

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **PRO-NAPROXEN EC**

Naproxen Enteric-Coated Tablets

Read this carefully before you start taking **PRO-NAPROXEN EC** 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 **PRO-NAPROXEN EC**.

Serious Warnings and Precautions

Heart and blood vessel problems:

- PRO-NAPROXEN EC can cause heart and blood vessel problems like heart attacks, stroke, blood clots, high blood pressure and heart failure. These can lead to death.
- The risk of having heart problems is higher if you take PRO-NAPROXEN EC for long periods of time and/or at higher doses and/or in people who have heart disease.
- Tell your healthcare professional if you have or had heart problems, high blood pressure or diabetes.

Stomach and intestine (gastrointestinal) problems:

- PRO-NAPROXEN EC can cause stomach and intestine problems like ulcers, inflammation, bleeding, holes/perforation, blockage or pain.

Talk to your healthcare professional about any medical conditions you have and drugs you are taking.

Pregnancy:

- DO NOT take PRO-NAPROXEN EC if you are pregnant and in a later stage of pregnancy (28 weeks or later).
- If you are pregnant and in an earlier stage of pregnancy (less than 28 weeks) only take PRO-NAPROXEN EC if you are told to do so by your healthcare professional.
- Medicines like PRO-NAPROXEN EC may cause harm to you and your baby. Your healthcare professional will need to closely monitor your health and that of your baby (including your amniotic fluid levels) if they prescribe PRO-NAPROXEN EC during this time.
- Tell your healthcare professional right away if you become pregnant, think you may be pregnant or want to get pregnant during your treatment with PRO-NAPROXEN EC.

What is PRO-NAPROXEN EC used for?

PRO-NAPROXEN EC is used in adults to:

- Treat of signs and symptoms of arthritis, disorder such as
 - Osteoarthritis
 - Rheumatoid arthritis
 - Ankylosing spondylitis
- help relieve:
 - minor aches and pains in muscles, bones and joints
 - mild to moderate pain with inflammation in sprains and strains and period cramps (primary dysmenorrhea).

How does PRO-NAPROXEN EC work?

- PRO-NAPROXEN EC (naproxen) belongs to a group of medicines called as a non-steroidal anti-inflammatory drug (NSAID). It can reduce the chemicals produced by your body which cause pain and swelling.
- PRO-NAPROXEN EC only treats the symptoms and relieve pain and inflammation as long as you take it. PRO-NAPROXEN EC does not cure the illness or stop it from getting worse.

What are the ingredients in PRO-NAPROXEN EC?

Medicinal ingredient: naproxen

Non-medicinal ingredients:

- PRO-NAPROXEN EC Tablets contain the following nonmedicinal ingredients: Chromateric White Deb 5018 WE, Colloidal Silicon Dioxide, Croscarmellose Sodium (Ac-Di-Sol), Dri Klear 042, Eudragit L30D, Magnesium Stearate, Povidone and Sodium Lauryl Sulphate.

PRO-NAPROXEN EC comes in following dosage forms:

- enteric coated tablets, 500 mg

Do not use PRO-NAPROXEN EC if you:

- have heart bypass surgery (planning to have or recently had).
- have severe, uncontrolled heart failure.
- are bleeding in the brain or other bleeding disorders.
- are pregnant and in a later stage of pregnancy (28 weeks or later).
- are currently breastfeeding (or planning to breastfeed).
- are allergic to naproxen or any of the other ingredients in this medicine or the container.
- have a history of asthma, hives, growths in your nose, sinus swelling or symptoms of an allergic reaction after taking acetylsalicylic acid (ASA) or other NSAIDs.
- have active stomach or intestine ulcers.
- have active bleeding from the stomach or gut.
- have inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis).
- have liver disease (active or severe).
- have kidney disease (severe or worsening).
- have high potassium in the blood.
- are under 18 years old.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-NAPROXEN EC. Talk about any health conditions or problems you may have, including if you:

