

MEDICATION GUIDE

Medication Guide for Diclofenac Sodium (dye-KLOE-fen-ak SOE-dee-um) and Misoprostol (MYE-soe-PROST-ol) Delayed-Release Tablets for oral use

What is the most important information I should know about diclofenac sodium and misoprostol delayed-release tablets?

Diclofenac sodium and misoprostol delayed-release tablets contains diclofenac (a nonsteroidal anti-inflammatory drug (NSAID)) and misoprostol, and can cause uterus to tear (uterine rupture), abortion, premature birth, or birth defects. The risk of uterine rupture increases as your pregnancy advances, if you have given birth to 5 or more children, and if you have had surgery on the uterus, such as a cesarean delivery.

Do not take diclofenac sodium and misoprostol delayed-release tablets if you are pregnant.

- Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with diclofenac sodium and misoprostol delayed-release tablets. If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with diclofenac sodium and misoprostol delayed-release tablets. Females who are able to become pregnant should use an effective form of birth control (contraception) during treatment with diclofenac sodium and misoprostol delayed-release tablets.

What is the most important information I should know about medicines containing Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

NSAIDs can cause serious side effects, including:

- **Increased risk of a heart attack or stroke that can lead to death.** This risk may happen early in treatment and may increase:
 - with increasing doses of NSAIDs
 - with longer use of NSAIDs

Do not take NSAID containing medicines right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

Avoid taking NSAID containing medicines after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

- **Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:**
 - anytime during use
 - without warning symptoms
 - that may cause death

The risk of getting an ulcer or bleeding increases with:

- past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
- taking medicines called “corticosteroids”, “antiplatelet drugs”, “anticoagulants”, “SSRIs”, or “SNRIs”
- increasing doses of NSAIDs
- older age
- longer use of NSAIDs
- poor health
- smoking
- advanced liver disease
- drinking alcohol
- bleeding problems

NSAID containing medicines should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

What are diclofenac sodium and misoprostol delayed-release tablets?

Diclofenac sodium and misoprostol delayed-release tablets contains 2 medicines:

1. Diclofenac is a non-steroidal anti-inflammatory drug (NSAID). **See “What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?”**
2. Misoprostol is a medicine used to protect the lining of the esophagus, stomach and intestines while taking diclofenac.

Diclofenac sodium and misoprostol delayed-release tablets are a prescription medicine used to treat:

- symptoms of osteoarthritis or rheumatoid arthritis in adults at high risk of developing stomach (gastric) and intestinal (duodenal) ulcers while taking NSAIDs.

It is not known if diclofenac sodium and misoprostol delayed-release tablets are safe and effective for use in children.

What are NSAIDs?

NSAIDs are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as different types of arthritis.

Who should not take diclofenac sodium and misoprostol delayed-release tablets?

Do not take diclofenac sodium and misoprostol delayed-release tablets:

- if you are pregnant.
- right before or after heart bypass surgery.
- if you currently have bleeding in your stomach (gastrointestinal bleeding).
- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- if you are allergic to diclofenac sodium and misoprostol, other prostaglandins or any other ingredients in diclofenac sodium and misoprostol delayed-release tablets. See the end of this Medication Guide for a list of ingredients in diclofenac sodium and misoprostol delayed-release tablets.

Before taking diclofenac sodium and misoprostol delayed-release tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems.
- have high blood pressure.
- have heart problems, including a history of heart failure or heart attack.
- have asthma.
- are pregnant or plan to become pregnant. See “Who should not take diclofenac sodium and misoprostol delayed-release tablets?”
- are breastfeeding or plan to breast feed.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. NSAIDs and some other medicines can interact with each other and cause serious side effects. **Do not start taking any new medicine without talking to your healthcare provider first.**

What are the possible side effects of NSAIDs?

NSAIDs can cause serious side effects, including:

See “What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions
- asthma attacks in people who have asthma
- **Other side effects of NSAIDs include:** stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness

Get emergency help right away if you get any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop taking your NSAID and call your healthcare provider right away if you get any of the following symptoms:

- nausea
- more tired or weaker than usual
- diarrhea
- itching
- your skin or eyes look yellow
- indigestion or stomach pain
- flu-like symptoms
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- unusual weight gain
- skin rash or blister with fever
- swelling of the arms, legs, hands and feet

If you take too much of your NSAID, call your healthcare provider or get medical help right away.

These are not all the possible side effects of NSAIDs. For more information, ask your healthcare provider or pharmacist about NSAIDs.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Other information about NSAIDs

- Aspirin is an NSAID but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some NSAIDs are sold in lower doses without a prescription (over-the-counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

General information about the safe and effective use of NSAIDs

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NSAIDs for a condition for which it was not prescribed. Do not give NSAIDs to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information about NSAIDs, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about NSAIDs that is written for health professionals.

Active ingredients: diclofenac sodium, misoprostol.

Inactive ingredients: colloidal silicon dioxide, corn starch, crospovidone, hydrogenated castor oil, hypromellose, lactose monohydrate, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, povidone, sodium hydroxide, talc, triethyl citrate.

This product's labeling may have been updated. For the most recent prescribing information, please visit www.microlabsusa.com.

For more information, go to www.microlabsusa.com or call 1-855-839-8195.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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