

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using ENTOCORT?

ENTOCORT contains the active ingredient budesonide. ENTOCORT is used to treat Crohn's disease. It can be used to treat acute attacks.

For more information, see Section [1. Why am I using ENTOCORT?](#) in the full CMI.

### 2. What should I know before I use ENTOCORT?

Do not use if you have ever had an allergic reaction to budesonide or any of the ingredients listed at the end of the CMI.

Do not take ENTOCORT if you have an infection.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ENTOCORT?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ENTOCORT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ENTOCORT?

- The usual dose is 3 capsules taken once daily.
- ENTOCORT should be taken in the morning, before breakfast.

More instructions can be found in Section [4. How do I use ENTOCORT?](#) in the full CMI.

### 5. What should I know while using ENTOCORT?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking ENTOCORT.</li><li>• Tell your doctor straight away if you think that you have been exposed to chicken pox or measles or have an infection while taking ENTOCORT. It may not be safe for you to continue taking ENTOCORT if you have an infection.</li><li>• Tell your doctor straight away become pregnant.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not eat grapefruit or drink grapefruit juice while you are taking ENTOCORT. Grapefruit juice, but not other fruit juices, can affect ENTOCORT levels in the body.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store it in a cool dry place where the temperature stays below 30°C away from moisture, heat or sunlight.</li></ul>

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

### 6. Are there any side effects?

Less serious side effects may include flatulence, being or feeling sick, pain or burning sensation in your stomach (indigestion), rapid heart rate or palpitations, headache, dizziness, swelling or rounding of the face, acne, weight gain and bruising more easily, back pain, muscle cramps or muscle weakness, increased sweating, tiredness, trouble sleeping, tremor, feeling nervous, mood swings, depression, anxiety or aggression, shaking, muscle spasms or twitching, menstrual problems, skin rash, itchiness or discolouration.

Serious side effects may include hypersensitivity (allergic) reactions such as rash, itching, hives on the skin, swollen face, tongue, throat or other parts of the body, shortness of breath, wheezing, blurred vision or other visual disturbances; and/or signs or symptoms of an infection such as having a fever.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ENTOCORT®

Active ingredient: *budesonide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ENTOCORT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ENTOCORT.**

Where to find information in this leaflet:

- [1. Why am I using ENTOCORT?](#)
- [2. What should I know before I use ENTOCORT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ENTOCORT?](#)
- [5. What should I know while using ENTOCORT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using ENTOCORT?

ENTOCORT contains the active ingredient **budesonide**. ENTOCORT belongs to the group of medicines called corticosteroids, which are used to help reduce inflammation in many parts of the body.

ENTOCORT is used to treat **Crohn's disease in adults**. 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.

### 2. What should I know before I use ENTOCORT?

#### Warnings

**Do not use ENTOCORT if:**

- you are allergic to budesonide, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- you have an infection or have had a recent infection (including chicken pox and measles)

**Check with your doctor if you:**

- have any other medical conditions including:
  - tuberculosis (infection of the lungs)
  - diabetes (high blood sugar)
  - liver problems
  - stomach ulcers
  - brittle bones (osteoporosis)
  - high blood pressure (hypertension)
  - eye problems (such as glaucoma or cataracts)
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

**Do not take 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.

It is not known if it is safe for you to take ENTOCORT while you are pregnant. It may affect your baby.

Like most corticosteroid medicines, it is recommended that you do not breastfeed while taking ENTOCORT as it is found in breast milk.

#### Children

**Do not give ENTOCORT to children.** There is no information available on its use in children.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ENTOCORT may interfere with each other, and these include:

- other corticosteroid medicines such as prednisolone or dexamethasone
- medicines used to treat fungal infections (e.g. ketoconazole)
- cimetidine, a medicine used to treat reflux and stomach ulcers
- medicines to treat human immunodeficiency virus (HIV) such as cobicistat

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ENTOCORT.**

### 4. How do I use ENTOCORT?

#### How much to take

- The usual dose is 3 capsules taken once daily.
- Continue taking ENTOCORT for as long as your doctor tells you. A treatment course should normally not exceed 12 weeks.
- ENTOCORT should not be stopped suddenly. The dose should be reduced gradually over the last 2 to 4 weeks.

## When to take ENTOCORT

- ENTOCORT should be taken in the morning, before breakfast.

## How to take ENTOCORT

- Swallow ENTOCORT capsules whole with a glass of water.

**Do not crush or chew the capsules.** If the granules are chewed or crushed they will not work properly.

## If you forget to use ENTOCORT

ENTOCORT should be used regularly at the same time each day.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

## If you use too much ENTOCORT

If you think that you have used too much ENTOCORT, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using ENTOCORT?

