

## Medication Guide

GIMOTI™ (jye-MOH-tee)  
(metoclopramide)  
nasal spray

Read this Medication Guide before you start taking GIMOTI 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 injection, metoclopramide orally disintegrating tablets [ODT], or metoclopramide oral solution), you should read the Medication Guide that comes with that product. Some of the information may be different. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

### What is the most important information I should know about GIMOTI?

#### GIMOTI 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 GIMOTI.

Your chances for getting tardive dyskinesia increase:

- the longer you take GIMOTI and the more GIMOTI you take. You should not take GIMOTI for more than 8 weeks at a time, and you should not take products containing metoclopramide (including GIMOTI) for more than 12 weeks at a time.
- if you are older, especially if you are an older woman.
- because you have diabetes.

It is not possible for your healthcare provider to know if **you** will get tardive dyskinesia if you take GIMOTI.

Call your healthcare provider right away if you get movements you cannot 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

Your healthcare provider may stop treatment with GIMOTI if you develop signs or symptoms of tardive dyskinesia.

See the section "**What are the possible side effects of GIMOTI?**" for more information about side effects.

### What is GIMOTI?

- GIMOTI is a prescription medicine used in adults to relieve the symptoms of slow stomach emptying in people with diabetes.
- GIMOTI is **not recommended** for use in people who:
  - have kidney or liver problems.
  - have been told that an enzyme in their body, called CYP2D6, breaks down (metabolizes) certain medicines in the body too slowly.
  - are also taking medicine called CYP2D6 inhibitors, which slows how fast the body breaks down (metabolizes) certain medicines.
- GIMOTI is not recommended for use in children.
- It is not known if GIMOTI is safe and effective in children.

### Do not take GIMOTI if you:

- have a history of tardive dyskinesia or have a problem controlling your muscles and movements after taking GIMOTI or a medicine that works like GIMOTI.
- have stomach or intestine problems that could get worse with GIMOTI, such as bleeding, blockage, or a tear in the stomach or bowel wall.
- have a type of tumor that can cause high blood pressure, such as pheochromocytoma.
- have epilepsy (seizures). GIMOTI can increase your chance for seizures and make them worse.
- are allergic to metoclopramide. GIMOTI can cause serious allergic reactions. Stop taking GIMOTI right away and get emergency help if you have any of these symptoms:

- swelling of your tongue, throat, lips, eyes, or face
- trouble swallowing or breathing
- skin rash, hives, sores in your mouth, or skin blisters

**Before taking GIMOTI, tell your healthcare provider about all of your medical conditions, including if you:**

- take insulin for your diabetes. Your dose may need to be changed.
- had problems controlling your muscle movements after taking any medicine.
- have Parkinson's disease.
- have kidney or liver disease.
- have or had depression or mental illness.
- have high blood pressure.
- have heart failure or heart rhythm problems.
- have breast cancer.
- drink alcohol.
- are pregnant or plan to become pregnant. GIMOTI may harm your unborn baby if taken during the end of pregnancy. Talk to your healthcare provider if you become pregnant while taking GIMOTI.
- are breastfeeding or plan to breastfeed. GIMOTI can pass into your breast milk and may harm your baby. It is important that you tell your baby's healthcare provider you are taking GIMOTI. You and your healthcare provider should decide if you will take GIMOTI or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

GIMOTI may affect the way other medicines work and other medicines may affect how GIMOTI works.

Tell your healthcare provider before you start or stop other medicines.

**Especially tell your healthcare provider if you take:**

- another medicine that contains metoclopramide, such as REGLAN tablets, REGLAN injection, metoclopramide orally disintegrating tablets (ODT), or metoclopramide oral solution.
- a medicine for Parkinson's disease.
- a blood pressure medicine.
- a medicine for depression, especially a monoamine oxidase inhibitor (MAOI).
- an anti-psychotic medicine, used to treat mental illness such as schizophrenia.
- insulin.
- medicines that can make you sleepy, such as anxiety medicines, sleep medicines, and narcotics.

