

IMPORTANT: PLEASE READ**PART III: CONSUMER INFORMATION**

Pr PRO-NAPROXEN EC
Naproxen

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 PRO-NAPROXEN EC. 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 PRO-NAPROXEN EC for you for one or more of the following medical conditions:

- For the treatment of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.
- For the relief of minor aches and pains in muscles, bones and joints, mild to moderate pain accompanied by inflammation in sprains and strains and primary dysmenorrhea.

What it does:

PRO-NAPROXEN EC (naproxen), as a non-steroidal anti-inflammatory drug (NSAID), can reduce the chemicals produced by your body which cause pain and swelling.

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

When it should not be used:

DO NOT TAKE PRO-NAPROXEN EC if you have any of the following medical conditions:

- Heart bypass surgery (planning to have or recently had)
- Severe, uncontrolled heart failure
- Bleeding in the brain or other bleeding disorders
- Current pregnancy (after 28 weeks of pregnancy)
- Currently breastfeeding (or planning to breastfeed)
- Allergy to ASA (Acetylsalicylic Acid) or other NSAIDs (Non - steroidal Anti-Inflammatory Drugs)
- Ulcer (active)
- Bleeding from the stomach or gut (active)
- Inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis)
- Liver disease (active or severe)
- Kidney disease (severe or worsening)
- High potassium in the blood

Patients who took a drug in the same class as PRO-NAPROXEN EC 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.

PRO-NAPROXEN EC should NOT be used in patients under 18 years of age since the safety and effectiveness have NOT been established.

What the medicinal ingredient is:

naproxen

What the important nonmedicinal ingredients are:

PRO-NAPROXEN EC Tablets contain the following nonmedicinal ingredients: colloidal silicon dioxide, croscarmellose sodium (Ac-Di-Sol), magnesium stearate, povidone, sodium lauryl sulphate, dri klear 042, eudragid L30D, chromateric white deb 5018 WE, purified water.

What dosage forms it comes in:

PRO-NAPROXEN EC is available as: enteric coated tablets (500 mg);

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 PRO-NAPROXEN EC:

- 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:

- 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 (small or large intestine)
- Previous bleeding in the brain
- Bleeding problems
- 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 polyps, long-term swelling of the sinus (chronic sinusitis) or hives

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;
- fertility may be decreased. The use of PRO-NAPROXEN EC is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping PRO-NAPROXEN EC should be considered.
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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. ASA, celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen
- Antacids
- Antidepressants
 - Selective Serotonin Reuptake Inhibitors (SSRIs)
 - e.g. citalopram, fluoxetine, paroxetine, sertraline
- Blood pressure medications
 - ACE (angiotensin converting enzyme) inhibitors
 - e.g. enalapril, lisinopril, perindopril, ramipril
 - ARBs (angiotensin II receptor blockers)
 - e.g. candesartan, irbesartan, losartan, valsartan
- Blood thinners
 - e.g. warfarin, ASA, clopidogrel
- Corticosteroids (including glucocorticoids)
 - e.g. prednisone
- Cyclosporin
- Digoxin
- Diuretics
 - e.g. furosemide, hydrochlorothiazide
- Lithium
- Methotrexate
- Oral contraceptives
- Oral hypoglycemics (diabetes medications)
- Tacrolimus

Your health care provider may prescribe low dose ASA (acetylsalicylic acid) as a blood thinner to reduce your risk of having a heart attack or stroke while you are taking PRO-NAPROXEN EC. 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 PRO-NAPROXEN EC and ASA than if you took PRO-NAPROXEN EC alone.

PROPER USE OF THIS MEDICATION

PRO-NAPROXEN EC is intended for use in patients greater than 18 years of age for the shortest possible duration.

Usual dose: 18 years of age and older:

Medical Condition	Starting Dose	Maximum Dose (per day)
Osteoarthritis/Rheumatoid Arthritis/Ankylosing Spondylitis	250 mg twice daily	1000 mg
Analgesia/Musculoskeletal Injuries	250 mg three times daily	1000 mg
Dysmenorrhea	500 mg initial dose then 250 mg every 6-8 hours	1250 mg

Naproxen (enteric coated tablets) 250 mg is not currently marketed by PRO DOC LTÉE in Canada.

Take PRO-NAPROXEN EC 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 PRO-NAPROXEN EC 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 PRO-NAPROXEN EC 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.

PRO-NAPROXEN EC should not be used in patients under 18 years of age since safety and effectiveness have NOT been established.

PRO-NAPROXEN EC tablets should be swallowed with food or milk. **PRO-NAPROXEN EC tablets should be swallowed whole; do not split, chew, or crush them.**

Missed Dose:

It may be a good idea to ask your doctor or pharmacist ahead of time what to do about missed doses. If you forget to take a dose of PRO-NAPROXEN EC take it as soon as possible, then just carry on with the regular times you take your medication. If you remember your missed dose close to the time of your next dose, do not take the missed dose.

Overdose:

If you think you have taken too much PRO-NAPROXEN EC, 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

PRO-NAPROXEN EC tablets may cause some side effects, especially when 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.

PRO-NAPROXEN EC 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 PRO-NAPROXEN EC, do NOT drive or operate machinery.

PRO-NAPROXEN EC 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 health care provider.

Check with your health care provider IMMEDIATELY if you develop chills, fever, muscle aches or pains, or other flu-like symptoms, 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

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

Symptom	STOP taking PRO-NAPROXEN EC and get emergency medical attention IMMEDIATELY	Stop taking PRO-NAPROXEN EC tablets and talk to your physician or pharmacist
Bloody or black tarry stools	√	
Shortness of breath, wheezing, any trouble breathing or chest tightness	√	
Skin rash, hives, swelling or itching	√	
Blurred vision, or any visual disturbance	√	
Any change in the amount or colour of your urine (red or brown)	√	
Any pain or difficulty experienced while urinating		√
Swelling of the feet, lower legs; 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, loss of appetite		√
Headaches, stiff neck		√
Mental confusion, depression		√
Dizziness, lightheadedness		√
Hearing problems		√

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

HOW TO STORE IT

PRO-NAPROXEN EC tablets: Store at room temperature (15 to 30°C). Store in a dry place.

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.

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/adverse-reaction-reporting.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.

MORE INFORMATION

If you want more information about PRO-NAPROXEN EC:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodqc.ca or info@prodqc.ca.

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