used to reduce cholesterol levels or reduce itching caused by liver problems.
- Steroid medicines, such as prednisolone or dexamethasone.
- Medicines that contain oestrogen, such as hormone replacement therapy (HRT) and some oral contraceptives.
- Ketoconazole used to treat infections caused by a fungus.
- 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.

ENTOCORD Capsules with food and drink

Do not drink grapefruit juice while you are taking ENTOCORD Capsules. It can affect the way the medicine works.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking ENTOCORD Capsules.

Driving and using machines

There is no information available regarding the effects of ENTOCORD Capsules on the ability to drive and take machines. An influence is however unlikely.

It is not always possible to predict to what extent ENTOCORD Capsules may interfere with your daily activities. You should ensure that you do not engage in the driving and using machines until you are aware of the measure to which ENTOCORD Capsules affects you.

ENTOCORD Capsules contain sugar (sucrose)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ENTOCORD Capsules.

ENTOCORD Capsules contain sodium

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

3. How to take ENTOCORD Capsules

Do not share medicine prescribed for you with any other person.

The dose is individual. Always take ENTOCORD Capsules exactly as your doctor, or pharmacist has told you.

Check with your doctor, pharmacist or nurse if you are not sure.

ENTOCORD Capsules should be swallowed whole together with water. For children and adults with difficulty swallowing, the capsules may be opened and the contents swallowed after mixing with a tablespoon of apple sauce. It is important that the contents of the capsules are not crushed or chewed.

Usual dose for adults:

The recommended daily dose in mild to moderate active disease is 9 mg. The dose can be given once daily as 3 capsules of 3 mg in the morning, for up to 8 weeks.

Usual dose for children (11 years and above, with a body weight over 25 kg):

The recommended daily dose in mild to moderate active disease is 9 mg. The dose can be given once daily as 3 capsules of 3 mg in the morning, for up to 8 weeks.

Your doctor will tell you how long to take ENTOCORD Capsules.

Usual dose for the elderly:

Dosage as for adults. However, experience with ENTOCORD Capsules in the elderly is limited.

Note:

Full effect is usually achieved within 2-4 weeks. Do not forget to take doses of ENTOCORD Capsules even if you start feeling better.

If your medication is changed from “cortisone” tablets (such as prednisone, prednisolone or methylprednisolone) to ENTOCORD Capsules, you may temporarily regain symptoms that may have bothered you earlier, e.g., rash, pain in muscles and joints. If any of these symptoms bothers you, or if symptoms such as headache, tiredness, nausea or vomiting occur, please contact your doctor, pharmacist or other healthcare professional.

If you take more ENTOCORD Capsules than you should

Follow the instructions of your doctor. However, if you by accident should take more ENTOCORD than

prescribed on a single occasion no harmful effects should occur. If too much ENTOCORD is taken over a longer period (months or more) it is possible that side effects may arise (see “Possible side effects”). If you think that this may have happened to you, please discuss it with your doctor, pharmacist or other healthcare professional.

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

If you forget to take ENTOCORD Capsules

If you forget to take an occasional dose of ENTOCORD Capsules, it is not necessary to make up the dose that you missed. Just continue with the next dose as prescribed.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ENTOCORD Capsules can have side effects.

Not all side effects reported for ENTOCORD Capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ENTOCORD Capsules, please consult your healthcare provider for advice.

If any of the following happens, stop taking ENTOCORD Capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ENTOCORD Capsules. You may need urgent medical attention or hospitalisation.

Side effects that you may get while you are using ENTOCORD Capsules are usually mild to moderate.

However, be sure to tell your doctor if any of the following side effects bothers you:

Frequent side effects:

- Facial swelling (puffiness) and weight gain (Cushingoid features)
- Low potassium levels (changes in salt balance) in the blood
- Behavioural changes such as nervousness, insomnia and mood swings
- Blurred vision
- Unusually fast or irregular heartbeat
- Indigestion
- Skin rash
- Itching
- Muscle cramps
- Behavioural changes such as feeling nervous, difficulty sleeping, mood swings and depression
- Menstrual problems

Less frequent side effects:

- Clouding of the eye's natural lens including the back of the lens, glaucoma (increased pressure in the eye)
- A discoloration of the skin resulting from bleeding underneath, typically caused by bruising
- Anxiety
- Aggression
- Trembling (tremor)
- Unintentional movements or extreme restlessness possibly accompanied by muscle spasms or twitching
- Growth retardation
- Severe allergic reactions

Side effects with unknown frequency:

- Allergic reactions which can cause swelling of the face, particularly eyelids, lips, tongue or throat (angioedema)

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ENTOCORD Capsules.

5. How to store ENTOCORD Capsules

Store at or below 30 °C. The capsules should be stored in the container.

Replace the cap firmly after use.

Store all medicine out of reach of children.

Do not store in a bathroom.

Do not take ENTOCORD Capsules after the expiry date marked on the label or the outer carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ENTOCORD Capsules contain

The active substance is budesonide and each capsule contains 3 mg budesonide.

The other ingredients that the capsule is filled with are:

Acetyl tri-n-butyl citrate, antifoam M, ethylcellulose, methacrylic acid copolymer, polysorbate 80, sucrose, talc and triethylcitrate.

Hard capsule body:

Black iron oxide CI 77.499, foodgrade oil, gelatin, silicon dioxide colloidal, sodium lauryl sulphate, titanium dioxide.

Cap:

Foodgrade oil, gelatin, red iron oxide, CI 77.491, silicon dioxide colloidal, sodium lauryl sulphate, titanium dioxide and yellow iron oxide, CI 77.492.

Printing ink consists of black iron oxide, CI 77.499, shellac, silicon antifoam, soya lecithin or ammonium hydroxide, black iron oxide, CI 77.499, potassium hydroxide and shellac.

What ENTOCORD Capsules look like and contents of the pack

A 2-piece hard gelatin capsule with opaque, light grey body and opaque, pink cap. The cap has black radial print CIR/3 mg.

50 or 100 capsules packed in a white round, HDPE container with a white polypropylene screw cap provided with a desiccator capsule.

Holder of Certificate of Registration

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