PART III: CONSUMER INFORMATION

PrNAPROXEN-NA
PrNAPROXEN-NA DF
Naproxen Sodium, USP

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 NAPROXEN-NA or NAPROXEN-NA DF. 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 NAPROXEN-NA or NAPROXEN-NA DF for you for one or more of the following medical conditions:

• For the relief of mild to moderately severe pain, accompanied by inflammation in conditions such as musculo skeletal trauma and post-dental extraction.
• For the relief of pain associated with post-partum cramping and dysmenorrhea.

What it does:
NAPROXEN-NA or NAPROXEN-NA DF (naproxen sodium), as a nonsteroidal anti-inflammatory drug (NSAID), can reduce the chemicals produced by your body which cause pain and swelling.

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

When it should not be used:
DO NOT TAKE NAPROXEN-NA or NAPROXEN-NA DF 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 NAPROXEN-NA or NAPROXEN-NA DF 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.

NAPROXEN-NA or NAPROXEN-NA DF 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 sodium

What the important non-medicinal ingredients are: NAPROXEN-NA or NAPROXEN-NA DF Tablets contain the following non-medicinal ingredients: Magnesium Stearate, Microcrystalline Cellulose, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Colloidal Silicon Dioxide and Purified Water. The coating suspension for both the 275 mg and 550 mg tablets contain FD&C Blue #2, Hypromellose, Polyethylene Glycol, Polysorbate and Titanium Dioxide.

What dosage forms it comes in:
NAPROXEN-NA or NAPROXEN-NA DF are available as: film coated tablets (275 mg and 550 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 NAPROXEN-NA or NAPROXEN-NA DF:
- **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 NAPROXEN-NA or NAPROXEN-NA DF is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping NAPROXEN-NA or NAPROXEN-NA DF 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 NAPROXEN-NA or NAPROXEN-NA DF. 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 NAPROXEN-NA or NAPROXEN-NA DF and ASA than if you took NAPROXEN-NA or NAPROXEN-NA DF alone.

PROPER USE OF THIS MEDICATION

Usual dose: 18 years of age and older:

Medical Condition	Starting Dose	Maximum Dose (per day)
• For the relief of mild to moderately severe pain, accompanied by inflammation in conditions such as musculo skeletal trauma and postdental extraction. • For the relief of pain associated with postpartum cramping and dysmenorrhea.	Two 275 mg tablets or one 550 mg tablet followed by one 275 mg tablet every six to eight hours as required.	Should not exceed 1375 mg.

Take NAPROXEN-NA or NAPROXEN-NA DF 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 NAPROXEN-NA or NAPROXEN-NA DF 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 NAPROXEN-NA or NAPROXEN-NA DF 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.

NAPROXEN-NA or NAPROXEN-NA DF is NOT recommended for use in patients under 18 years of age since safety and effectiveness have NOT been established.

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 NAPROXEN-NA or NAPROXEN-NA DF 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

NAPROXEN-NA or NAPROXEN-NA DF 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.

NAPROXEN-NA or NAPROXEN-NA DF 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 lightheaded after taking NAPROXEN-NA or NAPROXEN-NA DF, do NOT drive or operate machinery.

NAPROXEN-NA or NAPROXEN-NA DF 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 NAPROXEN-NA or NAPROXEN-NA DF and get emergency medical attention IMMEDIATELY**	**Stop taking NAPROXEN-NA or NAPROXEN-NA DF 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 NAPROXEN-NA or NAPROXEN-NA DF, see your health care provider.

HOW TO STORE IT

Store at room temperature (15 to 30°C) in a well-closed container. Protect from light. 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 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:

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- **Report online at 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.

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 found by Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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