

PART III: CONSUMER INFORMATION

**^{Pr} APO-CELECOXIB
Celecoxib Capsules**

Read this information each time you refill your prescription in case new information has been added.

This leaflet is a summary designed specifically for you to read. It will NOT tell you everything about APO-CELECOXIB. See your health care provider and pharmacist regularly and ask them questions about your health and any medications you take.

ABOUT THIS MEDICATION

What the medication is used for:

Your health care provider has prescribed APO-CELECOXIB for you for one or more of the following medical conditions:

- Osteoarthritis – relieve pain
- Rheumatoid Arthritis – relieve joint pain and swelling
- Ankylosing Spondylitis – relieve pain
- Sprains, After orthopaedic (bone and joint) surgery (NOT open heart surgery), dental extraction – to relieve short-term pain (maximum use of 7 days)

What it does:

APO-CELECOXIB (celecoxib), as a nonsteroidal anti-inflammatory drug (NSAID), can reduce the type of prostaglandins (chemicals), produced by your body which cause joint swelling, redness and pain. At prescribed doses, APO-CELECOXIB does not affect the type of prostaglandins that helps maintain the protective layer of the stomach, and reduces the chances of bleeding from the stomach.

APO-CELECOXIB, as a nonsteroidal anti-inflammatory drug (NSAID), does NOT cure your illness or prevent it from getting worse. APO-CELECOXIB can only relieve pain and reduce swelling as long as you continue to take it.

When it should not be used:

Do not take APO-CELECOXIB if you have any of the following medical conditions:

- Heart bypass surgery (planning to have or recently had)
- Severe, uncontrolled heart failure
- Allergy to celecoxib or any of the other ingredients in APO-CELECOXIB
- Allergy to sulfonamide drugs
- Allergy to ASA (Acetylsalicylic Acid) or other NSAIDs (Nonsteroidal Anti-Inflammatory Drugs)
- Pregnancy of more than 28 weeks (in your third trimester)
- Currently breastfeeding (or planning to breastfeed)
- Ulcer (active)

- Bleeding from the stomach or gut (active)
- Bleeding in the brain or other bleeding disorders
- Inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis)
- Liver disease (active or severe)
- Kidney disease (severe or worsening)
- High potassium in the blood

APO-CELECOXIB is NOT recommended for use in patients under 18 years of age since the safety and effectiveness of APO-CELECOXIB have NOT been established in these patients.

Patients who took a drug in the same class as APO-CELECOXIB after a type of heart surgery (coronary artery bypass grafting (CABG)) were more likely to have heart attacks, strokes, blood clots in the leg(s) or lung(s), and infections or other complications than those who did NOT take that drug.

What the medicinal ingredient is:

Celecoxib

What the nonmedicinal ingredients are:

- Crospovidone,
- FD&C Blue #2 Aluminium Lake edible ink for 100 mg capsules
- Gelatin
- Magnesium stearate
- Povidone
- Sodium lauryl sulphate
- Titanium dioxide
- iron oxide Yellow edible ink for 200 mg capsules.

What dosage forms it comes in:

Capsules, 100 mg and 200 mg

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

If you have, or previously had, any of the following medical conditions, see your health care provider to discuss treatment options other than APO-CELECOXIB:

- Heart Attack or Angina
- Stroke or Mini-stroke
- Loss of Vision
- Current Pregnancy (less than 28 weeks)
- Congestive Heart Failure
- Current Pregnancy (less than 28 weeks)
- Ulcer or bleeding from the gut

Also consult your healthcare provider if you are taking a dose of APO-CELECOXIB which is higher than 200mg per day or if you have been taking APO-CELECOXIB regularly for over 18 months. Patients in this situation have an increased risk of

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a serious cardiovascular side effect such as the ones described above.

