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2. Misoprostol

Misoprostol ⊲

Generic name: misoprostol [mye-so-PROS-toll]

Brand name: Cytotec

Dosage form: oral tablet (100 mcg; 200 mcg)

Drug class: Miscellaneous GI agents

Medically reviewed by Carmen Pope, BPharm. Last updated on May 24, 2024.

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What is misoprostol?

Misoprostol reduces stomach acid and helps protect the stomach lining from damage that can be caused by taking aspirin or a nonsteroidal anti-inflammatory drug (NSAID).

Misoprostol is a synthetic prostaglandin that works by "replacing" prostaglandins whose production is blocked by aspirin or NSAIDs. It is used to prevent stomach ulcers from developing during treatment with aspirin or an NSAID. Examples of NSAIDs include ibuprofen (Advil, Motrin), naproxen (Aleve), celecoxib, diclofenac, indomethacin, and meloxicam.

Misoprostol is used in a hospital setting to induce cervical ripening, labor induction in women with premature rupture of membranes, and treatment of serious post-partum hemorrhage, These uses are outside of the approved indications.

Misoprostol is also in combination with mifepristone or methotrexate to end an early pregnancy (medical abortion) or alone for early pregnancy loss (miscarriage).

Although FDA regulations allow certified healthcare professionals and pharmacies to dispense mifepristone and
misoprostol for medical abortion both in healthcare facilities and by telehealth and mail, certain state laws may not
allow this. For example, Louisiana has passed a bill that classifies mifepristone and misoprostol as dangerous
controlled substances which, once signed, would mean anyone possessing these abortion pills without a prescription
could face jail time and fines. Most abortions are already illegal in Louisiana.

When used for non-pregnancy-related conditions, misoprostol should not be used during pregnancy, and if you can become pregnant, you will need to have a negative pregnancy test before starting this treatment.

Misoprostol was FDA approved on December 27, 1988, under the brand Cytotec. Generic misoprostol is available.

Misoprostol side effects

Get emergency medical help if you have **signs of an allergic reaction**: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Misoprostol may cause serious side effects. Call your doctor at once if you have:

- · severe ongoing stomach discomfort or diarrhea; or
- dehydration--dizziness, confusion, feeling very thirsty, less urination.

Common misoprostol side effects may include:

· diarrhea and stomach pain.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Misoprostol side effects (more detail)

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Warnings

Misoprostol can cause birth defects, premature birth, uterine rupture, miscarriage, or incomplete miscarriage and dangerous uterine bleeding. Do not use misoprostol to prevent stomach ulcers if you are pregnant.

If you are able to become pregnant, you will need to have a negative pregnancy test before starting this treatment. You will also need to use effective birth control to prevent pregnancy during treatment.

Before taking this medicine

You should not use this medicine if you are allergic to misoprostol or other prostaglandins.

To make sure misoprostol is safe for you, tell your doctor if you have ever had:

- inflammatory bowel disease (IBD) or other intestinal problems;
- · heart disease; or
- if you are dehydrated.

May cause birth defects. Do not use if you are pregnant, unless misoprostol is beeing used for pregnancy related conditions. You must use effective birth control while using misoprostol and for at least 1 month after your last dose. Tell your doctor if you become pregnant.

You will need to have a negative pregnancy test before starting this treatment.

Stop taking this medicine and tell your doctor right away if you become pregnant during treatment.

Ask a doctor if it is safe to breastfeed while using this medicine.

Misoprostol pregnancy and breastfeeding warnings (more detail)

How should I take misoprostol?

Take misoprostol exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets.

Do not share misoprostol with another person, even if they have the same symptoms you have.

Misoprostol is usually taken four times a day with meals. The last dose of the day should be at bedtime. Follow your

doctor's instructions.

You may have nausea, stomach cramps, or diarrhea while taking this medicine, especially during the first few weeks after you start taking misoprostol. These symptoms usually last for about a week.

Call your doctor if you have severe nausea, stomach pain, or diarrhea lasting longer than 8 days.

Store at room temperature away from moisture and heat.

Dosing information

Usual Adult Dose for Duodenal Ulcer:

200 mcg orally 4 times a day after meals and at bedtime -Maintenance dose: 100 to 200 mcg orally 4 times a day

Usual Adult Dose for Gastric Ulcer:

200 mcg orally 4 times a day after meals and at bedtime -Maintenance dose: 100 to 200 mcg orally 4 times a day

Comment: Treatment should be taken for the duration of non-steroidal anti-inflammatory drug (NSAID) therapy.

