

**IMPORTANT: PLEASE READ**

**PART III: CONSUMER INFORMATION**

**P** **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 **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 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:**

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, 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.

CELECOXIB, as a nonsteroidal anti-inflammatory drug (NSAID), does NOT cure your illness or prevent it from getting worse. 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 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 CELECOXIB
- Allergy to Sulfonamide drugs
- Allergy to ASA (Acetylsalicylic Acid) or other NSAIDs (Nonsteroidal Anti-Inflammatory Drugs)

- Current Pregnancy (after 28 weeks of pregnancy)
- Currently Breastfeeding (or planning to breastfeed)
- Ulcer (active)
- Bleeding from the stomach or gut (active)
- Bleeding in the brain
- Inflammatory Bowel Disease (Crohn's Disease or Ulcerative Colitis)
- Liver Disease (active or severe)
- Kidney Disease (severe or worsening)
- High potassium in the blood

Safety and effectiveness of CELECOXIB have NOT been established in children under 18 years of age.

Patients who took a drug in the same class as 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 non-medicinal ingredients are:**

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

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

Before taking this medication tell your health care provider if you have any of the following:

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- **High Blood Pressure**
- **High Cholesterol**
- **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)**
- **Any other medical problem**

(e.g. enalapril, lisinopril, perindopril, ramipril)], ARBs (angiotensin II receptor blockers) (e.g. candesartan, irbesartan, losartan, valsartan

- Blood thinners e.g. warfarin (to prevent blood clots), ASA, clopidogrel
- Corticosteroids (including glucocorticoids) e.g. prednisone
- Cyclosporin
- Digoxin
- Diuretics Furosemide, hydrochlorothiazide
- Fluconazole
- Lithium
- Methotrexate
- Oral contraceptives
- Oral hypoglycemics (diabetes medications)
- Tacrolimus

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 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 CELECOXIB and ASA than if you take CELECOXIB alone.

**Fertility may be decreased. The use of 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;

## 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 or other NSAIDs (e.g. ASA, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen)
- Antacids
- Antidepressants [Selective serotonin receptor uptake inhibitor (SSRIs) (e.g. citalopram, paroxetine, fluoxetine, sertraline)]
- Blood pressure medications; ACE (angiotensin converting enzyme) inhibitors

## 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)
<b>Osteoarthritis</b> (18 years of age and older)	200 mg once a day or 100 mg twice a day	200 mg	not specified
<b>Rheumatoid Arthritis</b> (18 years of age and older)	100 mg twice a day	400 mg	not specified
<b>Ankylosing Spondylitis</b> (18 years of age and older)	200 mg once a day or 100 mg twice a day	200 mg	not specified
<b>Pain</b> (18 years of age and older)	400 mg on first day, then 200 mg once a day	400 mg	7 days

Take 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 CELECOXIB may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly, have other diseases or take other medications.

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If you will be using 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.**

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

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, or in case of an actual overdose, contact your Regional Poison Centre or your doctor immediately, so that medical attention may be given promptly.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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.

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 CELECOXIB, do NOT drive or operate machinery.

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.

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	✓	
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 lightheadedness		✓
Hearing problems		✓

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

### 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 and pets.**

### **Reporting Suspected Side Effects**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to:  
Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

### **MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

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