

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr DICLOFENAC-50

Diclofenac Sodium Delayed-Release Tablets

Read this carefully before you start taking **DICLOFENAC-50** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DICLOFENAC-50**.

Serious Warnings and Precautions

Heart and blood vessel problems:

- DICLOFENAC-50 can cause heart and blood vessel problems like heart attacks, stroke, blood clots, high blood pressure and heart failure. These can lead to death.
- The risk of having heart problems is higher if you take DICLOFENAC-50 for long periods of time and/or at higher doses and/or in people who have heart disease.
- Tell your healthcare professional if you have or had heart problems, high blood pressure or diabetes.

Stomach and intestine (gastrointestinal) problems:

- DICLOFENAC-50, can cause stomach and intestine problems like ulcers, inflammation, bleeding, holes/perforation, blockage pain.

Talk to your healthcare professional about any medical conditions you have and drugs you are taking.

Pregnancy:

- **DO NOT** take DICLOFENAC-50 if you are pregnant and in a later stage of pregnancy (28 weeks or later).
- If you are pregnant and in an earlier stage of pregnancy (less than 28 weeks) only take DICLOFENAC-50 if you are told to do so by your doctor.
- Medicines like DICLOFENAC-50 may cause harm to you and your baby. Your doctor will need to closely monitor your health and that of your baby (including your amniotic fluid levels) if they prescribe DICLOFENAC-50 during this time.
- Tell your healthcare professional right away if you become pregnant, think you may be pregnant or want to get pregnant during your treatment DICLOFENAC-50.

What is DICLOFENAC-50 used for?

- to treat patients 16 years and older with symptoms of arthritis disorders such as:
 - Osteoarthritis, including osteoarthritis of the hip
 - Rheumatoid arthritis

How does DICLOFENAC-50 work?

- DICLOFENAC-50 (diclofenac sodium) belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). They can reduce the chemicals produced by your body which cause pain and swelling.
- DICLOFENAC-50 only treats the symptoms and relieves pain as long as you take it. DICLOFENAC-50 does NOT cure your illness or stop it from getting worse.

What are the ingredients in DICLOFENAC-50 ?

Medicinal ingredient: Diclofenac sodium

Non-medicinal ingredients:

- Colloidal silicon dioxide, dextrans, FD & C yellow #6 aluminum lake, ferric oxide yellow, hydroxypropyl methylcellulose, methanol, magnesium stearate, methylcellulose, polyethylene glycol, polyvinylacetate phthalate, stearic acid, titanium dioxide and triethyl citrate.

DICLOFENAC-50 comes in the following dosage forms:

Delayed-release tablets, 50 mg.

Do not use DICLOFENAC-50 if you:

- Are planning to have or have recently had heart bypass surgery.
- Have severe, uncontrolled heart failure.
- Have bleeding in the brain or other bleeding disorders.
- Are pregnant and in a later stage of pregnancy (from 28 weeks or later).
- Are breastfeeding (or planning to breastfeed).
- Are allergic to diclofenac sodium or any of the ingredients in this medicine or the container.
- Have a history of asthma, hives, growths in your nose, sinus swelling or symptoms of an allergic reaction after taking acetylsalicylic acid (ASA) or other NSAIDs.
- Have active stomach or intestine ulcers.
- Have active bleeding from the stomach or gut.
- Have inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis).
- Have liver disease (active or severe).
- Have kidney disease (severe or worsening).
- Have high potassium in the blood.
- Are under 16 years of age.

To help avoid side effects and ensure proper use, talk to your health professional before you take DICLOFENAC-50. Talk about any health conditions or problems you may have, including if you:

- Have high blood pressure, high cholesterol or diabetes
- Have or had heart attacks, chest pain, heart disease, stroke or heart failure
- Have poor blood flow to your extremities (like your hands and feet)
- Smoke or used to smoke
- Drink a lot of alcohol
- Have a stomach infection
- Have recently had stomach or intestine tract surgery
- Have liver or kidney disease, urine problems or are dehydrated
- Have a history of ulcer or bleeding from the stomach or gut (small or large intestine)
- Previous bleeding in the brain
- Have other bleeding or blood problems
- Have asthma or other lung problems
- Have immune system problems
- Family history of allergy to NSAIDs, such as acetylsalicylic acid (ASA) or other NSAIDs
- Are on a low-salt diet
- Are pregnant, planning on becoming or become pregnant while taking DICLOFENAC-50.

