

CELEBREX RELIEF®

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 pharmacist or doctor.

1. Why am I taking CELEBREX RELIEF?

CELEBREX RELIEF contains the active ingredient celecoxib. CELEBREX RELIEF is used for the short-term treatment of acute pain in adults with muscle and joint injuries including ankle strain or back pain and for short-term treatment of period pain in adults. For more information, see Section [1. Why am I taking CELEBREX RELIEF?](#) in the full CMI.

2. What should I know before I take CELEBREX RELIEF?

Do not use if you have ever had an allergic reaction to celecoxib or any of the ingredients listed at the end of the CMI. **Talk to your pharmacist or 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 CELEBREX RELIEF?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CELEBREX RELIEF 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 CELEBREX RELIEF?

Follow all directions given to you by your doctor and pharmacist carefully. More instructions can be found in Section [4. How do I take CELEBREX RELIEF?](#) in the full CMI.

5. What should I know while taking CELEBREX RELIEF?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist, pharmacist, surgeon or anaesthetist you visit that you are taking CELEBREX RELIEF.Talk to your pharmacist or doctor if your symptoms do not improve.Tell your doctor immediately if you become pregnant.Tell your doctor immediately if you develop any skin rash (e.g. hives, spots).
Things you should not do	<ul style="list-style-type: none">Do not exceed the dose recommended by your pharmacist or doctor.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how CELEBREX RELIEF affects you.
Looking after your medicine	<ul style="list-style-type: none">Store below 25°C.Keep your capsules in their blister pack until it is time to take them.

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

6. Are there any side effects?

Common side effects are stomach pain, diarrhoea, indigestion, wind, swollen hands, ankles and feet, unexplained weight gain, dizziness, sore throat, runny nose, sinusitis, upper respiratory tract infection. **Serious side effects** are skin rash, hives, raised red, itchy spots, blistering & bleeding in the lips, eyes, mouth, nose and genitals, swelling, blistering or peeling skin, fever, chills, headache, sore throat, diarrhoea, aching joints & muscles, wheezing, swelling of the face, lip, mouth, tongue or throat, difficulty in swallowing or breathing, collapse, fainting, shortness of breath, tiredness, irregular heartbeat, chest pain, swollen or sore leg veins, severe stomach or throat pain, vomiting blood, black sticky bowel motions, bleeding or bruising more than usual, reddish or purple blotches under the skin, nausea, tiredness, itchiness, flu-like symptoms, yellowing of the skin or eyes (jaundice), short of breath, looking pale, loss or deterioration of hearing, confusion, eye redness, irritation or watering, experience sensations with any of the senses (sight, sound, touch, taste or feel) which may not be real, severe or persistent headache, fever, stiff neck, sensitivity to light and vomiting, sudden severe headache, loss of consciousness, sudden tingling, numbness or paralysis on one side the face, arm, leg or body, difficulty speaking, understanding, reading or writing, loss of coordination or balance. 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.

CELEBREX RELIEF®

Active ingredient: *celecoxib*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking CELEBREX RELIEF. **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 CELEBREX RELIEF.**

Where to find information in this leaflet:

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

1. Why am I taking CELEBREX RELIEF?

CELEBREX RELIEF contains the active ingredient celecoxib. CELEBREX RELIEF belongs to a group of medicines called Coxibs which are used to relieve pain and inflammation in a number of conditions.

CELEBREX RELIEF is used for short-term pain relief in conditions such as:

- muscle and joint injuries, including back pain and ankle sprain
- menstrual cramps or period pain.

Although CELEBREX RELIEF can relieve the symptoms of pain and inflammation, it will not cure your condition.

Your doctor, however, may have prescribed CELEBREX RELIEF for another purpose.

CELEBREX RELIEF is not recommended for use in children or adolescents under 18 years of age.

2. What should I know before I take CELEBREX RELIEF?

Warnings

Do not take CELEBREX RELIEF if:

- You have had an attack of asthma, hives, itching, skin rash or a runny nose after taking aspirin, or taking Non-Steroidal Anti-Inflammatory Drugs (NSAIDs, medicines used to treat pain and inflammation), including other Coxib medicines.
 - o Many medicines used to treat headache, period pain and other aches and pains contain aspirin or an NSAID.
 - o If you are allergic to aspirin, NSAIDs, or other Coxib medicines and take CELEBREX RELIEF, these symptoms may be severe.

- You are allergic to celecoxib, any of the ingredients listed at the end of this leaflet or sulfonamides, a group of medicines which include, for example, certain antibiotics (if you are not sure if you are taking one of these medicines ask your pharmacist). If you are allergic to sulfonamides or any of the capsule ingredients and take CELEBREX RELIEF, these symptoms may be severe. Some of the symptoms of an allergic reaction may include:

- o asthma, wheezing or shortness of breath
- o swelling of the face, lips, or tongue which may cause difficulty in swallowing or breathing
- o hives, itching or skin rash
- o fainting.

