

CELECOXIB GH

(celecoxib) capsules

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Celecoxib GH. 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 Celecoxib GH 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 Celecoxib GH is used for

Celecoxib GH 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.

Celecoxib GH also provides short term pain relief in conditions such as:

- Menstrual cramps or period pain.
- After surgery.
- Muscle and joint injuries.

Celecoxib GH contains celecoxib and belongs to a group of medicines called Coxibs which are used to

relieve pain and inflammation in a number of conditions.

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

Your doctor, however, may have prescribed Celecoxib GH for another purpose.

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

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

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

Before you take Celecoxib GH

When you must not take it

Do not take Celecoxib GH 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.**
- **have or have had problems with your blood circulation.**
- **have or if your doctor has told you that severe heart or blood vessel disease affecting the circulation in your brain or limbs.**
- **have severe liver problems.** Your doctor will decide if your condition is too severe to take this medicine.
- **have problems with your kidney function.**

- **are undergoing cardiac surgery called coronary artery bypass graft (CABG) surgery.**
- **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 are allergic to aspirin, NSAIDs, or other Coxib medicines and take Celecoxib GH, these symptoms may be severe.

- **have an allergy to:**
 - 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).

Symptoms of an allergic reaction to these medicines 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 Celecoxib GH, these symptoms may be severe.

Ask your doctor or pharmacist if any of this applies to you. Celecoxib GH may not be suitable for you if any of the conditions below apply to you. You:

- are already taking an NSAID.
- have an ulcer or gastric bleeding.
- have Irritable Bowel Disease.
- 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 take Celecoxib GH if 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.

Do not take Celecoxib GH if the packaging is torn or shows signs of tampering.

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

Before you start to take it

You must tell your doctor if you have any of the following health problems:

- you currently have diabetes.
- high blood pressure.
- 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.
- you have any allergies to:
 - any other medicines;
 - any other substances such as foods, dyes or preservatives;
- 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 celecoxib during pregnancy.

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

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

Discuss any questions you may have with your doctor if:

- you are breast-feeding or intend to breast-feed.
Small amounts of celecoxib passes into breast milk, therefore, the use of Celecoxib GH during breastfeeding should be discussed with your doctor.
- you have any other health problems including:
 - liver or kidney problems;
 - asthma, hives, itching, skin rash or a runny nose;
 - high blood pressure;
 - fluid retention or other medical conditions that can cause fluid retention;
 - peptic ulcer (ie. 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.
- you are taking Celecoxib GH 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.

- you drink large amounts of alcohol.
- you are a smoker.
- you currently have an infection.

If you are given Celecoxib GH 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 Celecoxib GH.

Taking other medicines

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

Some medicines and Celecoxib GH 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 antagonist, 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).

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

How to take Celecoxib GH

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 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 Celecoxib GH capsules 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 Celecoxib GH for up to 5 days.

How to take it

Swallow the capsules whole with a full glass of water. Celecoxib GH 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 Celecoxib GH.

How long to take it

Depending on your condition, you may need Celecoxib GH for a few days or for longer periods.

Celecoxib GH will not cure your condition but should help control pain, swelling and stiffness.

Keep taking Celecoxib GH 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 (eg. 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 Celecoxib GH 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, 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 take too much (overdose)

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

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

While you are taking Celecoxib GH

Things you must do

If you become pregnant while taking Celecoxib GH, tell your doctor immediately.

If you are about to start any new medicines, tell your doctor and pharmacist that you are taking Celecoxib GH.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Celecoxib GH.

If you develop any skin rash (eg. hives, spots) while being treated with Celecoxib GH, 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.

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

Things you must not do

Do not give Celecoxib GH to anyone else, even if they have the same symptoms or condition as you.

Do not take Celecoxib GH to treat any other complaints unless your doctor tells you to.

Side effects

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

Like other medicines, celecoxib can cause some side effects. If they occur, most are likely to be minor and temporary.

Ask your doctor or pharmacist any questions you may have.

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, 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:

- 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, 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, flulike 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.

These are serious side effects. You may need urgent medical attention.

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

Other side effects not listed above may 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 if you notice anything else that is making you feel unwell, even if it is not on this list.

After taking Celecoxib GH

Storage

Keep your capsules where young children cannot reach them.

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

Keep Celecoxib GH in a cool, dry place where the temperature stays at or below 25°C.

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

Heat and dampness can destroy some medicines.

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.

Disposal

If your doctor tells you to stop taking Celecoxib GH, or the capsules have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

Celecoxib 100 mg capsules are size '3' hard gelatin capsule having blue opaque cap imprinted with 'CX' in black ink and white opaque body with '100' in black ink. Containing white to off-white powder.

Celecoxib 200 mg capsules are Size '0' elongated hard gelatin capsule having gold opaque cap, imprinted with 'CX' in black ink and white opaque body imprinted with '200' in black ink, containing white to off-white powder.

The 100 mg capsule comes in blister pack of 10, 20, 30, 50, 60, and 120's.

The 200 mg capsule comes in blister pack of 10, 20, 30, 50, 60, and 120's.

Not all pack sizes are marketed.

Ingredients

Active ingredient

Each Celecoxib GH capsule contains 100 mg or 200 mg celecoxib.

Other ingredients

- lactose monohydrate;
- sodium lauryl sulfate;
- povidone;
- croscarmellose sodium;
- magnesium stearate;

The capsule shells contain:

- sodium lauryl sulfate;
- gelatin;
- acetic acid;
- silicon dioxide;
- purified water;
- titanium dioxide;
- iron oxide yellow (200 mg capsules only);
- citric acid;
- Brilliant Blue FCF (100 mg capsules only);
- Allura Red AC (100 mg capsules);

The printing inks, TekPrint SW-9008 Black Ink or Marking Solution
Black BKI004 Black Ink ACG
PAM BKI004 contains:

- iron oxide black;
- shellac.

Australian Registration Numbers

Celecoxib GH 100 mg: AUST R 196178.

Celecoxib GH 200 mg: AUST R 196188.

Distributor

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