Other Warnings:

Serious Side Effects: DICLOFENAC-50 can cause serious side effects, including:

- **Blood and bleeding problems:**
 - DICLOFENAC-50 can cause blood problems, bleeding and prolonged bleeding.
 - Taking DICLOFENAC-50 with the following drugs can increase the risk of bleeding:
 - anticoagulants (prevents blood clots), corticosteroids (anti-inflammatory) or antidepressants like selective serotonin reuptake inhibitors (SSRIs).
- **Serious skin reactions:** In rare cases, serious, life-threatening allergic and skin reactions have been reported with some NSAIDs, such as DICLOFENAC-50. These skin problems most often happen during the first month of treatment. Tell your healthcare professional immediately if you notice any changes in your skin both during and after treatment. DICLOFENAC-50 might cause you to become more sensitive to sunlight or UV light. 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 or UV light, talk to your healthcare professional.

Check-ups and testing: You will have regular visits with your healthcare professional during treatment with DICLOFENAC-50 to monitor your health. They will:

- Check your blood pressure.
- Check your eyes. DICLOFENAC-50 can cause blurred or reduced vision.
- Do blood and urine tests to check your liver, kidney and blood health.

Surgery: Tell any doctor, dentist, pharmacist or healthcare professional that you see, that you are taking this medicine. This is especially important if you are planning to have heart surgery.

Driving and Using Machines: DICLOFENAC-50 may cause eye or nervous system problems. This includes tiredness, trouble sleeping, blurred vision, spinning or dizziness (vertigo), hearing problems or depression. Be careful about driving or doing activities that require you to be alert. If you become drowsy, dizzy or light-headed after taking DICLOFENAC-50, do NOT drive or operate machinery.

Fertility in Women: DICLOFENAC-50 may affect your fertility. This means that it may be difficult for you to have a child. If you have trouble having a child, you might need to stop taking DICLOFENAC-50. Talk to your healthcare professional if you have questions about this.

Adults (65 years or older): Side effects like gastrointestinal problems may happen more often. Your healthcare professional might have you start with a lower dose of DICLOFENAC-50. They will monitor your health during and after treatment.

Tell your health professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with DICLOFENAC-50 :

- Acetaminophen, used to treat fever and pain
- Acetylsalicylic Acid (ASA) or other NSAIDs, used to treat pain, fever and inflammation, like:
 - e.g. ASA, celecoxib, diclofenac, diclofenac potassium, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen
- Alcohol
- Antacids, used to treat symptoms of excess stomach acid
- Blood pressure medications like enalapril, lisinopril, perindopril, Ramipril, candesartan, irbesartan, losartan, valsartan, metoprolol
- Corticosteroids (including glucocorticoids, such as prednisone, used as an anti-inflammatory
- Digoxin, used to treat heart disorders
- Phenytoin, used to treat seizures
- Trimethoprim, used to treat urinary tract infections
- Voriconazole, used to treat fungal infections
- Lithium, used as a mood stabilizer
- Medicines used as blood thinners or to prevent blood clots, like warfarin, ASA, clopidogrel
- Medicines used to lower the risk of organ rejection, like tacrolimus and cyclosporine
- Medicines used to treat bacteria infections (antibiotics) like rifampin, quinolone
- Medicines used to treat gout like sulfinpyrazone, probenecid
- Medicines used to lower extra fluid levels (diuretics) like furosemide, hydrochlorothiazide
- Medicines used to treat depression (antidepressants) like citalopram, fluoxetine,

paroxetine, sertraline

- Methotrexate, used to treat some kinds of cancer
- Medicines used to treat diabetes, like metformin or other oral hypoglycemics

How to take DICLOFENAC-50:

- Take DICLOFENAC-50 as directed by your healthcare professional. They should recommend the lowest dose possible for your treatment for the shortest time needed.
- **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.**
- It is best to take your dose at the same time each day.
- Take DICLOFENAC-50 tablets with food.
- You should remain standing or sitting upright (do not lie down) for about 15 to 30 minutes after taking the DICLOFENAC-50.
- If you will be using DICLOFENAC-50 for more than 7 days, see your health care provider regularly. They will check if it is working for you and if it is causing you any unwanted effects.

