PART III CONSUMER INFORMATION

[Pr] DICLOFENAC-SR
(Diclofenac sodium)

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-SR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will NOT tell you everything about 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-SR for you to relieve pain and swelling in rheumatoid arthritis and osteoarthritis, including degenerative joint disease of the hip.

What it does:
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-SR, as nonsteroidal anti-inflammatory drugs (NSAIDs) do NOT cure your illness or prevent it from getting worse. 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-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-SR**
- **Ulcer (active)**
- **Bleeding or perforation 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-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-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 non-medicinal ingredients are:
The slow-release 75 mg and 100 mg tablets (DICLOFENAC-SR) contain black ink, carnauba wax, cellulose compounds, cetyl alcohol, colloidal silicon dioxide, hypromellose magnesium stearate, polysorbate 80, povidone, red iron oxide, sucrose, talc, titanium dioxide.

What dosage forms it comes in:
DICLOFENAC-SR 75 mg Slow Release (SR) tablet: light pink, triangular, **SR 75** on one side and plain on the other.
DICLOFENAC-SR 100 mg Slow Release (SR) tablet: pink, round, **SR 100** on one side and plain on the other.

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

WARNINGS AND PRECAUTIONS

If you have, or previously had, any of the following conditions, see your health care provider to discuss treatment options other than DICLOFENAC-SR:

- **Heart Attack or Angina**
- **Stroke or Mini-stroke**
- **Loss of Vision**
- **Current Pregnancy (less than 28 weeks)**
- **Congestive Heart Failure**
- **High blood pressure**
- **Diabetes**
- **High levels of fats in your blood**
- **Smoking**

It is important to take the lowest dose of DICLOFENAC-SR that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk of side effects on the heart and blood vessels as small as possible.

Use of NSAIDS, such as DICLOFENAC-SR can result in increased blood pressure and /or worsening of congestive heart failure.

Use of NSAIDs, such as DICLOFENAC-SR, may

cause stomach and bowel problems (such as ulceration, perforation, obstruction and bleeding).

Before taking this medication, tell your health care provider if you have any of the following:

- Disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, or peripheral arterial disease), as treatment with DICLOFENAC-SR in these cases is not recommended.
- Risk factors for cardiovascular disease (see above) such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke.
- Diabetes mellitus or on a low sugar diet
- Atherosclerosis
- Poor circulation to your extremities
- 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-SR is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping DICLOFENAC-SR should be considered.
- if you have cardiovascular disease or risks for cardiovascular disease, your doctor will periodically re-evaluate whether you should continue treatment with DICLOFENAC-SR.
- Your doctor will monitor your kidney function, your liver function and your blood count to decide if DICLOFENAC-SR needs to be discontinued or if the dose needs to be changed.

If, at any time while taking DICLOFENAC-SR you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.

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

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

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 (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)
- Phenytoin (a medicine used to treat seizures).
- Probenecid
- Quinolone antibacterials (medicines used against infection)
- Sulfinpyrazone (a medicine used to treat gout)
- Tacrolimus (a medicine primarily used in patients who have received organ transplants)

- Trimethroprim (a medicine used to prevent or treat urinary tract infection)
- Voriconazole (a medicine used to treat fungal infections)

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-SR. Take only the amount of ASA prescribed by your health care provider. You are more likely to upset or damage you stomach if you take both DICLOFENAC-SR and ASA than if you took DICLOFENAC-SR alone.

PROPER USE OF THIS MEDICATION

DICLOFENAC-SR is used for maintenance therapy only.

Usual Dose for patients 16 years of age and older:

Medical Condition	Maintenance Dose	Maximum Dose (per day)
DICLOFENAC-SR 75 mg and 100 mg slow-release tablets		
Rheumatoid Arthritis	75 mg once daily	100 mg
Osteoarthritis	75 mg once daily	100 mg

Take 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-SR 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 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.

Swallow the tablet whole with water, do not chew or divide the tablet. It is best to take your dose at the same time each day.

To help reduce the possibility of stomach upset you should take 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.

Do not take suppositories by mouth.

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.

Missed dose:
If you forget to take your scheduled dose, you should not double the next scheduled dose to make up for the missed dose.

Overdose:

If you have accidentally taken more than the prescribed dose of 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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-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-SR, do NOT drive or operate machinery.

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 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 AND WHAT TO DO ABOUT THEM		
Symptom	**STOP taking DICLOFENAC-SR and get emergency medical attention IMMEDIATELY**	**STOP taking DICLOFENAC-SR and talk to your physician or pharmacist**
Bloody or black tarry stools, vomiting blood	√	
Spontaneous bleeding or	√	

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM		
Symptom	**STOP taking DICLOFENAC-SR and get emergency medical attention IMMEDIATELY**	**STOP taking DICLOFENAC-SR and talk to your physician or pharmacist**
bruising (signs of thrombocytopenia)		
Shortness of breath, wheezing, any trouble breathing or chest tightness	√	
Skin rash, hives, swelling or itching	√	
Skin rash with flacking or peeling (signs of dermatitis exfoliative).	√	
Purple skin patches (signs of purpura or Henoch-Schonlein purpura if caused by an allergy).	√	
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		√
Swelling mainly of the face and throat (signs of angioedema)		√
Vomiting or persistent indigestion, nausea, stomach pain or diarrhea		√
Yellow discolouration of the skin or eyes (signs of liver failure), with or without itchy skin		√
Malaise, fatigue, loss of appetite or « flu-like » symptoms		√
Headaches, stiff neck, fever, nausea, vomiting (signs of aseptic meningitis)		√
Mental confusion, depression		√
Dizziness, lightheadedness		√
Hearing problems		√
Rectal itching or bleeding		√
Right upper abdominal discomfort or pain		√

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

HOW TO STORE IT

Protect tablets from heat (i.e., store at temperatures between 15°C-30°C) and 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

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:

- 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, 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

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

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