

**PART III: CONSUMER INFORMATION**

**Pr Sandoz Celecoxib**  
Celecoxib Capsules  
100 mg and 200 mg

Read this carefully before you start taking **Sandoz Celecoxib** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Sandoz Celecoxib**.

**ABOUT THIS MEDICATION**

**What the medication is used for:**

Your healthcare provider has prescribed Sandoz 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:**

Sandoz 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, Sandoz 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.

Sandoz Celecoxib, as a nonsteroidal anti-inflammatory drug (NSAID), does NOT cure your illness or prevent it from getting worse. Sandoz 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 Sandoz 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 Sandoz 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 breast-feeding (or planning to breast-feed)**
- **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**

**Sandoz Celecoxib is NOT recommended for use in patients under 18 years of age since the safety and effectiveness of Sandoz Celecoxib have NOT been established in these patients.**

**Patients who took a drug in the same class as Sandoz 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:**

Carrageenan, colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate and talc. The capsules are made of gelatin and contain titanium dioxide. The 100 mg capsule contains FD&C Blue # 2 Aluminum Lake E132 and the 200 mg capsule contains Yellow Iron Oxide E172.

**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 healthcare provider to discuss treatment options to consider before taking Sandoz Celecoxib:**

- **Heart attack or angina**
- **Stroke or mini-stroke**
- **Loss of vision**
- **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 Sandoz Celecoxib which is higher than 200mg per day or if you have been taking Sandoz Celecoxib regularly for over 18 months. Patients in this situation have an increased risk of a serious cardiovascular side effect such as the ones described above.**

**BEFORE you use Sandoz 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

- 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

**Fertility may be decreased. The use of Sandoz Celecoxib is not recommended in women who have difficulty conceiving.**

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

**While taking this medication:**

- tell any other doctor, dentist, pharmacist or other healthcare 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 Sandoz Celecoxib. Patients with these conditions should not receive doses of Sandoz Celecoxib higher than 200 mg per day.

If, at any time while taking Sandoz 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 healthcare 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)

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

Your healthcare 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 Sandoz Celecoxib. Take only the amount of ASA prescribed by your healthcare provider. You are more likely to upset or damage your stomach if you take both Sandoz Celecoxib and ASA than if you take Sandoz Celecoxib alone.

**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 Sandoz Celecoxib only as directed by your healthcare 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 healthcare provider recommended. If possible, you should take the lowest dose of this medication for the shortest time period. Taking too much Sandoz 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 Sandoz Celecoxib for more than 7 days, see your healthcare 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.**

**Sandoz Celecoxib is NOT recommended for patients under 18 years of age since safety and effectiveness have NOT been established.**

Sandoz 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 think you have taken too much Sandoz Celecoxib, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Sandoz 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 healthcare provider.

Sandoz 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 Sandoz Celecoxib, do NOT drive or operate machinery.

Sandoz 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 discoloration, or vision changes. If you have a reaction from the sun, check with your healthcare provider.

Sandoz 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 healthcare provider IMMEDIATELY if you develop chills, fever, muscle aches or pains, or if 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 healthcare 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	√	
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		√
Pneumonitis (symptoms include trouble breathing, dry cough, tiredness)		√

***This is NOT a complete list of side effects. For any unexpected effects while taking Sandoz Celecoxib, contact your doctor or pharmacist.***

**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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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 between 15 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 the sight and reach of children and pets.**

**MORE INFORMATION**

This document, plus the full product monograph prepared for health professionals, can be obtained by contacting the sponsor, Sandoz Canada Inc., at: 1-800-361-3062

or

by written request at:

145, Jules-Léger

Boucherville, (QC), Canada

J4B 7K8

or by e-mail at :

medinfo@sandoz.com

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