

Gimoti[®]

(metoclopramide)
nasal spray

Instructions for Use



What is Gimoti[®] (metoclopramide) nasal spray?

GIMOTI is a prescription medicine used 30 minutes before meals and at bedtime for 2 to 8 weeks to relieve symptoms in adults with diabetes who have irregular or slow stomach emptying. Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks.

GIMOTI is not recommended for use in children under age 18.

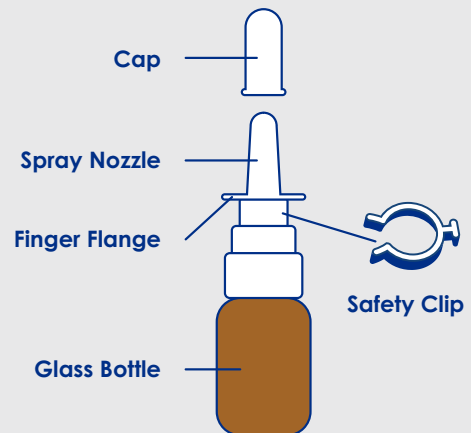
Read these Instructions for Use before you start using GIMOTI and each time you get a refill. This information does not take the place of talking to your healthcare professional about your medical condition or your treatment.



Important Information

- GIMOTI is for use in your nose only.
- Each GIMOTI bottle has enough medicine for 4 weeks of treatment when taken 4 times each day (recommended dosage).
- One dose is 1 spray in 1 nostril.
- Your GIMOTI bottle must be primed
 - before you use it for the first time
 - when the nasal spray has not been used for 2 weeks
- Store the GIMOTI bottle at 68°F to 77°F (20°C to 25°C).
- Throw away the GIMOTI bottle 4 weeks after opening even if the bottle contains unused medicine.
- Keep out of the reach of children.

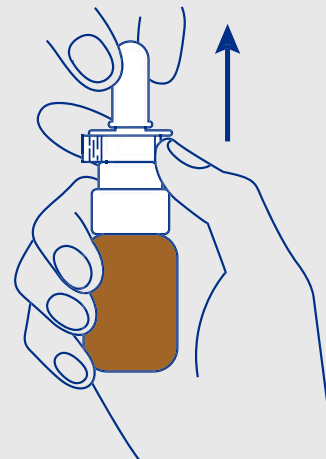
Parts of your GIMOTI bottle



Steps to use GIMOTI

Step 1 » Uncap the GIMOTI bottle

- Remove the cap from the spray nozzle by pulling straight up.

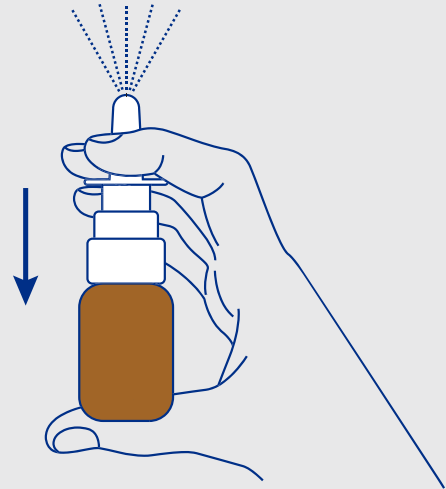


See next page for continued instructions.

Step 2 » Prime the GIMOTI bottle

- Your GIMOTI bottle must be primed
 - before you use it for the first time
 - when the nasal spray has not been used for 2 weeks or longer
- Remove the safety clip from the spray pump.
- Place your index finger and middle finger on each side of the finger flange and your thumb on the bottom of the glass bottle.
- Turn the spray nozzle away from your face, keeping the bottle upright. **Do not** spray into your eyes.
- Press down firmly and release 10 times on the finger flange until a spray appears from the spray nozzle. You may not see a spray the first few times you press down. After pressing down and releasing a spray 10 times, the GIMOTI bottle will be primed and ready to use.

If you are not able to press and release 10 sprays from the GIMOTI bottle, call your healthcare professional or pharmacist.



The GIMOTI bottle is now ready for use.

Step 3 » Use the GIMOTI bottle

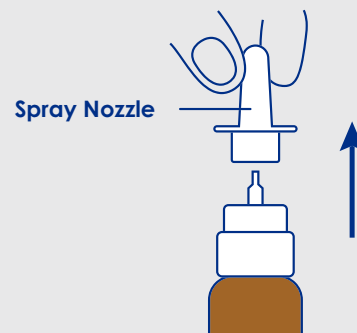
- Place the spray nozzle tip under one of your nostrils. Tilt your head slightly forward so the tip of the spray nozzle is aimed away from the center of your nose.
- Close the other nostril with your other index finger. Move the spray pump up so the tip of the nozzle is in your nostril.
- Hold the bottle upright and press down firmly on the finger flange until it stops moving to deliver a full dose.
- Release the finger flange and breathe in gently through the open nostril.
- Remove the spray pump nozzle tip from your nostril and breathe out slowly through your mouth.
- After use, wipe the spray nozzle with a clean tissue.

