

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

^{Pr}DICLOFENAC - 50

Diclofenac Sodium Enteric Coated Tablets
50 mg

^{Pr}DICLOFENAC - SR

Diclofenac Sodium Slow Release Tablets
75 and 100 mg

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 DICLOFENAC - 50 /DICLOFENAC - SR were approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DICLOFENAC - 50 / DICLOFENAC - SR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Your health care provider has prescribed DICLOFENAC - 50 or DICLOFENAC - SR for you to relieve pain and swelling in rheumatoid arthritis and osteoarthritis, including degenerative joint disease of the hip.

DICLOFENAC - 50 and DICLOFENAC - SR is used for maintenance therapy only.

What it does:

DICLOFENAC - 50 and DICLOFENAC - SR (diclofenac sodium), as nonsteroidal anti-inflammatory drugs (NSAIDs), can reduce the chemicals prostaglandins produced by your body which cause pain and swelling.

DICLOFENAC - 50 and DICLOFENAC - SR, as nonsteroidal anti-inflammatory drugs (NSAIDs) do NOT cure your illness or prevent it from getting worse. DICLOFENAC - 50 or DICLOFENAC - SR can only relieve pain and reduce swelling as long as you continue to take it.

When it should not be used:

DO NOT TAKE DICLOFENAC - 50 or DICLOFENAC - SR if you have any of the following 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 (hypersensitivity) to diclofenac sodium, or ASA (Acetylsalicylic Acid) or other NSAIDs (Nonsteroidal Anti-Inflammatory Drugs), or any of the nonmedicinal ingredients in DICLOFENAC - 50 or DICLOFENAC - SR .
- 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 DICLOFENAC - 50 and DICLOFENAC - SR 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.

DICLOFENAC - 50 and DICLOFENAC - SR should NOT be used in patients under 16 years of age since the safety and effectiveness have NOT been established.

What the medicinal ingredient is:

Diclofenac sodium

What the important non-medicinal ingredients are:

Each enteric coated tablet contains the non-medicinal ingredients dextrates, methylcellulose, stearic acid, magnesium stearate, colloidal silicon dioxide, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide, yellow ferric oxide, FD & C yellow #6, polyvinylacetate phthalate, triethyl citrate and methanol.

Each slow release tablet contains the non-medicinal ingredients dextrates, microcrystalline cellulose, hydroxyethyl cellulose, magnesium stearate, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide and red ferric oxide.

What dosage forms it comes in:

DICLOFENAC - 50 50 mg (enteric coated): light brown, round, identified '50' on one side.

DICLOFENAC - SR (slow release) 75 mg: light pink, triangular, identified 'PRO' over '75' on one side

DICLOFENAC - SR (slow release) 100 mg: pink, round, identified 'PRO' over '100' on one side.

Check with your pharmacist if the identifying markings or color appear different.

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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 DICLOFENAC - 50 or DICLOFENAC - SR :

- 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
- 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 DICLOFENAC - 50 or DICLOFENAC - SR is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping DICLOFENAC - 50 or DICLOFENAC - SR should be considered.

Long-term use of DICLOFENAC - 50 or DICLOFENAC - SR might increase the risk of heart attacks or strokes.

INTERACTIONS WITH THIS MEDICATION

What About Taking Other Drugs At The Same Time?

See 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):

- Acetaminophen
- Acetylsalicylic Acid (ASA) or other NSAIDs
e.g. ASA, celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen
- Alcohol
- Antacids
- Anti-depressants
- 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
 - Beta-blockers
e.g. metoprolol
- Blood thinners (medicine used to prevent blood clotting)
e.g. warfarin, ASA, clopidogrel
- Corticosteroids (including glucocorticoids) (medicines used to provide relief for inflamed areas of the body)
e.g. prednisone
- Cyclosporin or tacrolimus (a medicine primarily used in patients who have received organ transplants)
- Digoxin (a medicine used for heart problems)
- Diuretics (medicines used to increase the amount of urine)
e.g. furosemide, hydrochlorothiazide
- Lithium
- Methotrexate (a medicine used to treat some kinds of cancer or arthritis)
- Oral hypoglycemics (diabetes medications)
- Probenecid
- Quinolone antibacterials (medicines used against infection)

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 DICLOFENAC - 50 or DICLOFENAC - SR. 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 DICLOFENAC - 50 or DICLOFENAC - SR and ASA than if you took

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DICLOFENAC - 50 or DICLOFENAC - SR alone.