Swallow tablet whole with water at mealtime. Do NOT chew or divide the tablet.

Usual dose:

Patients 16 years of age and older:

- Your healthcare professional will decide on the best dosage for you based on your condition.
- Your healthcare professional may lower your dose, stop your treatment for a period of time or recommend that you stop treatment completely. This may happen if you:
 - experience serious side effects, or
 - your disease gets worse.

Overdose

If you think you, or a person you are caring for, have taken too much DICLOFENAC-50, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of DICLOFENAC-50, take the dose as soon as possible.
- Do not take a bigger dose to make up for the missed dose.

What are possible side effects from using DICLOFENAC-50?

These are not all the possible side effects you may have when taking DICLOFENAC-50. If you experience any side effects not listed here, tell your healthcare professional.

- Nausea, vomiting, diarrhea, constipation, stomach upset/abdominal pain, heartburn, indigestion, feeling gassy
- Headache, dizziness, light-headedness
- Feeling of burning/prickliness/numbing
- Confusion, hard to concentrate or think, short-term memory loss, nervousness
- Bruises
- Skin rash, itchy skin
- Taste disorder, thirst, dry mouth
- Muscle pain
- Mouth sores
- Hair loss
- Increased sweating
- Problems with your period (women)

Serious side effects and what to do about them

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Gastrointestinal (GI) problems (bleeding, blockage, holes, ulcers or inflammation in your GI tract): blood in vomit, black tarry or bloody stool, dizziness, stomach pain, bloating, loss of appetite, weight loss, nausea, vomiting, constipation or diarrhea, chills or fever, inflamed tongue, rectal itching or bleeding		✓	
Vertigo (a sense of severe spinning dizziness, light headedness)		✓	
UNCOMMON			
Anaphylaxis/hypersensitivity (severe allergic reactions): sudden wheeziness and chest pain or tightness; or swelling of eyelids, face, lips, tongue or throat, swelling or anaphylactic reaction/shock, chills, fever, muscle aches or pains, or other flu-like symptoms, low blood pressure			✓
Congestive heart failure			✓

(heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			
Cystitis (bladder infection): increased need to urinate, pain in the pelvis or lower back, frequent urination during the night, cloudy urine that may contain blood, burning or pain urinating		✓	
Liver problems (including hepatitis, liver failure): yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness			✓
Lung problems, asthma: increased shortness of breath, wheezing, difficulty breathing, cough and chest tightness, irregular heartbeat			✓
Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, feeling faint and possible irregular heartbeat			✓
Stroke (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side			✓

of the body, sudden headache, blurry vision, difficulty swallowing or speaking, or lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance			
RARE			
Hypertension (high blood pressure): fatigue, dizziness or fainting, chest pain	✓		
Kidney disorder/problems (including kidney failure): nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, rash, weight gain (from retaining fluid), loss of appetite, mental status changes (drowsiness, confusion, coma)		✓	
Serious Skin Reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, swelling of face and/or legs, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine or dark urine, hives, red or dry itchy skin, purple or red spots on skin			✓
VERY RARE			
Abnormal thoughts and behaviour, including depression: irritability,		✓	

difficulty sleeping or sleeping too much, changes in appetite or weight, reduced sex drive and thoughts of death or suicide, disorientated			
Aseptic meningitis (inflammation of the protective lining of the brain that is not caused by infection): Headaches, stiff neck, nausea and vomiting, fever or clouding of consciousness		✓	
Blood problems (low white and/or red blood cell or platelet count): feeling tired or weak, pale skin, bruising or bleeding for longer than usual if you hurt yourself, fever, chills		✓	
Tinnitus (hearing problems): includes ringing, buzzing, clicking or hissing in ears, loss of hearing		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

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

Do NOT keep expired medicine or medicine no longer needed. Return to your healthcare professional.

Keep out of reach and sight of children.

If you want more information about DICLOFENAC-50:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), or by contacting Pro Doc Ltée at : <http://www.prodoc.qc.ca>, 1 800 361-8559, or info@prodoc.qc.ca.

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