

MEDICATION GUIDE
METOCLOPRAMIDE TABLETS, USP
10 mg and 5 mg

Read the Medication Guide that comes with metoclopramide tablets before you start taking it and each time you get a refill. There may be new information. If you take another product that contains metoclopramide (such as metoclopramide injection, metoclopramide orally disintegrating tablets, or metoclopramide oral solution), you should read the Medication Guide that comes with that product. Some of the information may be different. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about metoclopramide tablets?

Metoclopramide tablets can cause serious side effects, including:

Abnormal muscle movements called tardive dyskinesia (TD). These movements happen mostly in the face muscles. You can not control these movements. They may not go away even after stopping metoclopramide tablets. There is no treatment for TD, but symptoms may lessen or go away over time after you stop taking metoclopramide tablets. Your chances for getting TD go up:

- the longer you take metoclopramide tablets and the more metoclopramide tablets you take. You should not take metoclopramide tablets for more than 12 weeks.
- if you are older, especially if you are a woman
- if you have diabetes

It is not possible for your doctor to know if you will get TD if you take metoclopramide tablets. Call your doctor right away if you get movements you can not stop or control, such as:

- lip smacking, chewing, or puckering up your mouth
- frowning or scowling
- sticking out your tongue
- blinking and moving your eyes
- shaking of your arms and legs

See the section “What are the possible side effects of metoclopramide tablets?” for more information about side effects.

What are metoclopramide tablets?

Metoclopramide tablets are a prescription medicine used:

- in adults for 4 to 12 weeks to relieve heartburn symptoms with gastroesophageal reflux disease (GERD) when certain other treatments do not work. Metoclopramide tablets relieve daytime heartburn and heartburn after meals. It also helps ulcers in the esophagus to heal.
- to relieve symptoms of slow stomach emptying in people with diabetes. Metoclopramide tablets help treat symptoms such as nausea, vomiting, heartburn, feeling full long after a meal, and loss of appetite. Not all these symptoms get better at the same time.

It is not known if metoclopramide tablets are safe and work in children.

Who should not take metoclopramide tablets?

Do not take metoclopramide tablets if you:

- have stomach or intestine problems that could get worse with metoclopramide tablets, such as bleeding, blockage, or a tear in the stomach or bowel wall
- have an adrenal gland tumor called a pheochromocytoma
- are allergic to metoclopramide tablets or anything in it. See the end of this Medication Guide for a list of ingredients in metoclopramide tablets.
- take medicines that can cause uncontrolled movements, such as medicines for mental illness
- have seizures

What should I tell my doctor before taking metoclopramide tablets?

Tell your doctor about all your medical conditions, including if you have:

- depression
- Parkinson's disease
- high blood pressure
- kidney problems. Your doctor may start with a lower dose.
- liver problems or heart failure. Metoclopramide tablets may cause your body to hold fluids.
- diabetes. Your dose of insulin may need to be changed.
- breast cancer
- you are pregnant or plan to become pregnant. It is not known if metoclopramide tablets will harm your unborn baby.
- you are breastfeeding. Metoclopramide can pass into breast milk and may harm your baby. Talk with your doctor about the best way to feed your baby if you take metoclopramide tablets.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Metoclopramide tablets and some other medicines may interact with each other and may not work as well, or cause possible side effects. Do not start any new medicines while taking metoclopramide tablets until you talk with your doctor.

Especially tell your doctor if you take:

- another medicine that contains metoclopramide, such as metoclopramide orally disintegrating tablets, or metoclopramide oral solution
- a blood pressure medicine
- a medicine for depression, especially a Monoamine Oxidase Inhibitor (MAOI)
- insulin
- a medicine that can make you sleepy, such as anti-anxiety medicine, sleep medicines, and narcotics.

If you are not sure if your medicine is one listed above, ask your doctor or pharmacist.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take metoclopramide tablets?

- Metoclopramide comes as a tablet you take by mouth.
- Take metoclopramide tablets exactly as your doctor tells you. Do not change your dose unless your doctor tells you.
- You should not take metoclopramide tablets for more than 12 weeks.
- If you take too much metoclopramide tablets, call your doctor or Poison Control Center right away.

What should I avoid while taking metoclopramide tablets?

- Do not drink alcohol while taking metoclopramide tablets. Alcohol may make some side effects of metoclopramide tablets worse, such as feeling sleepy.
- Do not drive, work with machines, or do dangerous tasks until you know how metoclopramide tablets affects you. Metoclopramide tablets may cause sleepiness.

What are the possible side effects of metoclopramide tablets?

Metoclopramide tablets can cause serious side effects, including:

- **Abnormal muscle movements.** See "What is the most important information I need to know about metoclopramide tablets?"
- **Uncontrolled spasms of your face and neck muscles, or muscles of your body, arms, and legs (dystonia).** These muscle spasms can cause abnormal movements and body positions. These spasms usually start within the first 2 days of treatment. These spasms happen more often in children and adults under age 30.
- **Depression, thoughts about suicide, and suicide.** Some people who take metoclopramide tablets become depressed. You may have thoughts about hurting or killing yourself. Some people who take metoclopramide tablets have ended their own lives (suicide).

- **Neuroleptic Malignant Syndrome (NMS).** NMS is a very rare but very serious condition that can happen with metoclopramide tablets. NMS can cause death and must be treated in a hospital. Symptoms of NMS include: high fever, stiff muscles, problems thinking, very fast or uneven heartbeat, and increased sweating.
- **Parkinsonism.** Symptoms include slight shaking, body stiffness, trouble moving or keeping your balance. If you already have Parkinson's disease, your symptoms may become worse while you are receiving metoclopramide tablets.

Call your doctor and get medical help right away if you:

- feel depressed or have thoughts about hurting or killing yourself
- have high fever, stiff muscles, problems thinking, very fast or uneven heartbeat, and increased sweating
- have muscle movements you cannot stop or control
- have muscle movements that are new or unusual

Common side effects of metoclopramide tablets include:

- feeling restless, sleepy, tired, dizzy, or exhausted
- headache
- confusion
- trouble sleeping

You may have more side effects the longer you take metoclopramide tablets and the more metoclopramide tablets you take.

You may still have side effects after stopping metoclopramide tablets. You may have symptoms from stopping (withdrawal) metoclopramide tablets such as headaches, and feeling dizzy or nervous.

Tell your doctor about any side effects that bother you or do not go away. These are not all the possible side effects of metoclopramide tablets.

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

How should I store metoclopramide tablets?

- Keep metoclopramide tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep metoclopramide tablets in the bottle it comes in. Keep the bottle closed tightly.

Keep metoclopramide tablets and all medicines out of the reach of children.

General information about metoclopramide tablets

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

This Medication Guide summarizes the most important information about metoclopramide tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about metoclopramide tablets that is written for health professionals.

What are the ingredients in metoclopramide tablets?

Active ingredient: metoclopramide

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