Always check the ingredients to make sure you can use this medicine.

- You suffer from chest pains or angina and they occur even when you are resting and are becoming more frequent, severe, or lasting longer than usual
- You have or have had problems with your blood circulation
- You have severe heart or blood vessel disease affecting the circulation in your brain or limbs
- You have congestive heart failure
- You have had a heart attack, a "mini" stroke or stroke or blood vessel disease affecting circulation of blood to your brain or limbs, especially in the last 3 months
- You have an ulcer or gastric bleeding
- You have problems with your kidney function
- You have liver problems
- Trying to become pregnant, or during the first 6 months of pregnancy, except on a doctor's advice. Do not use at all during the last 3 months of pregnancy.
- You are undergoing cardiac surgery called coronary artery bypass graft (CABG)
- You are aged 65 years or over, unless advised by a doctor.

Check with your pharmacist or doctor if you:

- have Irritable Bowel Disease
- have any other medical conditions:
 - o you currently have diabetes
 - o high blood pressure, heart failure or history of heart problems
 - o stroke or a history of stroke
 - o high cholesterol levels
 - o problems with the circulation on your limbs
 - o you have any allergies to any other medicines, any other substances such as foods, dyes or preservatives.
 - o you are breast-feeding or intend to breast-feed
 - o liver or kidney problems

- o asthma, hives, itching, skin rash or a runny nose
 - o fluid retention or other medical conditions that can cause fluid retention
 - o peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before
 - o vomiting blood or material that looks like coffee grounds
 - o bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
 - o bowel problems, such as ulcerative colitis.
 - o you are taking CELEBREX RELIEF together with any medicines used to treat high blood pressure and some other heart problems such as ACE inhibitors, angiotensin receptor antagonists, beta blockers and diuretics (also called fluid or water tablets). When taken together these medicines can cause kidney problems.
 - o you drink large amounts of alcohol
 - o you are a smoker
 - o you currently have an infection. If you are given CELEBREX RELIEF while you have an infection, it may hide some of the signs of an infection.
- take any medicines for any other condition.

Do not give CELEBREX RELIEF to a child or adolescent under the age of 18 years. Safety and effectiveness in children and adolescents younger than 18 years have not been established.

This medicine may not be suitable for you if any of the conditions above apply to you.

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

CELEBREX RELIEF use is not recommended in pregnancy unless your doctor considers it essential. If you are taking this medicine while pregnant, you may need to be closely monitored by your doctor.

Do not take CELEBREX RELIEF if you are in the last 3 months of your pregnancy.

NSAIDs, which are related medicines, have been associated with reversible infertility in some women. Use of NSAIDs in early pregnancy can increase the risk of spontaneous abortion.

CELEBREX RELIEF may affect your developing baby if taken during pregnancy. Particular caution should be exerted from the twentieth week of the pregnancy.

Discuss any questions you may have with your pharmacist or doctor. Your doctor can discuss with you the risks and benefits involved.

Talk to your pharmacist or doctor if you are breastfeeding or intend to breastfeed. Small amounts of celecoxib passes into breast milk, therefore taking this medicine during breast-feeding should be discussed with your doctor.

3. What if I am taking other medicines?

Tell your pharmacist or doctor 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 may interfere with CELEBREX RELIEF and affect how it works. These include:

- any medicines used to treat high blood pressure and some other heart problems such as ACE inhibitors, angiotensin receptor antagonists, beta blockers or diuretics (also called fluid or water tablets)
- digoxin, a medicine used to treat abnormal heart beats and some other heart problems
- warfarin or similar medicines including Eliquis (apixaban), Xarelto (rivaroxaban) or Pradaxa (dabigatran), medicines used to stop blood clots
- aspirin or salicylates, medicines used to treat pain
- corticosteroids such as prednisolone, medicines that are used to reduce inflammation
- certain medicines used to treat pain and inflammation called non-steroidal anti-inflammatory drugs (NSAIDs)
- antacids, medicines used to treat indigestion
- dextromethorphan, a medicine used to treat dry coughs
- some medicines used to treat diabetes
- methotrexate, a medicine used to treat arthritis and some cancers
- glucocorticoids, medicine used to treat arthritis.
- ciclosporin, a medicine used to suppress the immune system
- lithium, a medicine used to treat some types of depression
- carbamazepine, an antiepileptic agent
- fluconazole, an antifungal agent
- rifampicin, an antibiotic medicine used to treat bacterial infections

These medicines may be affected by CELEBREX RELIEF or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

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

4. How do I take CELEBREX RELIEF?

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your pharmacist or doctor for help.

