

Medication Guide

REGLAN ODT (REG-lan Oh-dee-tee) (metoclopramide orally disintegrating tablets)

Read the Medication Guide that comes with REGLAN ODT 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 REGLAN tablets, REGLAN injection, or metoclopramide oral syrup), 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 REGLAN ODT?

REGLAN ODT 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 REGLAN ODT. There is no treatment for TD, but symptoms may lessen or go away over time after you stop taking REGLAN ODT.

Your chances for getting TD go up:

- the longer you take REGLAN ODT and the more REGLAN ODT you take. You should not take REGLAN ODT 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 REGLAN ODT.

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 REGLAN ODT?" for more information about side effects.

What is REGLAN ODT?

REGLAN ODT is 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. REGLAN ODT relieves 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. REGLAN ODT helps 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 REGLAN ODT is safe and works in children.

Who should not take REGLAN ODT?

Do not take REGLAN ODT if you:

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

What should I tell my doctor before taking REGLAN ODT?

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. REGLAN ODT may cause your body to hold fluids.
- diabetes. Your dose of insulin may need to be changed.
- breast cancer
- phenylketonuria. REGLAN ODT contains aspartame.
- you are pregnant or plan to become pregnant. It is not known if REGLAN ODT will harm your unborn baby.
- you are breast-feeding. REGLAN ODT 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 REGLAN ODT.

Tell your doctor about all the medicines you take including, prescription and non-prescription medicines, vitamins, and herbal supplements. REGLAN ODT 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 REGLAN ODT until you talk with your doctor.

Especially tell your doctor if you take:

- another medicine that contains metoclopramide, such as REGLAN tablets, or metoclopramide oral syrup.
- a blood pressure medicine
- a medicine for depression, especially an Monoamine Oxidase Inhibitor (MAOI)
- insulin
- a medicine that can make you sleepy, such an 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 your doctor and pharmacist when you get a new medicine.

How should I take REGLAN ODT?

- REGLAN ODT comes as a tablet that melts in your mouth.
- Take REGLAN ODT exactly as your doctor tells you. Do not change your dose unless your doctor tells you.
- You should not take REGLAN ODT for more than 12 weeks.
- To take REGLAN ODT:
 - Leave the tablet in the bottle until you are ready to take it.
 - Use dry hands to take out a tablet. If your hands are wet, the tablets will melt.
 - Put the tablet on your tongue right away. Let it melt and then swallow. You do not need water to take REGLAN ODT.
- If you take too much REGLAN ODT, call your doctor or Poison Control Center right away.

What should I avoid while taking REGLAN ODT?

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

What are the possible side effects of REGLAN ODT?

Reglan ODT can cause serious side effects, including:

- **Abnormal muscle movements.** See “What is the most important information I should know about REGLAN ODT?”
- **Uncontrolled spasm 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 REGLAN ODT become depressed. You may have thoughts about hurting or killing yourself. Some people who take REGLAN ODT have ended their own lives (suicide).
- **Neuroleptic Malignant Syndrome (NMS).** NMS is a rare but very serious condition that can happen with REGLAN 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 already have Parkinson’s disease, your symptoms may become worse while you are receiving REGLAN ODT.

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 can not stop or control
- have muscle movements that are new or unusual

Common side effects include:

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

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

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

- Keep REGLAN ODT at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep REGLAN ODT in the bottle it comes in. Keep the bottle closed tightly.
- Keep REGLAN ODT dry so it does not melt.

Keep REGLAN ODT and all medicines out of the reach of children.

General information about REGLAN ODT

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use REGLAN ODT for a condition for which it was not prescribed. Do not give REGLAN 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 REGLAN ODT. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about REGLAN ODT that is written for health professionals. For more information go to www.alavenpharma.com or call 1-888-317-0001.

What are the ingredients in REGLAN ODT?

Active ingredient: metoclopramide

Inactive ingredients: aspartame, colloidal silicon dioxide, crospovidone, magnesium stearate, mannitol, aminoalkyl methacrylate copolymer, microcrystalline cellulose, natural and artificial orange flavor, povidone

Manufactured for

Alaven Pharmaceutical LLC, Marietta, GA 30062

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