- Have high blood pressure, high cholesterol or diabetes
- Have or had heart attacks, chest pain, heart disease, stroke or heart failure
- Have poor blood flow to your extremities (like your hands and feet)
- Smoke or used to smoke
- Drink a lot of alcohol
- Have a stomach infection

- Have liver or kidney problems, urine problems or are dehydrated
- Have a history of ulcer or bleeding from the stomach or gut (small or large intestine)
- Have other bleeding or blood problems
- Have asthma
- Are pregnant, planning on becoming or become pregnant while taking PRO-NAPROXEN EC.
- Have immune system problems

Other warnings you should know about:

Serious Side Effects: PRO-NAPROXEN EC can cause serious side effects, including:

- **Blood and bleeding problems:**
 - PRO-NAPROXEN EC can cause blood problems, bleeding and prolonged bleeding.
 - Taking PRO-NAPROXEN EC with the following drugs can increase the risk of bleeding:
 - anticoagulants (prevents blood clots), corticosteroids (anti-inflammatory) or antidepressants like selective serotonin reuptake inhibitors (SSRIs).
- **Serious skin reactions:** In rare cases, serious, life-threatening allergic and skin reactions have been reported with some NSAIDs, such as PRO-NAPROXEN EC. These skin problems most often happen during the first month of treatment. Tell your healthcare professional immediately if you notice any changes in your skin both during and after treatment.
PRO-NAPROXEN EC might cause you to become more sensitive to sunlight. 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, talk to your healthcare professional.

Check-ups and testing: You will have regular visits with your healthcare professional during treatment with PRO-NAPROXEN EC to monitor your health. They will:

- Check your blood pressure.
- Check your eyes. PRO-NAPROXEN EC can cause blurred or reduced vision.
- Do blood and urine tests to check your liver, kidney and blood health.

Surgery: Tell any doctor, dentist, pharmacist or healthcare professional that you see, that you are taking this medicine. This is especially important if you are planning to have heart surgery.

Driving and Using Machines: PRO-NAPROXEN EC may cause eye or nervous system problems. This includes tiredness, trouble sleeping, blurred vision, spinning or dizziness (vertigo), hearing problems or depression. Be careful about driving or doing 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.

Fertility in Women: PRO-NAPROXEN EC may affect your fertility. This means that it may be difficult for you to have a child. If you have trouble having a child, you might need to stop taking PRO-NAPROXEN EC. Talk to your healthcare professional if you have questions about this.

Adults (65 years or older): Side effects like gastrointestinal problems may happen more often. Your healthcare professional might have you start with a lower dose of PRO-NAPROXEN EC. They will monitor your health during and after treatment.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PRO-NAPROXEN EC:

- Acetylsalicylic Acid (ASA) or other NSAIDs, used to treat pain, fever and inflammation, like:
 - celecoxib, diclofenac, ibuprofen, naproxen
- Antacids, used to treat symptoms of excess stomach acid
- Medicines used to treat depression (antidepressants) like citalopram, fluoxetine, paroxetine, sertraline, and lithium
- Medicines used to treat high blood pressure like enalapril, ramipril, candesartan, irbesartan, propranolol
- Medicines used as blood thinners or to prevent blood clots, like warfarin, ASA, clopidogrel
- Medicines used to lower extra fluid levels (diuretics), like furosemide, hydrochlorothiazide
- Medicines used to treat diabetes, like sulphonylurea or other oral hypoglycemics
- Medicines used to treat bacteria infections (antibiotics) like quinolone or sulphonamide
- Medicines used to lower the risk of organ rejection, like tacrolimus and cyclosporin
- Corticosteroids (including glucocorticoids such as prednisone), used as an anti-inflammatory
- Cholestyramine, used to lower cholesterol levels
- Digoxin, used to treat heart disorders
- Hydantoin, used to treat seizures
- Medicines used to treat different cancers, like methotrexate and pemetrexed
- Oral birth control, used to prevent pregnancy
- Probenecid, used to prevent gout
- Alcohol

How to take PRO-NAPROXEN EC:

- Take exactly as your healthcare professional has told you. They should recommend the lowest dose possible for your treatment for the shortest time needed.
- Swallow PRO-NAPROXEN EC whole with food or milk. Do NOT split, chew or crush the tablets.
- **This medicine 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.**
- If you will be taking PRO-NAPROXEN EC for more than 7 days, see your healthcare professional regularly. They will check if PRO-NAPROXEN EC is working for you and if it is causing any side effects.