How much to take

- Muscle and joint injuries
 - 2 capsules as a single dose on the first day, then 1 capsule once or twice daily on subsequent days as required.
 - You may take CELEBREX RELIEF for up to 5 days.
- Menstrual cramps or period pain
 - 2 capsules as a single dose or divided on the first day, then 1 capsule once daily on subsequent days.
 - You may take an additional capsule on any given day, if needed.
 - You may take CELEBREX RELIEF for up to 5 days.

How to take it

Swallow the capsules whole with a full glass of water. CELEBREX RELIEF can be taken with or without food.

When to take CELEBREX RELIEF

- Take your medicine at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of CELEBREX RELIEF.

How long to take it

- Do not use for more than 5 days unless advised by your doctor.

If you take too much CELEBREX RELIEF

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

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

If you take too much CELEBREX RELIEF, you may feel tired, drowsy, sick, vomit, and have stomach pain. You may also have difficulty breathing and feel faint.

5. What should I know while taking CELEBREX RELIEF?

Things you should do

If you are about to be started on any new medicine, remind your pharmacist and doctor that you are taking CELEBREX RELIEF.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking CELEBREX RELIEF. It may affect other medicines used during surgery.

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

Talk to your pharmacist or doctor if your symptoms do not improve. Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Call your doctor straight away if you:

- **develop any skin rash (e.g. hives, spots) while being treated with CELEBREX RELIEF.** The onset of these events, if they occur, can occur at any time, but most often occur in the first month of treatment.

Things you should not do

- Do not take CELEBREX RELIEF to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CELEBREX RELIEF affects you.

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

Drinking alcohol

Tell your pharmacist or doctor if you drink alcohol.

Looking after your medicine

- Keep your capsules in a cool dry place where the temperature stays below 25°C.
- Keep your capsules in the pack until it is time to take them.
- If you take the capsules out of the pack they may not keep well.

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 window sills.

Keep it 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.

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?

Check with your doctor or pharmacist as soon as possible if you have any problems while taking CELEBREX RELIEF, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Do not be alarmed by this list of possible side effects. You may not get any of them.

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.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> stomach pain, diarrhoea, indigestion, wind swollen hands, ankles and feet, unexplained weight gain dizziness sore throat, runny nose, sinusitis, upper respiratory tract infection. 	<p>Speak to your pharmacist or doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

The below list includes serious side effects that may require urgent medical attention.

Serious side effects	What to do
<ul style="list-style-type: none"> skin rash, including hives, raised red, itchy spots blistering and bleeding in the lips, eyes, mouth, nose and genitals swelling, blistering or peeling of the skin, which may be accompanied by fever, chills, headache, sore throat, diarrhoea, aching joints and muscles other signs of allergic reaction such as wheezing, swelling of the face, lip, mouth, tongue or throat which may cause difficulty in swallowing or breathing collapse or fainting, shortness of breath or tiredness, irregular heartbeat, chest pain, swollen or sore leg veins severe stomach or throat pain, vomiting blood or black sticky bowel motions bleeding or bruising more than usual, reddish or purple blotches under the skin nausea, lethargy, itchiness, flu-like symptoms or yellowing of the skin or eyes (jaundice) 	<p>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.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> signs of anaemia such as tiredness, being short of breath and looking pale loss or deterioration of hearing confusion redness, irritation or watering of the eye(s) experience sensations with any of the senses (sight, sound, touch, taste or feel) which may not be real severe or persistent headache, fever, stiff neck, sensitivity to light and vomiting sudden severe headache, loss of consciousness, sudden tingling, numbness or paralysis on one side the face, arm, leg or body, difficulty speaking, understanding, reading or writing, loss of coordination or balance. 	<p>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.</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. 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

What CELEBEX RELIEF contains

Active ingredient (main ingredient)	Celecoxib 200 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> lactose monohydrate sodium lauryl sulfate povidone croscarmellose sodium colloidal anhydrous silica magnesium stearate <p>The capsule shells also contain the following inactive ingredients:</p> <ul style="list-style-type: none"> gelatin purified water titanium dioxide sodium lauryl sulfate yellow iron oxide

	<ul style="list-style-type: none"> • red iron oxide • black iron oxide • black imprinting ink S-1-17823 (ID 12108)
Potential allergens	Contains lactose, phenylalanine and trace quantities of sulfites.

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

What CELEBREX RELIEF looks like

CELEBREX RELIEF 200 mg: A light brown opaque cap and white opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with "MYLAN" over "CE 200" in black ink on the cap and body. The 200 mg capsules come in blister packs of 10 (AUST R 463627).

Who distributes CELEBREX RELIEF

Viatrix Pty Ltd
 Level 1, 30 The Bond
 30-34 Hickson Road
 Millers Point NSW 2000
www.viatrix.com.au
 Phone: 1800 274 276

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