IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

[Pr]APO-NAPROXEN
Naproxen Tablets
125 mg, 250 mg, 375 mg and 500 mg

[Pr]APO-NAPROXEN SR
Naproxen Sustained-Release Tablets
750 mg
[Pr]APO-NAPROXEN EC
Naproxen Enteric-Coated Tablets
250 mg, 375 mg and 500 mg
Apotex Standard

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-NAPROXEN.
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-NAPROXEN 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:
APO-NAPROXEN (naproxen), as a non-steroidal anti-inflammatory drug (NSAID), can reduce the chemicals produced by your body which cause pain and swelling.
APO-NAPROXEN, as a non-steroidal anti-inflammatory drug (NSAID), does NOT cure your illness or prevent it from getting worse.
APO-NAPROXEN 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-NAPROXEN 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 (Nonsteroidal 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 APO-NAPROXEN 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.

APO-NAPROXEN 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 non-medicinal ingredients are:
APO- NAPROXEN (immediate release) Tablets contain the following non-medicinal ingredients: methylcellulose, croscarmellose sodium, magnesium stearate, and colloidal silicon dioxide. The 250 and the 500 mg tablets also contain D&C yellow #10 and FD&C yellow #6; the 375 mg tablets contain only the latter; the 125 mg tablets contain the former and FD&C blue #2.
APO-NAPROXEN SR (sustained-release) tablets containthe following non-medicinal ingredients hydroxypropyl methylcellulose, FD&C yellow #6, D&C yellow #10, and magnesium stearate.
APO-NAPROXEN EC (enteric-coated) tablets contain the following non-medicinal ingredients methylcellulose, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, hydroxyethyl cellulose, polyethylene glycol, titanium dioxide, triethyl citrate, talc and methacrylic acid copolymer.

What dosage forms it comes in:
APO-NAPROXEN is available as immediate release tablets (125 mg, 250 mg, 375 mg and 500 mg); enteric coated tablets (250 mg, 375 mg and 500 mg) and sustained-release tablet (750 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 APO-NAPROXEN:

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

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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 APO-NAPROXEN is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping APO-NAPROXEN should be considered.

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 APO-NAPROXEN. 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-NAPROXEN and ASA than if you took APO-NAPROXEN alone.

PROPER USE OF THIS MEDICATION

APO-NAPROXEN (tablets) 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 (given as 500 mg twice daily)
Analgesia/ Musculoskeletal Injuries	250 mg three times daily	1000 mg (given as 500 mg twice daily)
Dysmenorrhea	500 mg initial dose then 250 mg every 6-8 hours	1250 mg (given in divided doses)

Take APO-NAPROXEN only as directed by your health care provider.

IMPORTANT: PLEASE READ

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

APO-NAPROXEN EC and APO-NAPROXEN SR have not been studied in subjects under the age of 18.

APO-NAPROXEN tablets should be swallowed with food or milk.

APO-NAPROXEN SR (sustained-release) and APO-NAPROXEN EC (enteric-coated) 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 APO-NAPROXEN 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:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

APO-NAPROXEN 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.

APO-NAPROXEN 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-NAPROXEN, do NOT drive or operate machinery.

APO-NAPROXEN 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, 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	STOP taking APO-NAPROXEN and get emergency medical attention IMMEDIATELY	Stop taking APO-NAPROXEN 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		√

IMPORTANT: PLEASE READ

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM		
Symptom	**STOP taking APO-NAPROXEN and get emergency medical attention IMMEDIATELY**	**Stop taking APO-NAPROXEN and talk to your physician or pharmacist**
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 APO-NAPROXEN, see your health care provider.

HOW TO STORE IT

Store at room temperature (15-30°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 the sight and reach of children.

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada,
    Postal Locator 0701E
    Ottawa, ON, K1A 0K9

  Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

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

For more information, please contact your doctor, pharmacist or other healthcare professional.

This document plus the full product monograph, prepared for health professionals can be obtained by contacting DISpedia at:

1-800-667-4708
This leaflet can also be found at: http://www.apotex.ca/products

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

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