

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 CELAXIB?

CELAXIB contains the active ingredient celecoxib. CELAXIB is used to relieve pain and inflammation in a number of conditions such as osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, menstrual cramps or period pain and muscle and joint injuries. For more information, see Section [1. Why am I taking CELAXIB?](#) in the full CMI.

2. What should I know before I take CELAXIB?

Do not take 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 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 CELAXIB?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CELAXIB 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 CELAXIB?

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

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

5. What should I know while taking CELAXIB?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist, surgeon or anaesthetist you visit that you are taking CELAXIB.• Tell your doctor immediately if you become pregnant.• Contact your doctor immediately if you develop any skin rash (e.g. hives, spots) while being treated with CELAXIB. |
| Things you should not do | <ul style="list-style-type: none">• Do not give CELAXIB to anyone else, even if they have the same symptoms or condition as you.• Do not take CELAXIB to treat any other complaints unless your doctor tells you to. |
| Driving or using machines | <ul style="list-style-type: none">• CELAXIB is not expected to affect your ability to drive a car or operate machinery. |
| Drinking alcohol | <ul style="list-style-type: none">• Tell your doctor if you drink alcohol. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep CELAXIB in a cool, dry place where the temperature stays at or 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 CELAXIB?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor if you notice any of the following: Stomach pain, diarrhoea, indigestion, wind, swollen hands, ankles and feet, unexplained weight gain, dizziness, sore throat, runny nose, sinusitis and upper respiratory tract infection.

Tell your doctor immediately or go to the Accident and Emergency at your nearest hospital if you notice any of the following: Signs of allergic reaction such as wheezing, swelling of the face, lips, mouth, tongue or throat, difficulty in swallowing or breathing; fever, flu-like symptoms, skin rash, hives, raised red, itchy spots, blistering and bleeding in the lips, eyes, mouth, nose and genitals, swelling, peeling skin, diarrhoea, aching joints and muscles; collapse or fainting, shortness of breath, 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; nausea, yellowing of the skin or eyes (jaundice); severe or persistent headache, 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.

This is not a complete list of possible side effects. 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.

CELAXIB®

Active ingredient: *celecoxib*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking CELAXIB. **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 CELAXIB.**

Where to find information in this leaflet:

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

1. Why am I taking CELAXIB?

CELAXIB contains the active ingredient **celecoxib**. CELAXIB belongs to a group of medicines called coxibs which are used to relieve pain and inflammation in a number of conditions.

CELAXIB is used to relieve the symptoms of joint pain, tenderness, swelling and stiffness in:

- osteoarthritis
- rheumatoid arthritis
- ankylosing spondylitis, a chronic inflammatory rheumatic disorder that primarily affects, but is not limited to, the spine.

CELAXIB also provides short-term pain relief in conditions such as:

- menstrual cramps or period pain
- after surgery
- muscle and joint injuries.

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

Your doctor, however, may have prescribed CELAXIB for another purpose.

Ask your doctor if you have any questions about why CELAXIB has been prescribed for you.

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

2. What should I know before I take CELAXIB?

Warnings

Do not take CELAXIB if:

- you have had an asthma attack, hives, itching, skin rash or a runny nose after taking aspirin or Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These are medicines that are used to treat pain and

inflammation and include other Coxib medicines. CELAXIB should not be used together with other NSAIDs.

- 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 CELAXIB, 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 CELAXIB, these symptoms may be severe.

Symptoms of an allergic reaction to these medicines 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 take 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 history of a heart attack, a "mini" stroke, 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 severe liver problems

Your doctor will decide if your condition is too severe to take this medicine.

- you are undergoing cardiac surgery called coronary artery bypass graft (CABG)
- the expiry date printed on the packaging has passed, even though the capsules may look alright.

If you take this medicine after the expiry date has passed, it may not work as well.

- the packaging is torn or shows signs of tampering.

If you are not sure if you should be taking CELAXIB, talk to your doctor.

Check with your doctor or pharmacist if you:

- have Irritable Bowel Syndrome (IBS)
- have any other medical conditions:
 - diabetes
 - high blood pressure, heart failure or have a history of heart problems
 - stroke or a history of stroke
 - high cholesterol levels
 - problems with the circulation in your limbs
 - have any allergies to any other medicines or any other substances such as foods, preservatives or dyes
 - liver or kidney problems
 - asthma, hives, itching, skin rash or a runny nose
 - fluid retention or other medical conditions that can cause fluid retention
 - peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one or have had peptic ulcers before
 - vomiting blood or material that looks like coffee grounds
 - bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
 - bowel problems such as ulcerative colitis
 - are taking CELAXIB 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.
 - drink alcohol
 - are a smoker
 - currently have an infection.
 - If you are given CELAXIB while you have an infection, it may hide some of the signs of an infection.

