

# CORTIMENT®

## Consumer Medicine Information (CMI) summary

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

### 1. Why am I taking CORTIMENT?

CORTIMENT is used in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where mesalazine (5-ASA) treatment is not enough or not tolerated. It contains the active ingredient budesonide, which is a corticosteroid.

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

### 2. What should I know before I take CORTIMENT?

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

**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 take CORTIMENT?](#) in the full CMI.

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

Some medicines may interfere with CORTIMENT 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 take CORTIMENT?

- Swallow the tablet whole with a glass of water. Do not chew, crush or break the tablets.
- CORTIMENT should be taken at the same time each day in the morning with or without food.

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

### 5. What should I know while taking CORTIMENT?

<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 CORTIMENT.</li><li>• <b>Call your doctor straight away if you become pregnant</b></li><li>• <b>If you are about to have any blood tests, tell your doctor that you are taking this medicine.</b></li><li>• <b>Keep all your doctor's appointments so that your progress can be checked.</b></li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking this medicine or change your dose without talking to your doctor.</li><li>• Do not give this medicine to anyone else, even if they have the same condition as you.</li><li>• <b>Do not drink grapefruit juice.</b></li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store CORTIMENT in a cool dry place where the temperature stays below 30°C</li><li>• Keep your tablets in the pack until it is time to take them.</li></ul>

For more information, see Section [5. What should I know while taking CORTIMENT?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention.

**Tell your doctor if you experience any side effects.** Rash and/or itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body and shortness of breath, wheezing or difficulty breathing may be a sign of an allergic reaction and you may require urgent medical attention in hospital. 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.

# CORTIMENT®

Active ingredient(s): [*budesonide*]

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

### 1. Why am I taking CORTIMENT?

CORTIMENT is used in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where mesalazine (5-ASA) treatment is not enough or not tolerated. It belongs to a class of medicines called corticosteroids.

CORTIMENT contains the active ingredient budesonide.

CORTIMENT is used to help reduce inflammation.

CORTIMENT is used to treat inflammation of the large intestine (colon), which is an area commonly affected in UC. The tablets release the active ingredient, budesonide, in a controlled manner along the colon.

### 2. What should I know before I take CORTIMENT?

#### Warnings

#### Do not take CORTIMENT if:

- you are allergic to budesonide, peanut oil, soy or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.

#### Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
  - infection (including viral, bacterial and/or fungal infections)
  - tuberculosis
  - high blood pressure
  - diabetes
  - osteoporosis
  - stomach ulcer
  - elevated eyeball pressure (glaucoma) or cataract
  - family history of diabetes or glaucoma
  - liver problems

- mental health problems such as depression
- scheduled to undergo surgery or are experiencing any other stresses.

- 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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

#### Chicken pox/Measles

- **Tell your doctor if you have NOT had chicken pox or measles or if you have been in contact with people with chicken pox or measles.**
- These infections may be more serious if you get them while taking CORTIMENT. Your doctor may want to vaccinate you for them before you start on CORTIMENT.

### 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 CORTIMENT may interfere with each other and affect how they work.**

**CORTIMENT may increase the effect of medicines that include:**

- medicines used to treat heart failure (e.g. cardiac glycosides such as digoxin).
- medicines used to treat high blood pressure and fluid build-up (e.g. diuretics).

**Medicines that may increase the effect of CORTIMENT include:**

- medicines used to treat fungal infections (e.g. ketoconazole or itraconazole).
- medicine used to treat HIV infections (e.g. HIV protease inhibitors).
- some medicines that contain oestrogens, such as oral contraceptives or hormone replacement therapies.

**Medicines that may reduce the effect of CORTIMENT include:**

- medicine used to treat epilepsy (e.g. carbamazepine).
- cholesterol-lowering medicines, antacids or medicines used to treat itch caused by liver problems (e.g. cholestyramine).

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

## 4. How do I take CORTIMENT?

### How much to take

- Usually, you will take one CORTIMENT 9 mg tablet daily.
- **Swallow the tablet whole with a glass of water. Do not chew, crush or break the tablets.**
- Follow the instructions provided and take CORTIMENT until your doctor tells you to stop.
- Usually, you will take this medicine daily for a maximum of eight weeks.

### When to take CORTIMENT

- CORTIMENT should be taken at the same time each day with or without food.

