

APO-Celecoxib Capsules

Celecoxib

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about celecoxib. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or

- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Celecoxib. It contains the active ingredient celecoxib.

Celecoxib is used to treat:

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

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

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

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

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

How it works

Celecoxib belongs to a group of medicines called NSAIDs which are used to relieve pain and inflammation in a number of conditions.

There is no evidence that this medication is addictive.

Use in children

This medicine should not be used in children or adolescents under 18 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if you have or have had any of the following:

- **severe heart disease**

- **blood vessel disease affecting the circulation in your brain or limbs**
- **chest pains or angina which occur even when you are resting and are becoming more frequent, severe, or lasting longer than usual**
- **severe liver problems**
- **recently undergone a coronary artery bypass graft (CABG)**
- **peptic ulceration or gastric intestinal bleeding**
- **severe kidney problems**
- **an attack of asthma, hives, itching, skin rash or a runny nose after taking Aspirin or other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), including other Coxib medicines.**
- **You are taking any other NSAIDs**
- **You are hypersensitive to, or have had an allergic reaction to, celecoxib, any of the ingredients listed at the end of this leaflet or sulfonamides, a group of medicines which include certain antibiotics (if you are not sure if you are taking one of these medicines ask your doctor or pharmacist).**

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash,

itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - diabetes
 - high blood pressure or fluid retention
 - high cholesterol levels
 - heart failure

- history of heart problems or stroke
 - circulation problems in your limbs
 - liver or kidney problems
 - asthma, hives, itching, skin rash or runny nose
 - peptic ulcer
 - vomiting blood or material that looks like coffee grounds
 - bleeding from the rectum, have black sticky bowel motions or bloody diarrhoea
 - low blood count
 - inflammatory bowel disease
 - an infection
3. You are currently pregnant, or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

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. It may affect your developing baby if taken during pregnancy.

4. You are currently breastfeeding, or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

Small amounts of celecoxib passes into breast milk, therefore taking it during breastfeeding should be discussed with your doctor.

5. You drink large amounts of alcohol
6. You are a smoker
7. You are planning to have surgery

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with celecoxib. These include:

- medicines 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)

- frusemide and thiazides, types of diuretics
- aspirin or salicylates, medicines used to treat pain
- metoprolol, a beta-blocker used for heart conditions, high blood pressure and migraines
- digoxin, a medicine used to treat abnormal heart beat and other heart problems
- fluconazole, an antifungal agent
- lithium, a medicine used to treat some mood disorders
- warfarin, apixaban, dabigatran, and rivaroxaban, medicines used to stop blood clots
- rifampicin, an antibiotic
- carbamazepine, a medicine used for epilepsy
- barbiturates, a class of medicines that cause sedation
- cyclosporin, an immune suppressant
- methotrexate, a medicine used to treat arthritis and some cancers
- antacids, medicines used to treat indigestion
- dextromethorphan, a dry cough suppressant
- medicines used to treat pain and inflammation called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or (cortico) steroids.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with celecoxib.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

Osteoarthritis

The recommended dose is 200 mg once daily or 100 mg twice daily.

Rheumatoid arthritis

The recommended dose is 100 mg twice daily.

Ankylosing spondylitis

The maximum recommended dose is 200 mg once daily or 100 mg twice daily.

Menstrual cramps or period pain

The recommended dose is 400 mg as a single dose on the first day and 200 mg once daily on the following days. The maximum recommended treatment duration is 5 days.

Muscle and joint injuries or after surgery

The recommended dose is 400 mg as a first dose followed by 200 mg once or twice daily as required for up to 5 days.

How to take it

Swallow the capsule whole with a glass of fluid.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

This medicine can be taken with or without food.

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of celecoxib.

How long to take it

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

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

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 celecoxib 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 to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Signs of an overdose with celecoxib may include:

- nausea, vomiting
- headache
- stomach pain
- drowsiness, tiredness
- difficulty in breathing
- impaired consciousness, feeling faint

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or are going into hospital.

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

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking celecoxib or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side

effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

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

Tell your doctor immediately if you notice any of the following.

These may be serious side effects and you may need urgent medical attention:

- 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
- signs of allergic reactions such as wheezing, swelling of the face, lips, tongue, mouth or throat which may cause difficulty in swallowing or breathing
- 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, looking pale, fainting
- irregular heartbeat, chest pain, swollen or sore leg veins
- 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 of the face,

arm, leg or body, difficulty speaking, understanding, reading or writing, loss of coordination or balance

- worsening epilepsy.

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

Other side effects not listed above may occur in some patients.

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

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Celecoxib looks like

APO-Celecoxib 100 mg capsules: Opaque, white capsules with 2 blue bands and marked "100" on the body.

Blister pack: 60 capsules.

APO-Celecoxib 200 mg capsules: Opaque, white capsules with 2 gold bands and marked "200" on the body.

Blister pack: 30 capsules.

* Not all strengths may be available.

Ingredients

Each capsule contains 100 mg or 200 mg of celecoxib as the active ingredient.

It also contains the following inactive ingredients:

- lactose monohydrate

- sodium lauryl sulfate
- croscarmellose sodium
- povidone
- magnesium stearate.

In addition, each capsule shell contains the following inactive ingredients:

- gelatin (with sulfites as residue)
- titanium dioxide
- sodium lauryl sulfate
- TekPrint™ SB-6018 Blue Ink (ARTG 2653) [for 100 mg capsules]
- TekPrint™ SB-3002 Gold Ink (ARTG 3426) [for 200 mg capsules].

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Celecoxib 100mg capsules (blister pack 60)

AUST R 226145.

APO-Celecoxib 200mg capsules (blister pack 30)

AUST R 226146.

Sponsor

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This leaflet was last updated in:

November 2018.