If you have not told your doctor or pharmacist about these things, tell them before you start taking CELAXIB.

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.

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.

There is no information on the use of CELAXIB during pregnancy.

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

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

Discuss any questions you may have with your doctor.

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

Small amounts of celecoxib passes into breast milk, therefore taking CELAXIB during breast-feeding should be discussed with your doctor.

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 may interfere with CELAXIB 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 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, a medicine used to treat arthritis
- ciclosporin, a medicine used to suppress the immune system
- lithium, a medicine used to treat some types of depression
- fluconazole, an antifungal agent
- rifampicin, an antibiotic medicine used to treat bacterial infections
- carbamazepine, an antiepileptic agent

Your doctor may need to adjust the dosage of these medicines, or provide additional advice if you are also taking CELAXIB.

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

4. How do I take CELAXIB?

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

They may differ from the information contained in this leaflet.

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

How much to take

Osteoarthritis

200 mg once daily or 100 mg twice daily.

Rheumatoid arthritis

100 mg twice daily.

Your doctor may increase the dose to 200 mg twice a day for a short period of time if you have a flare up.

Ankylosing spondylitis

100 mg twice daily or 200 mg once daily.

Menstrual cramps or period pain

400 mg as a single dose on the first day and 200 mg twice daily on following days. You may take CELAXIB for up to 5 days.

Muscle and joint injuries or after surgery

400 mg as a first dose followed by 200 mg once or twice daily as required. You may take CELAXIB for up to 5 days.

How to take it

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

When to take CELAXIB

- 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 CELAXIB

How long to take it

- Depending on your condition, you may need CELAXIB for a few days or for longer periods.
- CELAXIB will not cure your condition but should help control pain, swelling and stiffness.
- **Keep taking CELAXIB for as long as your doctor advises.**
- **Do not exceed the dose recommended by your doctor.**
- Your risk of developing heart or blood vessel diseases (e.g., heart attack) may increase with dose and duration of use even if you don't have a history of heart or blood vessel disease.
- **If you need to take CELAXIB for a long time see your doctor for regular check-ups so that they can monitor your condition and treatment.**

If you forget to take CELAXIB

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

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

Otherwise, take it as soon as you remember, then go back to taking your capsules as you would normally.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much CELAXIB

If you think that you or anyone else may have taken too much CELAXIB, urgent medical attention may be needed.

Symptoms of an overdose may include:

- feeling tired/ drowsiness
- feeling sick
- vomiting
- stomach pain
- difficulty breathing
- feeling faint

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.

5. What should I know while taking CELAXIB?

Things you should do

- **If you become pregnant while taking CELAXIB, tell your doctor immediately.**
- If you are about to start any new medicines, tell your doctor and pharmacist that you are taking CELAXIB.
- **Tell all doctors, dentists and pharmacists who are treating you that you are taking CELAXIB.**
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking CELAXIB.
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.

Call your doctor straight away if you:

- **develop any skin rash (e.g. hives, spots) while being treated with CELAXIB.**

The onset of these events, can occur at any time, but most often occur in the first month of treatment.

Things you should not do

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

Driving or using machines

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

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store below 25°C
- Keep your capsules in their blister pack until it is time to take them. If you take the capsules out of their container, 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 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?

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

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.

Do not be alarmed by this list of possible side effects.

You may not get any of them.

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. | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| 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• muscles weakness• other signs of allergic reaction such as wheezing, swelling of the face, lips, 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)• 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. | 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. You may need urgent medical attention. |

Not all of these side effects have been reported with CELAXIB but have been seen with similar medicines.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

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

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

What CELAXIB contains

| | |
|---|---|
| Active ingredient (main ingredient) | celecoxib 100 mg or 200 mg |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• lactose monohydrate• sodium lauryl sulfate• povidone• croscarmellose sodium• silica - colloidal anhydrous• magnesium stearate• gelatin• titanium dioxide• indigo carmine (100 mg only)• purified water• sodium lauryl sulfate• OPACODE monogramming ink S-1-17823 BLACK (ID 12108)• Black iron oxide (200 mg only)• Red iron oxide (200 mg only)• Yellow iron oxide (200 mg only) |
| Potential allergens | Lactose, phenylalanine and trace quantities of sulfites. |

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

What CELAXIB looks like

CELAXIB 100 mg - A No. 4, blue cap/white body, opaque, hard-shell gelatin capsule filled with white to off-white powder. Axially printed with MYLAN over CE 100 in black ink (AUST R 296389).

The 100 mg capsules come in blister packs of 60.

CELAXIB 200 mg - A No. 2, light brown/white body, opaque, hard-shell gelatin capsule filled with white to off-white powder. Axially printed with MYLAN over CE 200 in black ink (AUST R 296388).

The 200 mg capsules come in blister packs of 30.

Who distributes CELAXIB

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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CELAXIB® is a Viatris company trade mark

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