### If you forget to take CORTIMENT

CORTIMENT should be taken 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 take too much CORTIMENT

If you think that you have taken too much CORTIMENT, 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 taking CORTIMENT?

### Things you should do

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

- become pregnant.

Remind any doctor, dentist or pharmacist you visit that you are taking CORTIMENT.

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

**Keep all your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

### Things you should not do

- Do not stop taking this medicine or change your dose without talking to your doctor.
- Do not give this medicine to anyone else, even if they have the same condition as you.

### Consuming grapefruit

- **Do not eat grapefruit or drink grapefruit juice while you are taking CORTIMENT.**
- Grapefruit juice, but no other fruit juices, can affect budesonide levels in the body. This may increase the chances of getting unwanted side effects.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how CORTIMENT affects you.**

### Looking after your medicine

- Keep CORTIMENT in a cool dry place where the temperature stays below 30°C.
- Keep your tablets in the pack until it is time to take them.

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

Store it in a cool dry place 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 windowsills.

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

### When to discard your medicine

Do not take this medicine after the expiry date.

### Getting rid of any unwanted medicine

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

Do not take 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.

### Side effects

Side effects	What to do
Common side effects (affect more than 1 in 100 users):	<b>Speak to your doctor if you</b>

Side effects	What to do
<ul style="list-style-type: none"> <li>nausea (feeling sick) or headache</li> <li>dry mouth</li> <li>bloating, stomach pain or discomfort</li> <li>indigestion</li> <li>reflux or heartburn</li> <li>Cushing-like symptoms such as round face, acne, weight gain and a tendency to bruise easily</li> <li>muscle aches and pain</li> <li>muscle cramps</li> <li>muscle weakness or fatigue, thirst or a tingling sensation</li> <li>heavy or irregular menstruation in women</li> <li>skin rash or itchiness</li> <li>acne.</li> </ul> <p>Uncommon side effects (affect less than 1 in 100 users):</p> <ul style="list-style-type: none"> <li>high temperature, sore throat, runny nose, cough and chills</li> <li>flatulence</li> <li>dizziness</li> <li>swelling of the hands, ankles or feet</li> <li>back pain</li> <li>tremor</li> <li>muscle spasm</li> <li>reduced immune response to infection</li> <li>fast or irregular heart beats</li> <li>change in behaviour such as nervousness, trouble sleeping, mood swings or depression.</li> </ul> <p>Rare side effects (affect less than 1 in 1000 users):</p> <ul style="list-style-type: none"> <li>blurred vision</li> <li>aggression.</li> </ul>	<p><b>have any of these side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>rash, itching or hives on the skin</li> <li>swelling of the face, lips, tongue or other parts of the body</li> <li>shortness of breath, wheezing or difficulty breathing.</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>

### Discuss with your doctor if you have experienced symptoms of psychological problems while on CORTIMENT.

Psychological problems may develop when taking corticosteroids like CORTIMENT. In very rare cases, psychological problems have developed when high doses of corticosteroids were taken for a long time. This is particularly important if you are depressed and may be thinking about committing suicide.

### Medicines like CORTIMENT tablets (corticosteroids) may affect the normal production of steroid hormones in your body. The effects include:

- increased bone fragility (osteoporosis)
- glaucoma (high eyeball pressure)
- effect on the adrenal gland (small gland near the kidney).

**Your doctor may also tell you to take additional oral corticosteroids during periods of stress such as trauma and surgery.**

**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 CORTIMENT contains

<b>Active ingredient (main ingredient)</b>	budesonide
<b>Other ingredients (inactive ingredients)</b>	stearic acid [E570] lecithin (of soya origin) [E322] microcrystalline cellulose [E460] hypromellose [E463] lactose monohydrate silicon dioxide [E551] magnesium stearate [E470b].  methacrylic acid copolymer talc - purified [E553b] titanium dioxide [E171]

	triethyl citrate
<b>Potential allergens</b>	Peanut oil Soy

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

### **What CORTIMENT looks like**

CORTIMENT is a white to off-white, round, double convex tablet with a film coating, and 'MX9' engraved on one side of the tablet. The tablets are supplied in blister packs with aluminum press-through foil in a cardboard carton.

(AUST R 225849).

### **Who distributes CORTIMENT**

CORTIMENT is distributed in Australia by:

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street, Pymble, NSW 2073

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