

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrGD[®]-diclofenac/misoprostol 50 / PrGD[®]-diclofenac/misoprostol 75

diclofenac sodium and misoprostol enteric-coated tablets

Read this carefully before you start taking **GD-diclofenac/misoprostol** 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 **GD-diclofenac/misoprostol**.

Serious 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 GD-diclofenac/misoprostol:

- **Heart attack or angina (chest pain)**
- **Stroke or mini-stroke**
- **Congestive heart failure**
- **High risk for heart disease (e.g. High blood pressure, Diabetes, High levels of fats in your blood, Smoking)**

It is important to take the lowest dose of GD-diclofenac/misoprostol 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.

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

NSAIDs, like GD-diclofenac/misoprostol, may cause stomach and bowel problems (such as ulceration, perforation, obstruction, and bleeding).

Do not take GD-diclofenac/misoprostol if you are pregnant or think that you may be pregnant. GD-diclofenac/misoprostol may cause uterine contractions that are associated with abortion, premature birth, birth defects and fetal death.

What is GD-diclofenac/misoprostol used for?

- GD-diclofenac/misoprostol is used for short-term and long-term relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.

How does GD-diclofenac/misoprostol work?

GD-diclofenac/misoprostol contains two different medicines: diclofenac, a nonsteroidal anti-inflammatory drug (NSAID) and misoprostol, a drug that helps to protect the lining of your stomach (because NSAIDs can cause damage to your stomach).

GD-diclofenac/misoprostol helps to relieve joint pain, swelling, and stiffness by reducing the production of certain substances (prostaglandins) and by helping to control inflammation. GD-diclofenac/misoprostol does NOT cure your illness or prevent it from getting worse. GD-diclofenac/misoprostol can only relieve pain and reduce swelling as long as you continue to take it.

What are the ingredients in GD-diclofenac/misoprostol?

Medicinal ingredients: diclofenac sodium and misoprostol

Non-medicinal ingredients: Colloidal Silicon Dioxide, Corn Starch, Crospovidone, Hydrogenated Castor Oil, Hypromellose, Lactose, Magnesium Stearate, Methacrylic Acid Copolymer, Microcrystalline Cellulose, Povidone K-30, Sodium Hydroxide, Talc, Triethyl Citrate

GD-diclofenac/misoprostol comes in the following dosage forms:

- Tablets, 50 mg diclofenac/200 mcg misoprostol
- Tablets, 75 mg diclofenac/200 mcg misoprostol

Do not use GD-diclofenac/misoprostol if:

- You will be having or recently had Heart bypass surgery
- You are pregnant, planning to become pregnant or are in prolonged labor during childbirth
- You are breastfeeding or planning to breastfeed
- You have severe, uncontrolled heart failure
- You are allergic to diclofenac sodium, misoprostol, other NSAIDs or any ingredient found in GD-diclofenac/misoprostol
- You have gastrointestinal issues such as Ulcers, Bleeding from the stomach or gut, Inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis)
- You have bleeding in the brain or other bleeding disorders
- You have active or severe liver disease
- You have severe or worsening kidney disease
- You have high potassium in the blood
- You are taking other NSAIDs

Children and adolescents under the age of 18 should not use GD-diclofenac/misoprostol.

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

- Have liver disease or liver problems
- Have kidney disease or kidney problems
- Have disease of the heart or blood vessels such as uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, or peripheral arterial disease
- Have high risk factors for cardiovascular disease such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke.
- Have poor circulation to your extremities
- Previously had an ulcer or bleeding from the stomach or gut
- Previously had bleeding in the brain
- Have bleeding problems
- Have a family history of allergy to NSAIDs, such as acetylsalicylic acid (ASA), celecoxib, diclofenac, diflunisal, etodolac, fenoprofen, fluribiprofen, ibuprofen, indomethacin, ketoprofen,

ketorolac, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, rofecoxib, sulindac, tenoxicam, tiaprofenic acid, tolmetin, or valdecoxib (NOT a complete list)

- Have a family history of asthma, nasal polyps, long-term swelling of the sinus (chronic sinusitis) or hives
- Have a history of a severe drug hypersensitivity reaction (drug allergy) including skin problems
- Are on any special diet, such as a low-sodium diet
- Drink alcohol;

Other Warnings that you should know about:

Serious skin reactions:

In rare cases, serious, life-threatening skin reactions have been reported with some NSAIDs, such as GD-diclofenac/misoprostol. These skin problems most often happen during the first month of treatment. **STOP taking GD-diclofenac/misoprostol** and tell your healthcare professional immediately if you notice any changes in your skin both during and after treatment.

