

PART III: CONSUMER INFORMATION

Pr**DICLOFENAC EC**
(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 EC, 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 EC. 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 EC for you to relieve pain and swelling in rheumatoid arthritis and osteoarthritis, including degenerative joint disease of the hip.

What it does:

DICLOFENAC EC (diclofenac sodium), as a nonsteroidal anti-inflammatory drug (NSAID), can reduce the chemicals prostaglandins produced by your body which cause pain and swelling.

DICLOFENAC EC as a nonsteroidal anti-inflammatory drug (NSAID) does NOT cure your illness or prevent it from getting worse. DICLOFENAC EC 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 EC 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 EC
- 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 EC 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 EC 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:

DICLOFENAC EC (diclofenac sodium) 50 mg enteric coated tablets:

Each tablet contains the medicinal ingredient diclofenac sodium and non-medicinal ingredients: magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, silicon dioxide, sodium lauryl sulfate and sodium starch glycolate.

The film coating contains (50mg): hypromellose, iron oxide black, iron oxide red, iron oxide yellow, maltodextrin, methacrylic acid, polyethylene glycol, talc, titanium dioxide, triethyl citrate

Printing ink contains: black iron oxide, lecithin, shellac glaze, simethicone

What dosage forms it comes in:

DICLOFENAC EC (diclofenac sodium) 50 mg: Tan coloured, round, bi-convex, enteric film coated tablets, printed with black ink modified N/50 on one side and plain on the reverse.

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 EC:

- 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 EC 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 EC can result in increased blood pressure and /or worsening of congestive heart failure.

Use of NSAIDs, such as DICLOFENAC, 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 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 pregnant or 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 EC is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping DICLOFENAC EC 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 EC.
- Your doctor will monitor your kidney function, your liver function and your blood count to decide if DICLOFENAC EC needs to be discontinued or if the dose needs to be changed.

If, at any time while taking DICLOFENAC 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 EC might increase the risk of heart attacks or strokes.

DICLOFENAC EC 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 such as metformin)
- Phenytoin (a medicine used to treat seizures).
- Probenecid
- Quinolone antibacterials (medicines used against infection)
- Rifampin (an antibiotic medicine used to treat bacterial infections)
- Sulfapyrazone (a medicine used to treat gout)
- Tacrolimus (a medicine primarily used in patients who have received organ transplants)
- Trimethoprim (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 EC. 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 EC and ASA than if you took DICLOFENAC EC alone.

PROPER USE OF THIS MEDICATION

DICLOFENAC EC 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 EC 50 mg enteric-coated tablets		
Rheumatoid Arthritis	50 mg twice daily	100 mg
Osteoarthritis	50 mg twice daily	100 mg

Take DICLOFENAC EC 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 EC may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly and frail or if you have a low body weight, have other diseases or take other medications.

If you will be using DICLOFENAC EC 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 EC 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.

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 EC, **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 EC 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 EC 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 EC, do NOT drive or operate machinery.

DICLOFENAC EC 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 EC and get emergency medical attention IMMEDIATELY	STOP taking DICLOFENAC-EC and talk to your physician or pharmacist
Bloody or black tarry stools, vomiting blood	√	
Spontaneous bleeding or bruising (signs of thrombocytopenia)	√	
Shortness of breath, wheezing, any trouble breathing or chest tightness	√	
Skin rash, hives, swelling or itching	√	

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Skin rash with flaking 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		√

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Right upper abdominal discomfort or pain		√
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This is NOT a complete list of side effects. If you develop any other symptoms while taking DICLOFENAC EC, see your health care provider.

HOW TO STORE IT

Store between 15°-30°C.

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 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 (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- 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 (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

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

This document plus the full product monograph, prepared for health professionals can be found by contacting Sanis Health Inc., at:

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