

MEDICATION GUIDE

METOSOLV® (MĚ-tō-zolv) ODT (metoclopramide hydrochloride) **Orally Disintegrating Tablets**

Read the Medication Guide that comes with METOSOLV ODT before you take it and each time you get a refill. There may be new information. If you take another product that contains metoclopramide (such as REGLAN tablets, REGLAN ODT, REGLAN injection 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 METOSOLV ODT?

METOSOLV ODT can cause serious side effects, including:

Tardive dyskinesia (abnormal muscle movements). These movements happen mostly in the face muscles. You cannot control these movements. They may not go away even after stopping METOSOLV ODT. There is no treatment for tardive dyskinesia, but symptoms may lessen or go away over time after you stop taking METOSOLV ODT.

Your chances for getting tardive dyskinesia go up:

- the longer you take METOSOLV ODT and the more METOSOLV ODT you take. You should not take METOSOLV ODT for more than 12 weeks.
- if you are older, especially if you are an older woman
- if you have diabetes

It is not possible for your doctor to know if **you** will get tardive dyskinesia if you take METOSOLV ODT.

Call your doctor right away if you have movements you can not stop or control, such as:

- lip smacking, chewing, or puckering of your lips
- 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 METOSOLV ODT?” for more information about side effects.

What is METOSOLV ODT?

METOSOLV ODT is a prescription medicine used in adults:

- for 4 to 12 weeks to relieve heartburn symptoms of gastroesophageal reflux disease (GERD) when certain other treatments do not work.
- to relieve the symptoms of slow stomach emptying in people with diabetes.

It is not known if METOSOLV ODT is safe or works in children.

Who should not take METOZOLV ODT?

Do not take METOZOLV ODT if you:

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

What should I tell my doctor before taking METOZOLV ODT?

Before you take METOZOLV ODT, tell your doctor if you:

- have kidney or liver disease
- have depression or mental illness
- have high blood pressure
- have heart failure or heart rhythm problems
- have diabetes. Your dose of insulin may need to be changed.
- have Parkinson's disease
- have any other medical conditions
- drink alcohol
- are pregnant or plan to become pregnant. It is not known if METOZOLV ODT will harm your unborn baby.
- are breast-feeding or plan to breast-feed. METOZOLV ODT can pass into your milk and may harm your baby. You and your doctor should decide if you will take METOZOLV ODT or breast-feed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. METOZOLV ODT and some medicines can affect each other and may not work as well, or cause possible side effects. Do not start any new medicine while taking METOZOLV ODT until you talk with your doctor.

Especially tell your doctor if you take:

- another medicine that contains metoclopramide, such as REGLAN tablets, REGLAN ODT, or metoclopramide oral syrup
- a blood pressure medicine
- a medicine for depression, especially a monoamine oxidase inhibitor (MAOI)
- an anti-psychotic medicine
- insulin
- medicines that can make you sleepy, such as anti-anxiety medicines, sleep medicines, and narcotics.

Ask your doctor or pharmacist if you are not sure if your medication is listed above.

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

How should I take METOZOLV ODT?

- METOZOLV ODT comes as a tablet that melts in your mouth.
- Take METOZOLV ODT exactly as prescribed by your doctor. Do not change your dose unless your doctor tells you to.
- You should not take METOZOLV ODT for more than 12 weeks.
- Take METOZOLV ODT at least 30 minutes before eating and at bedtime.

To take METOZOLV ODT:

1. Leave the tablet in the sealed blister METOZOLV ODT pack until you are ready to take it.
2. Use dry hands to open a blister and take out a tablet. If the tablet breaks or crumbles throw it away and take a new tablet out of the blister pack.
3. Put the tablet on your tongue right away. Let it melt and then swallow. You do not need water to take METOZOLV ODT.

If you take too much METOZOLV ODT, call your doctor or Poison Control Center.

What should I avoid while taking METOZOLV ODT?

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

What are the possible side effects of METOZOLV ODT?**METOZOLV ODT can cause serious side effects, including:**

- Tardive dyskinesia (**abnormal muscle movements**). See “What is the most important information I should know about METOZOLV ODT?”
- **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 younger than 30.
- **Depression, thoughts about suicide, and suicide**. Some people who take METOZOLV ODT may become depressed. You may have thoughts about hurting or killing yourself. Some people who have taken metoclopramide products have ended their own lives (suicide).
- **Neuroleptic Malignant Syndrome (NMS)**. NMS is a rare but very serious condition that can happen with METOZOLV ODT. 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 have Parkinson’s Disease, your symptoms may become worse while you are taking METOZOLV ODT.
- **High blood pressure**. METOZOLV ODT can cause your blood pressure to increase.
- **Too much body water**. People who have certain liver problems or heart failure and take METOZOLV ODT may hold too much water in their body (fluid retention). Tell your doctor right away if you have sudden weight gain, or swelling of your hands, legs, or feet.

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

The most common side effects of METOZOLV ODT are:

- headache
- nausea
- vomiting
- tiredness
- sleepiness

You may have more side effects the longer you take METOZOLV ODT and the more METOZOLV ODT you take.

You may still have side effects after you stop METOZOLV ODT. You may have symptoms from stopping (withdrawal) METOZOLV ODT 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 METOZOLV ODT.

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

How do I store METOZOLV ODT?

- Store METOZOLV ODT at room temperature, between 68°F to 77°F (20°C to 25°C).
- Keep METOZOLV ODT away from moisture.
- Throw away any METOZOLV ODT that is not used.

Keep METOZOLV ODT and all medicines away from children.**General information about METOZOLV ODT**

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

This Medication Guide summarizes the most important information about METOZOLV ODT. If you would like more information about METOZOLV ODT, talk with your doctor. You can ask your doctor or pharmacist for information about METOZOLV ODT that is written for health professionals. For more information, call 1-866-669-7597.

What are the ingredients in METOZOLV ODT?

Active ingredients: metoclopramide hydrochloride

Inactive ingredients: gelatin, mannitol, mint flavoring, Acesulfame potassium (artificial sweetener), and trace amounts of sodium chloride and sodium hydroxide

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This Medication Guide has been approved by the U.S. Food and Drug Administration.
VENART-144-2/September 2011