

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

ENTOCORD® 0,02 mg/ml, (Enema)

Budesonide

The tablet contains sugar (lactose, 264,3 mg per tablet)

Each ml of vehicle contains the preservatives methylparaben (0,08 % *m/v*) and propylparaben (0,02 % *m/v*).

Read all of this leaflet carefully before you start using ENTOCORD 0,02 mg/ml Enema.

- 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 0,02 mg/ml enema has 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.

What is in this leaflet

1. What ENTOCORD 0,02 mg/ml enema is and what it is used for
2. What you need to know before you use ENTOCORD 0,02 mg/ml enema
3. How to use ENTOCORD 0,02 mg/ml enema
4. Possible side effects
5. How to store ENTOCORD 0,02 mg/ml enema
6. Contents of the pack and other information

1. What ENTOCORD 0,02 mg/ml enema is and what it is used for

ENTOCORD 0,02 mg/ml enema consists of two components – a dispersible tablet and a liquid. The tablet, which contains the medicine budesonide, must be dissolved in the liquid before use. The tablet will turn the liquid slightly yellowish.

ENTOCORD 0,02 mg/ml enema belongs to a group of medicines called glucocorticosteroids (a type of cortisone), which is used to reduce inflammation.

ENTOCORD 0,02 mg/ml enema is used to treat ulcerative colitis localised to the rectum and the lower large bowel. Ulcerative colitis is caused by inflammation in the bowel wall.

ENTOCORD 0,02 mg/ml enema reduces inflammation in the large bowel and the rectum. After preparation ENTOCORD 0,02 mg/ml enema is inserted into the rectum.

2. What you need to know before you use ENTOCORD 0,02 mg/ml enema

Do not use ENTOCORD 0,02 mg/ml enema:

- If you are allergic to budesonide or any of the other ingredients of ENTOCORD 0,02 mg/ml enema (listed in section 6).
- In children.
- If you have any ongoing infections such as bacterial, fungal or viral infection.

Warnings and Precautions

Take special care with ENTOCORD 0,02 mg/ml enema:

- Before administering ENTOCORD 0,02 mg/ml enema 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 0,02 mg/ml enema (tablet or liquid) like lactose and propylparaben or methylparaben, or to any other medicines.
- If you have or have had liver disease.
- ENTOCORD 0,02 mg/ml enema has been specifically prescribed for your current condition. Do not use it for other problems unless your doctor, pharmacist or other healthcare provider tells you to do so.
- If you or a member of your family has ever had mental health problems.

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

Other medicines and ENTOCORD 0,02 mg/ml enema

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

ENTOCORD 0,02 mg/ml enema can affect the way some medicines work and some medicines can have an effect on ENTOCORD 0,02 mg/ml enema.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Steroid medicines, such as prednisolone or dexamethasone.
- 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.
- Some medicines may increase the effects of ENTOCORD 0,02 mg/ml enema, and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).
- Some medicines to treat epilepsy such as carbamazepine.

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

Pregnancy, breastfeeding and fertility

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 using ENTOCORD 0,02 mg/ml enema.

Driving and using machines

ENTOCORD 0,02 mg/ml enema does not affect the ability to drive and use machines.

It is not always possible to predict to what extent ENTOCORD 0,02 mg/ml enema may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which ENTOCORD 0,02 mg/ml enema affects you.

ENTOCORD 0,02 mg/ml enema contains propylparaben and methylparaben and lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using ENTOCORD 0,02 mg/ml enema.

This medicine contains the preservatives propylparaben and methylparaben and may affect those who are sensitive to them.

3. How to use ENTOCORD 0,02 mg/ml enema

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

The dosage is individual. Always use ENTOCORD 0,02 mg/ml enema exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Before using ENTOCORD 0,02 mg/ml enema for the first time it is important that you read the enclosed “Instructions for use”. These instructions will tell you how to prepare and use ENTOCORD 0,02 mg/ml enema. Follow the instructions carefully.

Note: A prepared enema must be used immediately. It cannot be saved in the bottle.

Usual doses for adults and the elderly:

One ENTOCORD 0,02 mg/ml enema (tablet + liquid) per day (nightly), for 4 weeks. The best time to use ENTOCORD 0,02 mg/ml enema is at night, just before you got to bed. ENTOCORD 0,02 mg/ml enema will then stay in your bowel as long as possible while you are sleeping.

Full effect is usually achieved within 2 – 4 weeks. However, if your symptoms have not improved after 4 weeks of treatment, your doctor may prolong your treatment for another 4 weeks.

ENTOCORD 0,02 mg/ml enema should be used regularly as prescribed. Do not forget to use ENTOCORD 0,02 mg/ml enema even if you start feeling better.

Note:

If your medication is changed from “cortisone” tablets (such as prednisone, prednisolone or methylprednisolone) to ENTOCORD 0,02 mg/ml enema you may temporarily regain symptoms, which may have bothered you earlier, 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, pharmacist or other healthcare provider.

If you use more ENTOCORD 0,02 mg/ml enema than you should

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

Do not use ENTOCORD 0,02 mg/ml enema more often or over a longer period than your doctor, pharmacist or other healthcare provider has prescribed. However, if you by accident should take more ENTOCORD 0,02 mg/ml enema than prescribed on a single occasion no harmful effects should occur. If too much ENTOCORD 0,02 mg/ml enema is used 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 healthcare provider.

If you forget to administer ENTOCORD 0,02 mg/ml enema

If you forget to administer an occasional dose of ENTOCORD 0,02 mg/ml enema it is not necessary to make up for the dose you missed. Just continue with the next dose as prescribed.

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

4. Possible side effects

ENTOCORD 0,02 mg/ml enema can have side effects.

