

CELOSTEA®

Celecoxib Capsules 100mg, 200mg



What is in this leaflet

This leaflet answers some common questions about Celostea.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Celostea against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Celostea is used for

Celostea is used to treat the pain and inflammation (swelling, redness and soreness) in:

- osteoarthritis,
- rheumatoid arthritis, and
- ankylosing spondylitis.

These are all conditions of the joints.

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

Celostea is also used to treat short-term pain and painful menstrual periods.

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

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

Your doctor may have prescribed it for another reason.

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

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

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take Celostea

When you must not take it

Do not take Celostea if you have an allergy to:

- any medicine containing celecoxib.
- any of the ingredients listed at the end of this leaflet.
- sulphonamides, a group of antibiotics used to treat bacterial infections.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Celostea if you have:

- experienced asthma, hives, skin rash or a runny nose after aspirin or Non-steroidal Anti-inflammatory Drugs (NSAIDs, medicines used to relieve pain, swelling and other symptoms of inflammation),

including other Coxib medicines.

- heart or blood vessel disease affecting your blood circulation.
- stomach ulcers or bleeding.
- severe liver problems
- problems with your kidney function.

Do not take this medicine with NSAIDs.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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:

- heart problems, stroke or problems with the circulation in your limbs.
- high blood pressure, high cholesterol levels or diabetes.
- ulcer in the stomach or duodenum.
- bleeding from the rectum (back passage), black sticky bowel motions or bloody diarrhoea.
- vomiting blood or material that looks like coffee grounds.
- liver or kidney problems.
- asthma, hives, itching or skin rash.
- fluid retention.

Tell your doctor if you are taking any ACE inhibitors, beta-blockers or angiotensin receptor antagonists (medicines used to treat high blood pressure and some other heart problems) and diuretics (also called fluid tablets).

When taken together with Celostea these medicines can cause kidney problems.

Tell your doctor if you are a smoker or drink large amounts of alcohol.

Tell your doctor if you currently have an infection.

Celostea may hide some of the signs of an infection.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Related medicines, NSAIDs, have been associated with reversible infertility in some women.

There is no information on the use of Celostea during pregnancy. Celostea passes into breast milk in small amounts. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Celostea.

Taking other medicines

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

Some medicines and Celostea may interfere with each other. These include:

- 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 tablets).
- fluconazole, an antifungal agent.
- lithium, a medicine used to treat some types of depression.

- antacids, medicines used to treat heartburn and indigestion.
- warfarin or similar medicines including Eliquis (apixaban), Xarelto (rivaroxaban) or Pradaxa (dabigatran), medicines used to prevent blood clots.
- glucocorticoids, steroid hormones used to treat diseases caused by an overactive immune system.
- Cyclosporin, methotrexate, medicines used to suppress the immune system.
- some medicines used to treat epilepsy.
- Digoxin, a medicine used to treat various heart conditions.

These medicines may be affected by Celostea 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 Celostea

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 box/bottle, ask your doctor or pharmacist for help.

How much to take

Osteoarthritis

200 mg once daily or 100 mg twice daily, or as directed by your doctor.

Rheumatoid arthritis

100 mg or 200 mg twice daily.

Ankylosing spondylitis

200 mg once daily or 100 mg twice daily, or as directed by your doctor.

Management of short-term pain and painful menstrual periods

400 mg as a single dose on the first day followed by 200 mg once daily on subsequent days. If needed an additional 200 mg can be taken on subsequent days.

How to take it

Swallow the capsules whole with a full glass of water.

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.

It does not matter if you take this medicine before or after food.

How long to take it

Depending on your condition, you may need to take Celostea for a few days or for longer periods.

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

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 medicine as you would normally.

Do not take a double dose to make up for the dose that 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 National Poisons Centre (0800 POISON or 0800 764 766) 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 Celostea. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include feeling tired, drowsy, sick, vomiting and stomach pain. You may also have difficulty breathing and feel faint.

While you are taking Celostea

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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

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

Things you must not do

Do not take Celostea 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Celostea.

This medicine helps most people with arthritis, ankylosing spondylitis, short term pain and painful menstrual periods, but it may have unwanted side effects in a few people. 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.

Do not be alarmed by the following lists 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 upset including feeling sick, nausea, vomiting, heartburn, indigestion, cramps
- diarrhoea, pain in the stomach, wind
- dizziness
- headache, migraine
- swollen hands, ankles or feet
- sleeplessness
- 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 if you notice any of the following:

- sudden or severe itching, skin rash, hives
- severe blistering and bleeding in the lips, eyes, mouth, nose and genitals
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- fainting, seizures or fits
- pain or tightness in the chest
- severe pain or tenderness in the stomach
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions or bloody diarrhoea

- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- Flu-like symptoms or signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- yellowing of the skin and eyes, also called jaundice
- signs of anaemia, such as tiredness, being short of breath, and looking pale
- difficulty hearing, deafness
- eye problems such as blurred vision, sore red eyes
- severe dizziness
- a change in the colour of urine passed, blood in the urine
- a change in the amount or frequency of urine passed, burning feeling when passing urine
- hair loss or thinning
- fast or irregular heartbeats, also called palpitations
- unusual weight gain
- hallucinations (seeing, feeling or hearing things that are not there)
- feeling nervous, anxious, confused or depressed
- sleepiness, lack of energy
- leg cramps, unusual muscle stiffness
- numbness, pain or weakness in the arms, legs, hands or feet

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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After taking Celostea

Storage

Keep your capsules in the pack/bottle until it is time to take them.

If you take the capsules out of the pack/bottle they may not keep well.

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

Do not store Celostea 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

Celostea 100 mg capsule: blue opaque cap and a white opaque body printed with MYLAN over CE 100 in black ink.
Blister packs of 60 capsules.

Celostea 200 mg capsule: light brown opaque cap and a white opaque body printed with MYLAN over CE 200 in black ink.
Blister packs of 30 capsules.

Ingredients

Active ingredient:

Celostea 100 mg capsules contain 100 mg of celecoxib as the active ingredient.

Celostea 200 mg capsules contain 200 mg of celecoxib as the active ingredient.

Inactive ingredients:

Celostea capsule core also contains

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

Celostea capsule shells (100 mg) also contain:

- Titanium dioxide
- FD&C Blue #2
- Gelatin
- Sodium lauryl sulfate.
- Black printing ink (Opacode Black S-1-17823)

Celostea capsule shells (200 mg) also contains:

- Iron oxide black
- Iron oxide red
- Iron oxide yellow
- Titanium dioxide
- Gelatin
- Sodium lauryl sulfate
- Black printing ink (Opacode Black S-1-17823)

Contains lactose, sulfites and phenylalanine.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Celostea is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Information

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