

CELAXIB

contains the active ingredient celecoxib

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about CELAXIB.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking CELAXIB against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What CELAXIB is used for

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

- osteoarthritis,
- rheumatoid arthritis and
- 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.

CELAXIB belongs to a group of medicines called Coxibs which are used to relieve pain and

inflammation in a number of conditions.

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

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

Your doctor may have prescribed it for another reason.

CELAXIB is available only with a doctor's prescription.

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

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

Before you take CELAXIB

When you must not take it

Do not take CELAXIB if you have an allergy to:

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

Some of the symptoms of an allergic reaction may include

- asthma, wheezing or shortness of breath

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

If you are allergic to sulfonamides or any of the capsule ingredients and take CELAXIB, these symptoms may be severe.

Do not take CELAXIB if 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.

Do not take CELAXIB if you have or have had problems with your blood circulation.

Do not take CELAXIB if your doctor has told you that you have severe heart or blood vessel disease affecting the circulation in your brain or limbs.

Do not take CELAXIB if you have severe liver problems.

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

Do not take CELAXIB if you have problems with your kidney function.

Do not take CELAXIB if you are undergoing cardiac surgery called coronary artery bypass graft (CABG).

Do not take CELAXIB if you have had an attack of asthma, hives, itching, skin rash or a runny nose after taking aspirin or Non-Steroidal Anti-Inflammatory Drugs (NSAIDs, medicines used to

treat pain and inflammation), including other Coxib medicines.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or an NSAID.

If you allergic to aspirin, NSAIDs, or other Coxib medicines and use CELAXIB, these symptoms may be severe.

Ask your doctor or pharmacist if any of this applies to you:

- you are already taking an NSAID
- you have an ulcer or gastric bleeding
- you have Irritable Bowel Disease
- you have heart failure
- 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.

Do not give CELAXIB 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.

Do not take this medicine after the expiry date printed on the pack, even though the capsules may look alright, or if the packaging is torn or shows signs of tampering.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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

Tell your doctor if you have or have had any of the following medical conditions:

- diabetes
- high blood pressure

- fluid retention or other medical conditions that can cause fluid retention
- high cholesterol levels
- heart failure or have a history of heart problems
- stroke or a history of stroke
- problems with the circulation in your limbs
- liver or kidney problems
- asthma, hives, itching, skin rash or a runny nose
- 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.

Tell your doctor if you are pregnant or plan 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.

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.

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

Small amounts of celecoxib pass into breast milk, therefore taking

CELAXIB while breastfeeding should be discussed with your doctor.

Tell your doctor if you 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.

Tell your doctor if you drink large amounts of alcohol.

Tell your doctor if you are a smoker.

Tell your doctor if you 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 about any of the above, tell him/her before you start taking CELAXIB.

Taking other medicines

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

Some medicines and CELAXIB may interfere with each other. 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
- fluconazole, an antifungal agent
- lithium, a medicine used to treat some types of depression
- 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
- 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
- cyclosporin, a medicine used to suppress the immune system
- 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).

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

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

How to take CELAXIB

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 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 daily 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 it

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 for

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.

Continue taking your medicine for as long as your doctor tells you to.

It is important to keep taking your medicine even if you feel well.

Do not exceed the dosage 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 he/she can monitor your condition and treatment.

If you forget to take it

If 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, and 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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much CELAXIB. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking CELAXIB

Things you must do

If you are about to be started on any new medicine, remind your

doctor and pharmacist that you are taking CELAXIB.

Tell any other doctors, dentists and pharmacists who treat 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.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you develop any skin rash (e.g. hives, spots) while being treated with CELAXIB, contact your doctor immediately.

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 must not do

Do not take CELAXIB 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.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Side effects

Tell your doctor or pharmacist 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. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- stomach pain, diarrhoea, indigestion, wind
- swollen hands, ankles and feet, unexplained weight gain
- dizziness
- sore throat, runny nose, sinusitis, upper respiratory tract infection.

The above list includes the more common side effects of your medicine.

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

- 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
- muscle weakness
- 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)
- 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.

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

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

Other side effects not listed above may also occur in some people.

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

You may not get any of them.

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

After taking CELAXIB

Storage

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.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store CELAXIB or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

CELAXIB 100 mg: A blue 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 100" in black ink on the cap and body. The 100 mg capsules come in blister packs of 60.

CELAXIB 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 30.

Ingredients

CELAXIB 100 mg contains 100 mg of celecoxib as the active ingredient per capsule.

CELAXIB 200 mg contains 200 mg of celecoxib as the active ingredient per capsule.

CELAXIB capsules also contain the following inactive ingredients:

- lactose monohydrate
- sodium lauryl sulfate
- povidone
- croscarmellose sodium
- silica - colloidal anhydrous
- magnesium stearate

The capsule shells also contain the following inactive ingredients:

- gelatin
- titanium dioxide
- indigo carmine (100 mg only)
- purified water
- sodium lauryl sulfate
- Black imprinting ink S-1-17823
- Black iron oxide (200 mg only)
- Red iron oxide (200 mg only)
- Yellow iron oxide (200 mg only)

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

CELAXIB is supplied in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian registration numbers:

CELAXIB 100 mg:

AUST R 296389

CELAXIB 200 mg:

AUST R 296388

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