Use: Reducing the risk of NSAID-induced gastric ulcers in patients at high risk of complications from gastric ulcers (e.g., patients who are elderly, with concomitant debilitating disease) or at high risk of developing gastric ulceration (e.g., history of gastric ulcer)

Usual Adult Dose for NSAID-Induced Ulcer Prophylaxis:

200 mcg orally 4 times a day after meals and at bedtime

-Maintenance dose: 100 to 200 mcg orally 4 times a day

Comment: Treatment should be taken for the duration of non-steroidal anti-inflammatory drug (NSAID) therapy.

Use: Reducing the risk of NSAID-induced gastric ulcers in patients at high risk of complications from gastric ulcers (e.g., patients who are elderly, with concomitant debilitating disease) or at high risk of developing gastric ulceration (e.g., history of gastric ulcer)

Usual Adult Dose for Labor Induction or Cervical Ripening:

American College of Obstetricians and Gynecologists (ACOG) Recommendations:

25 mcg vaginally every 3 to 6 hours

-Some patients may require doses of 50 mcg every 6 hours

Comments:

- -The manufacturer states that use outside of the approved indication should be reserved for hospital use only.
- -Some experts state that this drug is a more efficient method of labor (compared to oxytocin) in patients before 28 weeks' gestation.
- -Higher doses may be associated with a higher risk of adverse events (e.g., uterine tachysystole with fetal heart rate decelerations).
- -Use should be avoided during the third trimester or in patients with a history of cesarean delivery or major uterine

surgery.

Use: Cervical ripening and labor induction in women with premature rupture of membranes

Usual Adult Dose for Postpartum Bleeding:

ACOG Recommendations:

800 to 1000 mcg rectally once

Use: Management of postpartum hemorrhage

International Federation of Gynecology Obstetrics (FIGO) Recommendations: 600 mcg orally OR 800 mcg sublingually once immediately after delivery

Comments:

- -The manufacturer states that use outside of the approved indication should be reserved for hospital use only.
- -Prior to administration of treatment, abdominal palpitation is recommended to confirm that there are no additional babies in utero.
- -The dose is not based upon the patient's weight.
- -The addition of this drug to oxytocin was not shown to provide additional benefit, but may increase the risk of adverse events.

Use: Prevention of postpartum hemorrhage in settings where oxytocin is not available

Usual Adult Dose for Abortion:

ACOG Recommendations

First Trimester of Pregnancy:

- -Early Pregnancy Loss: 800 mcg intravaginally once; a second dose may be given if there is no response to the first dose no sooner than 3 hours after the first dose, and usually within 7 days
- -Incomplete Abortion: 600 mcg orally once
- -Missed Abortion: 800 mcg intravaginally OR 600 mcg sublingually once; the dose may be repeated every 3 hours for 2 additional doses

FDA-approved use for termination of an early pregnancy

The usual dosage for a medical abortion is 200 mg of mifepristone on Day 1, followed 24 to 48 hours later by 800 mcg misoprostol taken buccally (see below).

- The pregnancy must not be over 70 days (10 weeks) gestation. This means 70 days or less have passed since the first day of the woman's last menstrual period (10 weeks or less).
- The mifepristone tablet is swallowed whole.
- The misoprostol tablets are taken buccally which means between your top lip and gum (in your cheek pouch).
 - Place 2 misoprostol tablets in each cheek pouch for 30 minutes and then swallow anything left over with a drink of water or another liquid.
- The medicines may not work as well if you take misoprostol sooner than 24 hours after mifepristone or later than 48 hours after mifepristone.

Comments:

- -Pain medications should be provided.
- -Patients that are Rh(D) negative and unsensitized: Rh(D)-immune globulin should be given within 72 hours of administration of the initial dose.
- -Follow-up treatment should be made within 7 to 14 days to ensure complete expulsion has occurred.
- -If treatment fails, surgical options may need to be considered.

Use: Treatment of early pregnancy loss, incomplete abortion, missed abortion, or termination of an early pregnancy.

Detailed Misoprostol dosage information

What happens if I miss a dose?

Take the missed dose of misoprostol as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and take only the next regularly scheduled dose. Do not take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking misoprostol?

Ask your doctor before using an antacid, and use only the type your doctor recommends. Some antacids can increase your risk of diarrhea while you are taking misoprostol.

Follow your doctor's instructions about any restrictions on food, beverages, or activity.

What other drugs will affect misoprostol?

Tell your doctor about all your other medicines, especially:

antacids.

This list is not complete. Other drugs may interact with misoprostol, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

Misoprostol drug interactions (more detail)

Does misoprostol interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

misoprostol
+
Enter a drug name
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1. Cytotec Package Insert

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Patient resources

Other brands

Cytotec

Professional resources

- Misoprostol monograph
- Misoprostol (FDA)

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Related treatment guides

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- Duodenal Ulcer

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal

Medical Disclaimer

DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

ം Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

□ Drug history at FDA

User Reviews & Ratings

7.8 / 10

722 Reviews

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Misoprostol 200 mcg (G 5008)





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