

APX-CELECOXIB

celecoxib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APX-CELECOXIB. 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 APX-CELECOXIB against the benefits it is expected to have for you.

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

Read this leaflet carefully before you start APX-CELECOXIB and keep it with the medicine.

You may need to read it again.

What APX-CELECOXIB is used for

APX-CELECOXIB 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.

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

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

APX-CELECOXIB 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 APX-CELECOXIB can relieve the symptoms of pain and inflammation, it will not cure your condition.

Your doctor, however, may have prescribed APX-CELECOXIB for another purpose.

Ask your doctor if you have any questions about why APX-CELECOXIB has been prescribed for you.

APX-CELECOXIB 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 it

When you must not take it

Do not take APX-CELECOXIB 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 you have 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)**
- **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 APX-CELECOXIB, these symptoms may be severe.
- **you 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 APX-CELECOXIB, these symptoms may be severe.

Ask your doctor or pharmacist if any of this applies to you. APX-CELECOXIB 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 APX-CELECOXIB 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 APX-CELECOXIB if the packaging is torn or shows signs of tampering.

If you are not sure if you should be taking APX-CELECOXIB, 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 APX-CELECOXIB during pregnancy.

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

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

Discuss any questions you may have with your doctor.

- **you are breast-feeding or intend to breast-feed**

Small amounts of celecoxib passes into breast milk, therefore taking APX-CELECOXIB during breast-feeding 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 (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.

- **you are taking APX-CELECOXIB 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 APX-CELECOXIB 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 APX-CELECOXIB.

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 APX-CELECOXIB 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 medicines 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 APX-CELECOXIB.

How to take APX-CELECOXIB

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

They may differ from the information 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 APX-CELECOXIB 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 APX-CELECOXIB for up to 5 days.

How to take it

Swallow the capsules whole with a glass of fluid. APX-CELECOXIB 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 APX-CELECOXIB.

How long to take it

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

APX-CELECOXIB will not cure your condition but should help control pain, swelling and stiffness.

Keep taking APX-CELECOXIB 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 APX-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 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 APX-CELECOXIB. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking it

Things you must do

If you become pregnant while taking APX-CELECOXIB, tell your doctor immediately.

If you are about to start any new medicines, tell your doctor and pharmacist that you are taking APX-CELECOXIB.

Tell all doctors, dentists and pharmacists who are treating you that you are taking APX-CELECOXIB.

If you develop any skin rash (e.g. hives, spots) while being treated with APX-CELECOXIB, 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 APX-CELECOXIB to anyone else, even if they have the same symptoms or condition as you.

Do not take APX-CELECOXIB 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 APX-CELECOXIB, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, APX-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

- 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.

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

Not all of these side effects have been reported with APX-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 APX-CELECOXIB

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 APX-CELECOXIB 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 APX-CELECOXIB, or the capsules have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

- APX-CELECOXIB 100mg – Opaque, white capsules with 2 blue bands and marked “100” on the body. The 100mg capsules come in blister packs of 60.
- APX-CELECOXIB 200mg – Opaque, white capsules with 2

gold bands and marked “200”
on the body.
The 200 mg capsules come in
blister packs of 30.

Ingredients

Active ingredient

The active ingredient in APX-
CELECOXIB is celecoxib.

- APX-CELECOXIB 100mg -
100mg celecoxib/capsule
- APX-CELECOXIB 200mg -
200mg celecoxib/capsule

Other ingredients

- lactose monohydrate
- sodium lauryl sulfate
- povidone
- croscarmellose sodium
- magnesium stearate
- gelatin
- titanium dioxide
- TekPrint™ SB-6018 Blue Ink
(ARTG 2653) /100 mg capsule
- TekPrint™ SB-3002 Gold Ink
(ARTG 3426) /200 mg capsule

APX-CELECOXIB contains lactose
and may contain traces of sulfites.

APX-CELECOXIB does not
contain sucrose, gluten, tartrazine or
other azo dyes.

Sponsor

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