Replace the cap on the spray nozzle by pushing straight down. Place the safety clip back onto the spray pump.



Step 4 » Clean the GIMOTI spray pump nozzle

- If the spray pump nozzle becomes clogged, remove it for cleaning by grasping the base of the spray nozzle and pulling up.
- Soak the spray nozzle in warm water and rinse. Do not try to unblock the spray nozzle by inserting a pin or other sharp object because this will damage the spray nozzle.
- Dry the spray nozzle at room temperature. When the spray nozzle is dry, place it back on the GIMOTI bottle.



Disposal instructions: If there is no take-back program available in your area, throw away GIMOTI bottles in the household trash.

Please see complete Important Safety Information on pages 3-4, including Boxed Warning. Also see complete Prescribing Information and Medication Guide.

Important Safety Information

Gimoti® (metoclopramide) nasal spray

What is Gimoti® (metoclopramide) nasal spray?

GIMOTI is a prescription medicine used 30 minutes before meals and at bedtime for 2 to 8 weeks to relieve symptoms of slow stomach emptying in adults with diabetes. Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks.

GIMOTI is not recommended for use in children under age 18.

Important facts about GIMOTI

This is a summary of important information you need to know about GIMOTI. This information does not take the place of talking with your healthcare professional 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, mostly of the face or tongue muscles. You cannot control these movements, and they may not go away even after stopping GIMOTI. Your chances of getting tardive dyskinesia increase

- **The longer you take metoclopramide and the more metoclopramide 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 (e.g., age 65 years and older)**
- **If you have diabetes**

Call your healthcare professional 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.

Do not use 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 intestinal 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)
- Are allergic to metoclopramide. 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 starting GIMOTI, tell your healthcare professional about all your medical conditions, especially if you have

- Problems controlling your muscle movements after taking any medicine
- Parkinson's disease
- Pheochromocytoma
- Kidney or liver disease
- Depression or mental illness
- High blood pressure

Also tell your healthcare professional if you are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed, or drink alcohol.

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

Speak with your healthcare professional before you start or stop any other medicines.

Please see additional Important Safety Information on next page.

Important Safety Information (cont'd)

Especially tell your healthcare professional if you take

- Another medicine that contains metoclopramide, such as REGLAN® tablets
- Medicine for Parkinson's disease
- Blood pressure medicine
- Medicine for depression, especially a monoamine oxidase inhibitor (MAOI)
- Antipsychotic medicine used to treat mental illness, such as schizophrenia
- Insulin
- Medicines that can make you sleepy, such as anxiety medicines, sleep medicines, and narcotics

What should I avoid while taking GIMOTI?

- Do not drink alcohol while taking GIMOTI
- GIMOTI may cause sleepiness or dizziness. Do not drive, operate machinery, or do potentially dangerous activities until you know how GIMOTI affects you

What are other possible side effects of 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)
 - parkinsonism – slight shaking, body stiffness, and trouble moving or keeping your balance
 - being unable to sit still or feeling that you need to move your hands, feet, or body (akathisia)
- Neuroleptic Malignant Syndrome (NMS) – a very rare but very serious condition. NMS can lead to death and must be treated in a hospital
- Depression, thoughts about suicide, and suicide
- High blood pressure
- Too much body water
- Increased prolactin

Call your healthcare professional 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/or increased sweating
- Have muscle movements that you cannot stop or control
- Have muscle movements that are new or unusual

The most common side effects of GIMOTI include

- Unpleasant taste after dosing
- Headache
- Tiredness

These are not all the possible side effects of GIMOTI. Ask your healthcare professional for medical advice about side effects.

You may report side effects related to Evoke Pharma products by calling **1-833-4-GIMOTI (1-833-444-6684)** or emailing GIMOTImedinfo@evokepharma.com. If you prefer to report these to the FDA, either visit www.FDA.gov/medwatch or call **1-800-FDA-1088**.

This information should not take the place of you talking with your doctor or healthcare professional. If you have any questions about your condition, or if you would like more information about GIMOTI, talk to your doctor or pharmacist. Only you and your healthcare professional can decide if GIMOTI is right for you.

Please see complete [Prescribing Information](#), including [Boxed Warning](#), and [Medication Guide](#).

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