PATIENT & CAREGIVER EDUCATION

Diclofenac and Misoprostol

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Arthrotec

Brand Names: Canada

Arthrotec; GD-Diclofenac/Misoprostol 50; GD-Diclofenac/Misoprostol 75; PMS-Diclofenac-Misoprostol

Warning

- This drug may raise the risk of heart and blood vessel problems like heart attack and stroke. These effects can be deadly. The risk may be greater if you have heart disease or risks for heart disease. However, it can also be raised even if you do not have heart disease or risks for heart disease. The risk can happen within the first weeks of using this drug and may be greater with higher doses or long-term use. Do not

use this drug right before or after bypass heart surgery.

- This drug may raise the chance of severe and sometimes deadly stomach or bowel problems like ulcers or bleeding. The risk is greater in older people, and in people who have had stomach or bowel ulcers or bleeding before. These problems may occur without warning signs.
- Do not take this drug if you are pregnant. Use during pregnancy may cause early births, birth defects, loss of the unborn baby, or tears in the uterus (uterine rupture). The risk of uterine rupture is higher later in pregnancy, if you have had uterine surgery like a C-section, or if you have given birth to 5 or more children.
- If you are able to get pregnant, a pregnancy test will be done to show that you are NOT pregnant before starting this drug. Talk with your doctor.
- Start taking this drug only on the second or third day of your next normal menstrual period after the negative pregnancy test.
- You may need to have a pregnancy test while taking this drug. Talk with your doctor.
- If you may become pregnant, you must use birth

control while taking this drug. If you get pregnant, call your doctor right away.

- Do not share this drug with others.

What is this drug used for?

- It is used to treat arthritis in patients who have more chance of getting ulcers.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have an allergy to aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen or naproxen.
- If you have ever had asthma caused by a salicylate drug like aspirin or a drug like this one like NSAIDs.
- If you have any of these health problems: GI (gastrointestinal) bleeding or kidney problems.
- If you have any of these health problems: Heart failure (weak heart) or a recent heart attack.
- If you are taking any other NSAID, a salicylate drug like aspirin, or pemetrexed.

- If you are having your fertility checked.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have your blood work checked if you are on this drug for a long time. Talk with your doctor.
- High blood pressure has happened with drugs like this one. Have your blood pressure checked as you have been told by your doctor.
- Talk with your doctor before you drink alcohol.
- If you smoke, talk with your doctor.
- If you have asthma, talk with your doctor. You may be more sensitive to this drug.

- Do not take more than what your doctor told you to take. Taking more than you are told may raise your chance of severe side effects.
- Do not take this drug for longer than you were told by your doctor.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- The chance of heart failure is raised with the use of drugs like this one. In people who already have heart failure, the chance of heart attack, having to go to the hospital for heart failure, and death is raised. Talk with the doctor.
- The chance of heart attack and heart-related death is raised in people taking drugs like this one after a recent heart attack. People taking drugs like this one after a first heart attack were also more likely to die in the year after the heart attack compared with people not taking drugs like this one. Talk with the doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- NSAIDs like this drug may affect egg release (ovulation). This may affect being able to get pregnant. This goes back to normal when this drug is stopped. Talk with the doctor.

- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine; black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.
- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of high potassium levels like a heartbeat that does not feel normal; feeling confused; feeling weak,

lightheaded, or dizzy; feeling like passing out; numbness or tingling; or shortness of breath.

- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Chest pain or pressure.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.
- Feeling very tired or weak.
- Flu-like signs.
- Severe skin reactions may happen with this drug. These include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and other serious reactions. Sometimes, body organs may also be affected. These reactions can be deadly. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin; red or irritated eyes; sores in your mouth, throat, nose, eyes, genitals, or any areas of skin; fever; chills; body aches; shortness of breath; or swollen glands.
- Liver problems have happened with drugs like this one. Sometimes, this has been deadly. Call your doctor right away if you have signs of liver problems like dark urine,

tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Constipation, diarrhea, stomach pain, upset stomach, or throwing up.
- Heartburn.
- Gas.
- Dizziness.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take with or without food. Take with food if it causes an upset stomach.
- Do not take antacids that have magnesium with this drug.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all

information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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