PROPER USE OF THIS MEDICATION

Usual dose:

Medical Condition (Age Group)	Maintenance Dose	Maximum Dose (per day)*
DICLOFENAC - 50 50 mg enteric coated tablets		
Rheumatoid Arthritis (16 years of age and older)	Maintenance dose only: 50 mg 2 times a day	100 mg
Osteoarthritis (16 years of age and older)	Maintenance dose only: 50 mg 2 times a day	100 mg
DICLOFENAC - SR 75 mg and 100 mg slow release tablets		
Rheumatoid Arthritis (16 years of age and older)	75 mg once daily	100 mg
Osteoarthritis (16 years of age and older)	75 mg once daily	100 mg

* If your symptoms are not adequately controlled, you should contact your doctor, who may increase the total daily dose to a maximum of 150 mg in divided doses for a short period and with close monitoring. If you are older than 65 years, have liver problems, kidney problems, or heart problems, the maximum total dose per day should not exceed 100 mg of DICLOFENAC - 50 (50 mg twice a day).

Take DICLOFENAC - 50 or DICLOFENAC - SR 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 DICLOFENAC - 50 or DICLOFENAC - SR may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly, have other diseases or take other medications.

Whether you have been prescribed oral tablets make sure that you do not take more than a total of 100 mg per day, unless directed by your doctor.

If you will be using DICLOFENAC - 50 or DICLOFENAC - SR 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.

DICLOFENAC - 50 (enteric coated tablets):

DICLOFENAC - 50 tablets are an extended release product. **Tablets should be swallowed whole with water and must not be divided or chewed.**

Taking DICLOFENAC - SR Tablets Once A Day
If you are taking DICLOFENAC - SR 100 mg tablet or DICLOFENAC - SR 75 mg tablet **once** a day, it is best to take this tablet at the same time each day unless your doctor has told you differently.

Taking DICLOFENAC - SR Tablets Twice A Day
If your doctor has prescribed 150 mg of DICLOFENAC - SR for a short period of time, you should take DICLOFENAC - SR 75 mg tablet twice a day, in the morning and evening.

To help reduce the possibility of stomach upset you should take DICLOFENAC - 50 or DICLOFENAC - SR tablets 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. If stomach upset (indigestion, nausea, vomiting, stomach pain or diarrhea) occurs and continues, contact your doctor

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.

DICLOFENAC - 50 or DICLOFENAC - SR is NOT recommended for use in patients under 16 years of age since safety and effectiveness have NOT been established.

Missed Dose:

If you forget to take one or more doses of DICLOFENAC - 50 (diclofenac sodium) 50 mg tablets or DICLOFENAC - SR (diclofenac sodium) 75 mg and 100 mg tablets, you should not increase the dose of DICLOFENAC - 50 (diclofenac sodium) or DICLOFENAC - SR to make up for the missed dose or doses, but you should continue taking your tablet at the next prescribed or regular time.

Overdose

If you have accidentally taken more than the prescribed dose of DICLOFENAC - 50 tablets or DICLOFENAC - SR tablets **contact your doctor, pharmacist or poison control centre immediately, or go to the hospital emergency unit at once.** You may require medical attention.

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SIDE EFFECTS AND WHAT TO DO ABOUT THEM

DICLOFENAC - 50 or DICLOFENAC - SR 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.

DICLOFENAC - 50 or DICLOFENAC - SR 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 DICLOFENAC - 50 or DICLOFENAC - SR, do NOT drive or operate machinery.

DICLOFENAC - 50 or DICLOFENAC - SR 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 AND WHAT TO DO ABOUT THEM		
Symptom	STOP taking DICLOFENAC - 50 or DICLOFENAC - SR and get emergency medical attention IMMEDIATELY	STOP taking DICLOFENAC - 50 or DICLOFENAC - SR 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 discoloration of the skin or eyes (signs of liver failure), with or without itchy skin		*
Malaise, fatigue, loss of appetite		*
Headaches, stiff neck		*
Mental confusion, depression		*
Dizziness, lightheadedness		*
Hearing problems		*
Rectal itching or bleeding		*

This is NOT a complete list of side effects. If you develop any other symptoms while taking DICLOFENAC - 50 and/or DICLOFENAC - SR, see your health care provider.

HOW TO STORE IT

Store at room temperature between (15°C-30°C) and protect from high humidity.

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

Keep this and all medication out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

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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:

- Report on line 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 0701C
Ottawa, ON 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

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

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at : 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca

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