Not all side effects reported for ENTOCORD 0,02 mg/ml enema are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ENTOCORD 0,02 mg/ml enema, please consult your healthcare provider for advice.

If any of the following happens, stop using ENTOCORD 0,02 mg/ml enema 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 0,02 mg/ml enema. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- an effect on the adrenal gland (a small gland near the kidney)
- an inflamed pancreas with symptoms such as upper abdominal pain, nausea and vomiting

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- feeling sad (depression)
- gas in stomach or bowels (flatulence)
- nausea
- runny stomach (diarrhoea)
- stomach pain and constipation
- skin rash (urticaria)
- itching (exanthema)

Less frequent side effects:

- a slowing of the rate of growth of children and adolescents
- nervousness
- restlessness
- difficulty in falling asleep (insomnia)
- feeling agitated
- aggression
- unintentional movements or extreme restlessness possibly accompanied by muscle spasms or twitching
- glaucoma (increased pressure in the eye)
- clouding of the eye's natural lens including the back of the lens
- blurred vision
- a sore that develops on the lining of the oesophagus, stomach or small intestine
- skin discoloration resulting from bleeding beneath the skin
- changes in bone mineral density (thinning of the bones)

Side effects with unknown frequency:

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, 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 0,02 mg/ml enema.

5. How to store ENTOCORD 0,02 mg/ml enema

Store at or below 30 °C.

Do not use after the expiry date stated on the label / carton / bottle

Return all unused medicine to your pharmacist.

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

Store all medicines out of reach of children.

6. Contents of the pack and other information

What ENTOCORD 0,02 mg/ml enema contains

The active substance is budesonide.

ENTOCORD 0,02 mg/ml enema (tablet and liquid) contains 2 mg of budesonide per 100 ml.

One tablet contains: budesonide 2,3 mg, lactose, colour [riboflavine (E101)], crospovidone, colloidal anhydrous silica, and magnesium stearate.

One bottle (115 ml) of liquid contains: sodium chloride, preservatives methylparaben (E128), propylparaben (E216), and water.

What ENTOCORD 0,02 mg/ml enema looks like and contents of the pack

ENTOCORD 0,02 mg/ml enema consists of 2 components: a dispersible tablet and a vehicle.

Dispersible tablet:

A faintly yellow, circular, biconvex tablet, packed in aluminium blister.

Vehicle:

A clear, colourless solution in a plastic bottle, with an individually packed rectal nozzle.

The tablets are packed in an aluminium foil. Each plastic bottle with liquid is provided with an individually packed nozzle. Plastic bags to protect your hand when you administer the enema are included in the package. See the enclosed "Instructions for use".

Each box contains 7 tablets, 7 individually packed nozzles and 7 plastic bottles of vehicle.

Holder of Certificate of Registration

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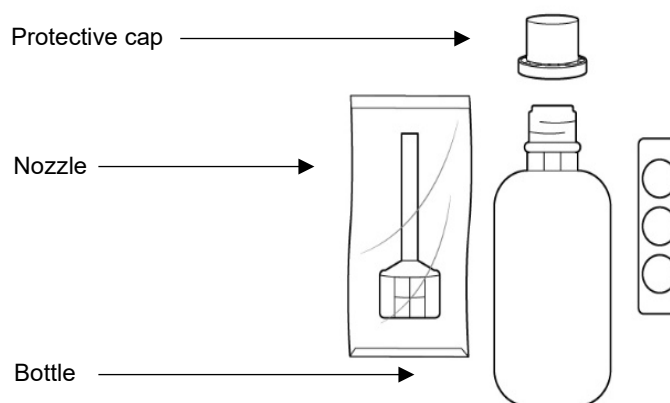
Registration number

29/11.81/0638

INSTRUCTIONS FOR USE/HANDLING:

ENTOCORD 0,02 mg/ml enema should be used in the evening before going to bed.

ENTOCORD 0,02 mg/ml enema consists of two components – a tablet and a liquid. The tablet must be dissolved in the liquid before use.



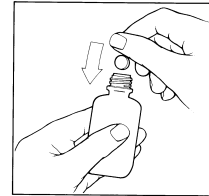
Read the following information before you use

ENTOCORD 0,02 mg/ml enema. Follow the instructions carefully.

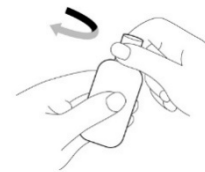
How to prepare ENTOCORD 0,02 mg/ml

enema:

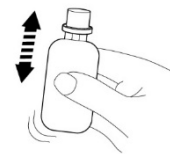
1. Unscrew the cap of one of the plastic bottles.
2. Take a tablet from the aluminium foil pack and put it into the bottle.



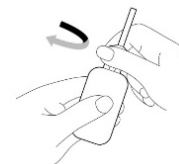
3. Replace the cap onto the bottle and screw the cap tightly.



4. Shake the bottle vigorously for at least 15 seconds or until the tablet has dissolved and a slightly yellowish liquid has been formed.



5. Unscrew the cap.
6. Unpack the nozzle and screw the nozzle on the bottle.



7. The enema is now ready and should be used immediately.
8. Insert your hand in the plastic bag and grip the bottle.



9. Lie down on your left side. Shake the bottle again, then take off the protective cap. Gently

insert the nozzle into your rectum and empty the contents of the bottle.

10. Take the nozzle out of your rectum. Roll over on your stomach. Stay in this position for 5 minutes.

11. To discard the enema bottle, remove the plastic bag from your hand by pulling it over the bottle.



12. Choose a comfortable position to go to sleep. Try to keep the enema in as long as possible, preferably the whole night.

Note: After preparation ENTOCORD 0,02 mg/ml enema is intended for immediate use.