Driving and Operating Heavy Machinery:

GD-diclofenac/misoprostol may cause visual disturbances, dizziness, vertigo or drowsiness. Do not operate heavy machinery if you experience these effects while taking GD-diclofenac/misoprostol.

Light Sensitivity:

GD-diclofenac/misoprostol may cause you to become more sensitive to sunlight. 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, stop taking GD-diclofenac/misoprostol and talk to your healthcare professional.

SPECIAL NOTE FOR WOMEN OF CHILDBEARING AGE:

Do not take GD-diclofenac/misoprostol if you are pregnant or think you are pregnant or during prolonged labour. Do not start GD-diclofenac/misoprostol until you have been tested to confirm that you are not pregnant. Do not get pregnant or try to get pregnant while you are taking GD-diclofenac/misoprostol and for at least one month (or through one menstrual cycle) after you stop taking it. This means using an effective form of birth control which you should discuss with your doctor. Stop taking GD-diclofenac/misoprostol, and contact your doctor immediately if you do become pregnant during GD-diclofenac/misoprostol therapy.

Misoprostol may cause uterine contractions (contractions of the uterus), premature birth, birth defects and abortion or may otherwise harm the unborn developing baby. Misoprostol has been reported to cause the uterus to tear when given after the eighth week of pregnancy. Tearing of the uterus can result in severe bleeding, hysterectomy, and/or maternal or fetal death. Therefore, if you are pregnant, you must not take this drug.

Diclofenac can potentially prolong labor.

Abortions caused by misoprostol are likely to be incomplete. An incomplete abortion may

result in very serious medical complications, resulting in hospitalization, surgery and possibly infertility, and may result in maternal death.

Do not use GD-diclofenac/misoprostol if you are breastfeeding or planning to breastfeed. The body changes misoprostol to the active form of the drug, misoprostol acid, which could get into the breast milk and cause significant diarrhea in the infant.

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

The following may interact with GD-diclofenac/misoprostol:

- Acetylsalicylic Acid (ASA) or other NSAIDs (e.g. ASA, celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen). Your healthcare provider may prescribe low dose ASA while you take GD-diclofenac/misoprostol. Only take ASA as directed by your healthcare provider.
- Antacids. Do not take antacids that contain magnesium (because they can cause diarrhea) while you are taking GD-diclofenac/misoprostol. Ask your pharmacist to help you select a suitable brand.
- Antidepressants
- Selective Serotonin Reuptake Inhibitors (SSRIs) (e.g. citalopram, fluoxetine, paroxetine, sertraline)
- Blood pressure medications. Using GD-diclofenac/misoprostol with blood pressure drugs may increase your risk of kidney failure. This is more likely if you are elderly or dehydrated.
- Diuretics (e.g. furosemide, hydrochlorothiazide)
- ACE (Angiotensin converting enzyme) inhibitors (e.g. enalapril, lisinopril, perindopril, ramipril)
- ARBs (angiotensin II receptor blockers) (e.g. candesartan, irbesartan, losartan, valsartan)
- Beta-blockers
- Blood thinners (e.g. warfarin, ASA, clopidogrel). Using GD-diclofenac/misoprostol with a blood-thinner increases the risk of bleeding. This can occur in the stomach or anywhere.
- Corticosteroids (including glucocorticoids) (e.g. prednisone)
- Cyclosporin
- Digoxin
- Lithium
- Methotrexate
- Oral hypoglycemics (diabetes medications)
- Phenytoin (a medicine used to treat seizures)
- Tacrolimus
- Sulfapyrazone (a medicine used to treat gout)
- Voriconazole (a medicine used to treat fungal infections)
- Drinking alcohol while taking GD-diclofenac/misoprostol may increase your risk of gastrointestinal problems. Do not drink alcoholic beverages while taking this medication.