### Things you should do

**If you have not had chicken pox or measles, avoid close contact with anyone who has these diseases while you are taking ENTOCORT.**

**Call your doctor straight away if you:**

- think that you have been exposed to chicken pox or measles
- have an infection while taking ENTOCORT. It may not be safe for you to continue taking ENTOCORT if you have an infection.
- become pregnant

Remind any doctor, dentist, pharmacist or dentist you visit that you are using ENTOCORT.

### Things you should not do

- Do not eat grapefruit or drink grapefruit juice while you are taking ENTOCORT. Grapefruit juice, but not other fruit juices, can affect ENTOCORT levels in the body. This may increase the chance of getting unwanted side effects.
- Do not stop using this medicine suddenly. If you need to stop taking ENTOCORT, your doctor will tell you how to do it gradually.

## Other things you should know

- Your doctor may do tests to check how the adrenal glands are working while you are taking ENTOCORT. If you have changed from or used high doses of oral corticosteroids over a long period of time, your adrenal glands may be affected.
- Your doctor may tell you to take additional oral corticosteroids during periods of stress such as trauma and surgery.

## Driving or using machines

This medicine is not expected to affect your ability to drive a car or operate machinery.

## Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 30°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Digestive system:</b> <ul style="list-style-type: none"><li>• flatulence</li><li>• feeling or being sick</li><li>• stomach (abdominal) pain or burning (indigestion)</li></ul> <b>General body:</b> <ul style="list-style-type: none"><li>• headache</li><li>• dizziness</li><li>• swelling or rounding of the face</li><li>• weight gain</li><li>• bruising more easily</li></ul> <b>Heart:</b> <ul style="list-style-type: none"><li>• rapid heart rate or palpitations</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>  <b>[Insert appropriate action]</b>

<p><b>Mental health:</b></p> <ul style="list-style-type: none"> <li>• trouble sleeping</li> <li>• feeling tired</li> <li>• tremor</li> <li>• feeling nervous</li> <li>• mood swings</li> <li>• depression, anxiety or aggression</li> </ul> <p><b>Muscles and bones:</b></p> <ul style="list-style-type: none"> <li>• muscle cramps or muscle weakness (may be due to low levels of potassium in blood)</li> <li>• shaking muscle spasms or twitching</li> <li>• back pain</li> </ul> <p><b>Reproductive:</b></p> <ul style="list-style-type: none"> <li>• menstrual problems</li> </ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"> <li>• skin rash, itchiness or discolouration</li> <li>• acne</li> <li>• increased sweating</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• may include rash, itching or hives on the skin, skin redness, swollen face, lips, eyes, tongue or throat or other parts of the body, or trouble breathing</li> </ul> <p><b>Eyes:</b></p> <ul style="list-style-type: none"> <li>• blurred vision or other visual disturbances</li> </ul> <p><b>Infection:</b></p> <ul style="list-style-type: none"> <li>• signs or symptoms of an infection such as having a fever</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What ENTOCORT contains

<b>Active ingredient (main ingredient)</b>	budesonide
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• ethylcellulose</li> <li>• tributyl acetylcitrate</li> <li>• methacrylic acid copolymer</li> <li>• triethyl citrate</li> <li>• dimeticone 1000</li> <li>• polysorbate 80</li> <li>• purified talc</li> <li>• Sugar Spheres (ARTG No. 2535)</li> </ul> <p>The capsule shell is made from:</p> <ul style="list-style-type: none"> <li>• gelatin</li> <li>• titanium dioxide</li> <li>• iron oxide black</li> <li>• iron oxide red</li> <li>• iron oxide yellow, colloidal anhydrous silica, liquid paraffin and sodium lauryl sulfate.</li> </ul> <p>The capsules are printed with:</p> <ul style="list-style-type: none"> <li>• TekPrint SW-9008 Black Ink (ARTG PI No. 2328)</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ENTOCORT looks like

ENTOCORT modified release capsules are two-piece hard gelatin capsules, size 1 with an opaque light grey body and an opaque pink cap. The cap has black print "CIR 3 mg".

ENTOCORT is supplied in bottles containing 90 capsules (AUST R 62812)

### Who supplies ENTOCORT

Chiesi Australia Pty Ltd  
 Level 7, Suite 1, 500 Bourke Street,  
 Melbourne, VIC 3000  
 Email: [medinfo.au@chiesi.com](mailto:medinfo.au@chiesi.com)  
 Website: [www.chiesi.com.au](http://www.chiesi.com.au)

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