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

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

**How should I take GIMOTI?**

- **Read the step-by-step Instructions for Use that come with your GIMOTI prescription.**
- Take GIMOTI exactly as your healthcare provider tells you. Do not change your dose unless your healthcare provider tells you to.
- GIMOTI comes as a liquid in a glass bottle with a spray pump attached.
- You should not take GIMOTI for more than 8 weeks at a time.
- You should not take medicines containing metoclopramide (including GIMOTI) for more than 12 weeks at a time.
- Take GIMOTI at least 30 minutes before each meal and at bedtime.
- If you are not certain that the spray entered the nose, skip the dose and take your next dose at your regular schedule time. Do not take an extra dose at the schedule time. If you miss a dose of GIMOTI, skip that dose and take your next dose at your regular scheduled time. Do not take an extra dose to make up for a missed dose.
- If you take too much GIMOTI, call your poison control center at 1-800-222-1222 or go to the nearest emergency room right away.

### **What should I avoid while taking GIMOTI?**

- Do not drink alcohol while taking GIMOTI. Alcohol may make some side effects of GIMOTI worse, such as feeling sleepy.
- Do not drive, operate machinery, or do other dangerous activities until you know how GIMOTI affects you. GIMOTI may cause sleepiness or dizziness.

### **What are the possible side effects of GIMOTI?**

#### **GIMOTI can cause serious side effects, including:**

- **Tardive dyskinesia (abnormal muscle movements).** See “**What is the most important information I need to know about GIMOTI?**”
- **Other changes in muscle control and movement, such as:**
  - **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 and speech problems. These spasms usually start within the first 2 days of treatment. Rarely, these muscle spasms may cause trouble breathing. These spasms happen more often in adults less than 30 years of age.
  - **Parkinsonism.** Symptoms include slight shaking, body stiffness, and trouble moving or keeping your balance. If you already have Parkinson's Disease, your symptoms may become worse while you are taking GIMOTI.
  - **Being unable to sit still or feeling you need to move your hands, feet, or body (akathisia).** Symptoms can include feeling jittery, anxious, irritated, or unable to sleep (insomnia), feeling the need to walk around (pacing), and tapping your feet. Your healthcare provider may stop your treatment with GIMOTI if you develop these symptoms.
- **Neuroleptic Malignant Syndrome (NMS).** NMS is a very rare, but very serious condition that can happen with GIMOTI. 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.
- **Depression, thoughts about suicide, and suicide.** Some people who take GIMOTI may become depressed, even if they have no history of depression. You may have thoughts about hurting or killing yourself. Some people who have taken metoclopramide have ended their own lives (suicide).
- **High blood pressure.** GIMOTI can cause your blood pressure to increase. Your healthcare provider may stop your treatment if GIMOTI causes your blood pressure to increase very fast.
- **Too much body water.** People who have certain liver problems or heart failure and take GIMOTI may hold too much water in their body (fluid retention). Tell your healthcare provider right away if you have sudden weight gain, or swelling of your hands, legs, or feet.
- **Increased prolactin.** Tell your healthcare provider if your menstrual periods stop or your breasts get larger and make milk. These symptoms go away when you stop taking GIMOTI.

#### **Call your healthcare provider 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 GIMOTI include:

- unpleasant taste
- headache
- tiredness

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

You may still have side effects after stopping GIMOTI. You may have symptoms from stopping GIMOTI such as headaches and feeling dizzy or nervous.

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of GIMOTI. 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 GIMOTI?**

- Store GIMOTI at room temperature between 68°F to 77°F (20°C to 25°C).
- Throw away (discard) GIMOTI 4 weeks after opening even if the bottle contains unused medicine.

**Keep GIMOTI and all medicines out of the reach of children.**

**General information about the safe and effective use of GIMOTI.**

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

You can ask your pharmacist or healthcare provider for information about GIMOTI that is written for health professionals.

**What are the ingredients in GIMOTI?**

**Active ingredient:** metoclopramide

**Inactive ingredients:** benzalkonium chloride, citric acid monohydrate, edetate disodium dihydrate, purified water, sodium citrate dihydrate, sorbitol.

Manufactured for Evoke Pharma, Inc. by Patheon, a Division of Thermo Fisher.  
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For more information, go to [www.evokepharma.com](http://www.evokepharma.com) or call 1-833-4-GIMOTI (1-833-444-6684).