How to take GD-diclofenac/misoprostol:

- GD-diclofenac/misoprostol should be swallowed whole.
- Take GD-diclofenac/misoprostol immediately after a meal or with food or milk.

- Remain standing or sitting for 15-30 minutes after taking the medicine. This helps prevent irritation that may lead to trouble swallowing.
- **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.**
- Your healthcare provider will prescribe the lowest effective dose of GD-diclofenac/misoprostol to help avoid side effects. Take GD-diclofenac/misoprostol exactly as directed by your healthcare provider.

Usual dose:

Adults: Take 50 mg of diclofenac twice daily. The maximum daily dose is 100 mg of diclofenac.

Overdose:

Symptoms of overdose may include stomach pain, confusion, drowsiness, low muscle tone, shaking hands that you cannot control, seizures, shortness of breath, diarrhea, fever, rapid or pounding heartbeat, slow heartbeat, dizziness or fainting.

If you think you, or a person you are caring for, have taken too much GD-diclofenac/misoprostol, 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 GD-diclofenac/misoprostol, take the next dose at the regular time. Do not take a double dose to catch up for the missed dose. It is important that GD-diclofenac/misoprostol be taken as prescribed. Try to remember to take GD-diclofenac/misoprostol at the appropriate time. Having a regular routine associated with taking your medicine will help.

What are possible side effects from using GD-diclofenac/misoprostol?

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

- GD-diclofenac/misoprostol 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 health care provider.
- Elderly, frail, or debilitated patients often seem to experience more frequent or more severe side effects.
- 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.
- Stomach upset is one of the common problems with NSAIDs. If stomach upset (indigestion, nausea, vomiting, stomach pain or diarrhea) occurs and continues, contact your doctor.
- Because misoprostol increases mucus production some patients experience diarrhea. Keep taking your GD-diclofenac/misoprostol. It is just a sign that the drug is working. Usually the diarrhea goes away in two to three days. If it is not gone after a week, check with your doctor.
- While your body gets used to misoprostol you may feel a crampy pain in your stomach. Like the diarrhea it usually goes away in a few days. If it doesn't, check with your doctor.

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	
VERY COMMON			
Indigestion, nausea, abdominal pain or diarrhea	✓		
COMMON			
Dizziness, light headedness	✓		
Headaches	✓		
Insomnia	✓		
Skin rash, itching			✓
Vomiting, constipation, gas, burping	✓		
UNCOMMON			
Bleeding			✓
Bloody or black tarry stools			✓
Blurred vision or any visual disturbance			✓
Change in heart rate or rhythm, change in blood pressure, heart failure, blood clot, stroke			✓
Malaise, fever, swelling, chills		✓	
Menses pain, abnormal vaginal bleeding, vaginal infection		✓	
Shortness of breath, wheezing, any trouble in breathing or tightness in the chest			✓
Skin bruising, hives or swelling			✓
Sore throat or mouth sores		✓	
Vomiting blood			✓
RARE			
Breast pain		✓	
Nightmare	✓		
Pancreatitis: abdominal pain, nausea, vomiting, loss of appetite			✓
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, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often,			✓

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	
less urine or dark urine, hives, red or dry itchy skin, purple or red spots on skin, bruising			
Swelling of the feet or lower legs		✓	
Yellow skin or eyes, dark urine (red or brown)			✓
UNKNOWN FREQUENCY			
Agranulocytosis: fever, chills. Flu-like symptoms. Weakness		✓	
Benign mass in the intestine, trouble with swallowing			✓
Hearing problems		✓	
Hemolytic Anemia: Fatigue and short of breath		✓	
Infections: Sepsis (infection of the whole body)			✓
Nausea, fatigue, lethargy, diarrhea, pruritus, yellow discoloration of the skin or eyes with or without itchy skin, right upper quadrant tenderness, and «flu-like» symptoms			✓
Seizure, stiff neck, shaking, loss of consciousness, change in mood or thoughts			✓

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/drug.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 15-25°C and protect from heat and humidity.

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

Keep out of reach and sight of children.

If you want more information about GD-diclofenac/misoprostol:

- 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 the sponsor, GenMed, a division of Pfizer Canada ULC, at: 1-800-463-6001.

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