

PART III: CONSUMER INFORMATION

DAYPRO (Oxaprozin)

Read this information each time you refill your prescription in case new information has been added.

This leaflet is part III of a three-part "Product Monograph" published when Daypro was approved for sale in Canada and is designed specifically for-you to read. It will NOT tell you everything about Daypro. 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:

Daypro (oxaprozin) which has been prescribed to you by your doctor is used to treat the symptoms of rheumatoid arthritis and osteoarthritis.

What it does:

Daypro (oxaprozin), as a nonsteroidal anti-inflammatory drug (NSAID), helps to relieve joint pain, swelling and stiffness by reducing the production of certain substances (prostaglandins) and by helping to control inflammation. Daypro, does NOT cure arthritis, but it promotes suppression of the inflammation and the tissue damaging effects resulting from this inflammation. Daypro can only relieve pain and reduce swelling as long as you continue to take it.

When it should not be used:

DO NOT TAKE Daypro 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 Daypro 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.

Daypro is not recommended for patients under 18 years of age since safety and effectiveness have not been established.

What the medicinal ingredient is:

Oxaprozin

What the important nonmedicinal ingredients are:

Cellulose, corn starch, hypromellose, magnesium stearate, methylcellulose, polacrillin potassium, polyethylene glycol, titanium dioxide

What dosage forms it comes in:

Caplet 600 mg

WARNINGS AND PRECAUTIONS

Serious Warning and Precautions:

If you have, or previously had, any of the following medical conditions, see your healthcare provider to discuss treatment options other than Daypro:

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

BEFORE you use Daypro talk to your doctor or pharmacist 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
- 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 chronic urticaria (hives);
 - you are on any special diet, such as a low-sodium or low-sugar diet;
 - any other medical problem(s) such as alcohol abuse, etc.

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

WHILE taking Daypro:

- tell any other doctor, dentist, pharmacist or other healthcare professional that you consult or 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 Daypro is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping Daypro should be considered.
- check with your doctor if you are not getting any relief of your arthritis or if any problems develop;
- report any untoward reactions to your doctor; this is very important as it will aid in the early detection and prevention of potential complications.
- your regular medical checkups are essential.

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. ASA, celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen)
- Antidepressants
 - Selective Serotonin Reuptake Inhibitors (SSRIs) (e.g. citalopram, fluoxetine, paroxetine, sertraline)
- Antimalarials
- Beta-blockers
- 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)
- Cimetidine/ranitidine
- Corticosteroids (including glucocorticoids) (e.g. prednisone)
- Cyclosporin/tacrolimus
- Diuretics (e.g. furosemide, hydrochlorothiazide)
- Gold salts
- Glyburide
- Lithium
- Methotrexate
- Oral hypoglycemics (diabetes medications)
- Phenytoin

Do not take ASA (acetylsalicylic acid), ASA-containing

compounds, or other drugs used to relieve symptoms of arthritis while taking Daypro unless directed to do so by your physician. Your healthcare 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 Daypro. 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 Daypro and ASA than if you took Daypro alone.

PROPER USE OF THIS MEDICATION

Usual Dose:

Medical Condition	Starting Dose	Maximum Dose (per day)
Rheumatoid arthritis	1200 mg once daily	1800 mg (1200 mg in the morning and 600 mg in the evening)
Osteoarthritis	1200 mg once daily (your doctor may decrease your dose to 600 mg once daily)	1200 mg once daily

Daypro is usually taken once a day, after breakfast or with some food or milk. Some people are told by their doctor to take it twice a day. The first dose is taken in the morning and the second in the evening. When Daypro is taken twice a day, the morning dose may be larger than the evening dose. To lessen stomach upset, take this medicine immediately after a meal or with food or milk. Also, you should remain standing or sitting upright (i.e. do not lie down) for about 15-30 minutes after taking the medicine. This helps to prevent irritation that may lead to trouble swallowing.

Take Daypro 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 doctor healthcare provider ordered. If possible, you should take the lowest dose of this medication for the shortest time period.** Taking too much Daypro may increase the chance of unwanted and sometimes dangerous side effects, especially if you are an elderly patient, have other disease or take other medications.

If you will be using Daypro for more than 7 days, see your healthcare provider regularly to discuss whether this medicine is working for you and if it causing you any unwanted effects. Be sure to take Daypro regularly as prescribed. In some types of arthritis, up to two weeks may pass before you feel the full effects of this medicine. During treatment, your doctor may decide to adjust the dosage according to your response to the medication.

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.

Daypro is NOT recommended for use in patients under 18 years of age since safety and effectiveness have NOT been established.

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Missed Dose:

Skip the missed dose and take the next dose at the scheduled time.

Overdose:

The symptoms of overdose may include lethargy, drowsiness, nausea, vomiting, and stomach pain. If you take more than the prescribed dose, contact your healthcare provider immediately, even if there are no signs of discomfort or poisoning.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Daypro may cause some undesirable reactions 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 healthcare provider.

Daypro 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 Daypro, do NOT drive or operate machinery.

Daypro 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 healthcare 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.

Check with your doctor immediately if you experience unexpected weakness while taking this medication, or if you vomit any blood or have dark or bloody stools.

Elderly, frail, or debilitated patients often seem to experience more frequent or more severe side effects.

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

Symptom	STOP taking Daypro and get emergency medical attention IMMEDIATELY	STOP taking Daypro and talk your doctor or pharmacist
Bloody or black tarry stools	✓	
Shortness of breath, wheezing, any trouble in breathing or	✓	

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

Symptom	STOP taking Daypro and get emergency medical attention IMMEDIATELY	STOP taking Daypro and talk your doctor or pharmacist
tightness in the chest		
Skin rash, hives or swelling, 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 or lower legs; weight gain		✓
Vomiting or persistent indigestion, nausea, stomach pain or diarrhea		✓
Yellow discoloration 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 Daypro, see your healthcare provider..

HOW TO STORE IT

Store at 15-25°C. Protect from light. 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 reach of children.**

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REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadrmp@hc-sc.gc.ca

By regular mail:

Canadian Adverse Drug Reaction Monitoring Program
(CADRMP)

Marketed Health Products Directorate

Health Canada

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals may be obtained by contacting the sponsor, Pfizer Canada Inc., at:
1-800-463-6001

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