

Entocort®

Budesonide 3 mg capsules

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Entocort**. It does not contain all the information that is known about **Entocort**. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Entocort** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Entocort is used for

Entocort is used to treat Crohn's disease. It can be used to treat acute attacks.

Crohn's disease is an inflammatory disease of the bowel. It mainly affects the small bowel and the first part of the large bowel and causes symptoms such as stomach pain, diarrhoea and fever.

Entocort contains budesonide. It belongs to the group of medicines called corticosteroids, which are used to help reduce inflammation in many parts of the body. **Entocort** capsules are designed to release their contents gradually in the last part of the small bowel (the ileum) and the first part of the large bowel. Hence the name **Entocort** CIR – 'controlled ileal release'. Entocort capsules reduce inflammation in the small bowel and also in the first part of the large bowel.

Your doctor will have explained why you are being treated with **Entocort** and told you what dose to take. **Follow your directions given to you by your doctor carefully.** They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Entocort is not addictive.

Entocort is only available with a doctor's prescription.

Before you use Entocort

When you must not take it

Do not take **Entocort** if you have an allergy to:

- any medicine containing budesonide
- any ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body.

Do not use Entocort if you are pregnant, think you might be pregnant or are breastfeeding unless your doctor says to do so. Ask your doctor about the risks and benefits involved.

There is very limited experience with **Entocort** capsules in pregnant or breastfeeding women.

Do not give Entocort to children. There is only limited information available about the use of **Entocort** in children.

Do not use after the use by (expiry date) printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use Entocort if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

Before you start to use it

You must tell your doctor if you have any allergies to any other medicines, foods preservatives or dyes.

Tell your Doctor if you have or have had any medical condition, especially the following:

- any recent infection (including chicken pox and measles)
- tuberculosis
- diabetes
- liver disease
- stomach ulcers
- brittle bones (osteoporosis)
- high blood pressure
- eye problems (such as glaucoma or cataracts)

It may not be safe for you to take **Entocort** if you have any of these conditions.

Tell your doctor if you have NOT had chicken pox or measles. These diseases may be more serious if you get them while taking **Entocort**. Your doctor may want to vaccinate you for them before you start on **Entocort**.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and **Entocort** may interfere with each other. These include:

- other corticosteroid medicines such as tablets, asthma inhalers, nasal sprays, eye/nose drops
- medicines used to treat fungal infections (eg ketoconazole)
- cimetidine, a medicine used to treat reflux and stomach ulcers
- Some medicines may increase the effects of Entocort Capsules and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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

These medicines may be affected by **Entocort** or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **Entocort**.

How to use Entocort

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

How much to take

The usual dose of **Entocort** is 3 capsules taken once daily in the morning, before breakfast.

Swallow Entocort capsules whole with a glass of water. Do not crush or chew the capsules. If the granules are chewed or crushed they won't work properly. Always eat some food after you take **Entocort**.

How long to take it

A treatment course is usually 8 weeks.

It may take 2-4 weeks to get the full effect from **Entocort**. Do not forget to take it even if you feel better. **Treatment with Entocort must not be stopped suddenly.** The dose needs to be reduced over the last 2-4 weeks. **Follow your doctor's directions carefully.** They may differ from the information contained in this leaflet.

If you forget to take it

If you forget to take an occasional dose of **Entocort** capsules it is not necessary to make up for the dose you missed. Just take the next dose as usual. **Don't double the dose.** If you have trouble remembering when you take your medicine, ask your pharmacist or doctor for some hints.

While you are using Entocort

Things you must do

Take Entocort exactly as your doctor has prescribed.

If you have not had chicken pox or measles, avoid close contact with anyone who has these diseases while you are taking **Entocort**. Tell your doctor straight away if you think that you have been exposed to chicken pox or measles.

Tell your doctor if you have an infection while you are taking Entocort. It may not be safe for you to continue taking **Entocort** if you have an infection.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking **Entocort**. Tell any other doctors, dentists and pharmacists who are treating you that you are taking **Entocort**.

If you become pregnant while using **Entocort**, tell your doctor or pharmacist immediately.

Things you must not do

Do not take Entocort with grapefruit or grapefruit juice. Grapefruit juice, but not other fruit juices, may increase the effect of **Entocort**. This may increase the chance of getting unwanted side effects.

Do not stop taking Entocort unless your doctor tells you to. You need to reduce the dose gradually before stopping. Your doctor will tell you how to do this.

Do not use **Entocort** to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

Things to be careful of

Be careful when drinking alcohol while you are using Entocort.

Tell your doctor if you have an infection while you are taking **Entocort**. It may not be safe for you to continue taking **Entocort** if you have an infection.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

Overdose

Telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre Ph: 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Entocort, even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Entocort. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- indigestion, flatulence
- rapid heart rate or palpitations
- swelling / rounding of the face
- muscle cramps
- tiredness
- trouble sleeping
- tremor, feeling nervous
- mood swings
- depression, anxiety or aggression
- shaking, muscle spasms or twitching
- menstrual problems
- blurred vision
- skin rash, itchiness or discolouration
- blurred vision or other visual disturbance

These side effects are usually mild.

If your medicine has been changed from 'cortisone' capsules (eg. prednisolone) to Entocort capsules, you may notice symptoms such as rash, or pain in muscles and joints. If this happens or you get headaches, feel sick, vomit, or feel tired please contact your doctor.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe rash

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything else that is making you feel unwell. Some people may get other side effects while taking Entocort.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using Entocort.

After using Entocort

Storage

Keep your capsules in the bottle until it is time to take them. Replace the cap firmly after use. If you take **Entocort** out of the bottle it will not keep well. **Keep the capsules in a cool dry place where the temperature stays below 30°C. Do not store Entocort or any other medicine in the bathroom or near a sink.** Heat and dampness can destroy some medicines.

Keep Entocort where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave Entocort in the car on hot days.

Disposal

Ask your pharmacist what to do with any capsules you have left over if your doctor tells you to stop taking them, or you find that they have expired.

Product description

What Entocort looks like

Entocort is a hard gelatine capsule, with an opaque, light grey body and an opaque, pink cap. It is printed with CIR 3 mg, and comes in packs of 100.

Ingredients

Each **Entocort** capsule contains 3 mg of micronised budesonide as the active ingredient, plus:

- ethylcellulose
- acetyltributyl citrate
- methacrylic acid copolymer
- triethylcitrate (E1505)
- antifoam M
- polysorbate 80 (E433)
- talc [E553b]
- sucrose

Each capsule is made from gelatine (E441), with colouring agents titanium dioxide (E171) and iron oxide (E172).

Marketed by:

Made in Sweden.
Packed by AstraZeneca
Pharmaceutical Co., Ltd.,
Wuxi, Jiangsu, China for:

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11 June 2021