Before you use APO-CELECOXIB talk to your doctor or pharmacist if you have any of the following:

- **Disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, or peripheral arterial disease)**
- **Risk factors for cardiovascular disease (see above) such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood**
- **Diabetes Mellitus or on a low sugar diet**
- **Atherosclerosis**
- **Poor circulation to your extremities**
- **Smoker or ex-smoker**
- **Kidney disease or urine problems**
- **Previous ulcer or bleeding from the stomach or gut**
- **Previous bleeding in the brain**
- **Bleeding problems**
- **Family history of allergy to sulfonamide drugs**
- **Family history of allergy to NSAIDs, such as acetylsalicylic acid (ASA), celecoxib, diclofenac, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, rofecoxib, sulindac, tenoxicam, tiaprofenic acid, tolmetin, or valdecoxib (NOT a complete list)**
- **Family history of asthma, nasal polyp, long-term swelling of the sinus (chronic sinusitis) or hives**
- **Gastrointestinal problems (problems with your stomach and/or intestine)**
- **Current pregnancy**
- **Any other medical problem**

Fertility may be decreased. The use of APO-CELECOXIB is not recommended in women who have difficulty conceiving.

Also, before taking this medication, tell your health care provider if you are planning to get pregnant.

While taking this medication:

- tell any other doctor, dentist, pharmacist or other health care professional that you see, that you are taking this medication, especially if you are planning to have heart surgery;
- do NOT drink alcoholic beverages while taking this medication because you would be more likely to develop stomach problems;
- If you have cardiovascular disease or risks

for cardiovascular disease, your doctor will periodically re-evaluate whether you should continue treatment with APO-CELECOXIB. Patients with these conditions should not receive doses of APO-CELECOXIB higher than 200 mg per day.

If, at any time while taking APO-CELECOXIB you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, seek emergency medical treatment immediately.

INTERACTIONS WITH THIS MEDICATION

Talk to your health care provider and pharmacist if you are taking any other medication (prescription or non-prescription) such as any of the following (NOT a complete list):

- Acetylsalicylic acid (ASA) or other NSAIDs (e.g. diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen)
- Antacids or proton pump inhibitors (omeprazole)
- Antidepressants [Selective serotonin receptor uptake inhibitor (SSRIs) (e.g. citalopram, paroxetine, fluoxetine, sertraline)]
- Blood pressure medications, such as ACE (angiotensin converting enzyme) inhibitors (e.g. enalapril, lisinopril, perindopril, ramipril), ARBs (angiotensin II receptor blockers) (e.g. candesartan, irbesartan, losartan, valsartan), beta blockers (e.g. metoprolol)
- Blood thinners (to prevent blood clots), such as warfarin, apixaban, rivaroxaban, dabigatran, ASA, clopidogrel
- Corticosteroids (including glucocorticoids) e.g. prednisone
- Cyclosporin
- Digoxin
- Diuretics such as furosemide, hydrochlorothiazide
- Fluconazole
- Lithium
- Dextromethorphan (found in some cough medications)
- Tacrolimus

Using APO-CELECOXIB with a blood thinner such as warfarin increases the risk of bleeding, which can be fatal, especially in older patients.

Your health care provider may prescribe low dose ASA (acetylsalicylic acid) as a blood thinner for the prevention of having a heart attack or stroke while you are taking APO-CELECOXIB. Take only the amount of ASA prescribed by your health care provider. You are more likely to upset or damage your stomach if you take both APO-CELECOXIB and ASA than if you take APO-CELECOXIB alone.

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PROPER USE OF THIS MEDICATION

Dose: 18 years of age and older only

Medical Condition	Starting Dose	Maximum Dose (per day)	Maximum Duration of Treatment (days)
Osteoarthritis (18 years of age and older)	200 mg once a day or 100 mg twice a day	200 mg	not specified
Rheumatoid Arthritis (18 years of age and older)	100 mg twice a day	400 mg	not specified
Ankylosing Spondylitis (18 years of age and older)	200 mg once a day or 100 mg twice a day	200 mg	not specified
Pain (18 years of age and older)	400 mg on first day, then 200 mg once a day	400 mg	7 days

Take APO-CELECOXIB only as directed by your health care provider. **Do NOT take more of it, do NOT take it more often and do NOT take it for a longer period of time than your health care provider recommended. If possible, you should take the lowest dose of this medication for the shortest time period.** Taking too much APO-CELECOXIB may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly, have other diseases or take other medications.