Usual dose:

Adult 18 years and older:

- Your healthcare professional will decide on the best dosage for you based on your condition.
- Your healthcare professional may lower your dose, stop your treatment for a period of time or recommend that you stop treatment completely. This may happen if you:
 - experience serious side effects, or
 - your disease gets worse.

Overdose:

If you think you, or a person you are caring for, have taken too much PRO-NAPROXEN EC, contact a health professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of PRO-NAPROXEN EC, take the dose as soon as possible. Take your next dose at the usual time.
- If it is close to the time of your next dose, skip the missed dose. Take your next dose at the usual time.
- Do not take two doses at the same time to make up for a forgotten dose.

What are possible side effects from using PRO-NAPROXEN EC:

These are not all the possible side effects you may have when taking PRO-NAPROXEN EC. If you experience any side effects not listed here, tell your healthcare professional.

- Nausea, vomiting, diarrhea, constipation, stomach upset/abdominal pain, heartburn, indigestion, feeling gassy
- Headache, dizziness, light-headedness
- Feeling of burning/prickliness/numbing
- Confusion, hard to concentrate or think, short-term memory loss, nervousness
- Bruises
 - Skin rash
- Taste disorder, thirst, dry mouth
- Muscle pain
- Mouth sores
- Hair loss
- Increased sweating
- Problems with your period (women)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Gastrointestinal (GI) problems (bleeding, blockage, holes, ulcers or inflammation in your GI tract): blood in vomit, black tarry or bloody stool, dizziness, stomach pain, bloating, loss of appetite, weight loss, nausea, vomiting, constipation or diarrhea, chills or fever		√	
Hypertension (high blood pressure): fatigue, dizziness or fainting, chest pain	√		
UNCOMMON			
Anaphylaxis/hypersensitivity (severe allergic reactions): sudden wheeziness and chest pain or tightness; or swelling of eyelids, face, lips, tongue or throat, swelling or anaphylactic reaction/shock			√
Aseptic meningitis (inflammation of the protective lining of the brain that is not caused by infection): Headaches, stiff neck, nausea and vomiting, fever or clouding of consciousness		√	

Blood problems (low white and/or red blood cell or platelet count): feeling tired or weak, pale skin, bruising or bleeding for longer than usual if you hurt yourself, fever, chills		√	
Congestive heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			√
Cystitis (bladder infection): increased need to urinate, pain in the pelvis or lower back, frequent urination during the night, cloudy urine that may contain blood, burning or pain urinating		√	
Depression (sad mood that will not go away): difficulty sleeping or sleeping too much, changes in appetite or weight, reduced sex drive and thoughts of death or suicide.		√	
Kidney disorder/problems (including kidney failure): nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, rash, weight gain (from retaining fluid), loss of appetite, mental status changes (drowsiness, confusion, coma)		√	
Liver problems (including hepatitis, liver failure, cholestasis): yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness		√	
Lung problems, asthma: increased shortness of breath, wheezing, difficulty breathing, cough and chest tightness, irregular heartbeat			√
Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-			√

headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat.			
Stroke (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurry vision, difficulty swallowing or speaking, or lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance			√
Tinnitus (hearing problems): includes ringing, buzzing, clicking or hissing in ears, loss of hearing		√	
Vertigo (a sense of severe spinning dizziness, lightheadedness)		√	
RARE			
Serious Skin Reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, swelling of face and/or legs, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine or dark urine, hives, red or dry itchy skin, purple or red spots on skin			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.

Storage:

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

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

Keep out of reach and sight of children.

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 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>); Or by contacting Pro Doc Ltée at : 1-800-351-8559, www.prodoc.qc.ca, or medinfo@prodoc.qc.ca.

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