If you will be using APO-CELECOXIB for more than 7 days, see your health care provider regularly to discuss whether this medicine is working for you and if it is causing you any unwanted effects.

This medication has been prescribed specifically for you. Do NOT give it to anyone else. It may harm them, even if their symptoms seem to be similar to yours.

APO-CELECOXIB is NOT recommended for patients under 18 year of age since safety and effectiveness have NOT been established.

APO-CELECOXIB can be taken with or without food.

Missed Dose:

Take the dose you missed as soon as you remember, then take the next dose at the scheduled time.

Overdose:

If you take more than the prescribed dose, contact your health care provider immediately.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

APO-CELECOXIB may cause some side effects, especially if used for a long time or in large doses. When these side effects occur, you may require medical attention. Report all symptoms or side effects to your health care provider.

APO-CELECOXIB may cause you to become drowsy or tired. Be careful about driving or participating in activities that require you to be alert. If you become drowsy, dizzy or light-headed after taking APO-CELECOXIB, do NOT drive or operate machinery.

APO-CELECOXIB may cause you to become more sensitive to sunlight. Any exposure to sunlight or sunlamps may cause sunburn, skin blisters, skin rash, redness, itching or discolouration, or vision changes. If you have a reaction from the sun, check with your health care provider.

APO-CELECOXIB can cause abnormal laboratory test results. Your doctor will decide when to perform laboratory tests and will interpret the results. They may check kidney function, liver function, amount of blood cells and other functions.

Your doctor will decide when to measure the amount of your amniotic fluid during pregnancy.

Check with your health care provider IMMEDIATELY if you develop chills, fever, muscle aches or pains, or other flu-like symptoms occur, especially if they occur before or together with a skin rash. These symptoms may be the first signs of a **SERIOUS ALLERGIC REACTION** to this medication.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / Effect	STOP Taking Drug and Get Emergency Medical Attention IMMEDIATELY	STOP Taking Drug and Talk to Your Health Care Provider
Bloody or black tarry stools	✓	
Shortness of breath, wheezing, any trouble breathing or chest tightness	✓	
Skin rash, hives, swelling or itching	✓	
Blurred vision or other visual disturbance	✓	
Sudden severe headache or worsening of headache, vomiting, dizziness, fainting, disturbance of vision or speech, or weakness or numbness in the face, arm or leg	✓	

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SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM		
Symptom / Effect	STOP Taking Drug and Get Emergency Medical Attention IMMEDIATELY	STOP Taking Drug and Talk to Your Health Care Provider
Change in urine (amount or colour) (dark red or brown)	✓	
Pain or difficulty urinating		✓
Feet or lower leg swelling; weight gain		✓
Vomiting or persistent indigestion, nausea, stomach pain or diarrhea		✓
Yellow discolouration of the skin or eyes with or without itchy skin		✓
Malaise, fatigue, or loss of appetite		✓
Headaches, stiff neck		✓
Mental confusion or depression		✓
Dizziness or light-headedness		✓
Hearing problems		✓
Pneumonitis (symptoms include trouble breathing, dry cough, tiredness)		✓

This is NOT a complete list of side effects. If you develop any other symptoms while taking APO-CELECOXIB, see your health care provider.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

Store at room temperature, between 15°C and 30°C.

Do NOT keep outdated medicine or medicine no longer needed. Any outdated or unused medicine should be returned to your pharmacist.

Keep out of reach of children.

MORE INFORMATION

If you want more information about APO-CELECOXIB:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this patient medication information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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