

MEDICATION GUIDE
REGLAN (Reg-lan)
(metoclopramide)
injection

You or your caregiver should read the Medication Guide before you start receiving REGLAN injection and before you get another dose of REGLAN injection. There may be new information. If you take another product that contains metoclopramide (such as REGLAN tablets, REGLAN ODT, 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 to your doctor about your medical condition or your treatment.

What is the most important information I should know about REGLAN?

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

Your chances for getting TD go up:

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

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?” for more information about side effects.

What is REGLAN?

REGLAN is a prescription medicine used to:

- relieve symptoms of slow stomach emptying in people with diabetes

- prevent nausea and vomiting that can happen with cancer chemotherapy
- prevent nausea and vomiting that may happen after surgery, if your doctor decides that you should not be treated with a stomach tube and suction
- help make it easier to insert a tube into the small intestine in both adults and children, if the tube does not pass into the stomach normally.
- to help empty stomach contents or to help barium move through your intestine, when you get an X-ray examination of the stomach or small intestine. It is not known if REGLAN is safe and works in children except when used to help insert a tube into the small intestine.

Who should not receive REGLAN?

Do not receive REGLAN if you:

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

What should I tell my doctor before receiving REGLAN?

Tell your doctor about all of 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 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 REGLAN will harm your unborn child.
- you are breastfeeding. REGLAN is passed into human milk and may harm your baby. Talk with your doctor about the best way to feed your baby if you take REGLAN.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. REGLAN and some other medicines can affect each other and may not work as well, or cause possible side effects. Do not start any new medicines while receiving REGLAN 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)
- 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 will I receive REGLAN?

- REGLAN will be given to you by intravenous (IV) infusion into your vein or by intramuscular (IM) injection into a large muscle. Where and how you receive your REGLAN injection (IV or IM) will depend on why you are receiving it.
- Certain side effects can happen if REGLAN is given too fast. See the section “What are the possible side effects of REGLAN?”
- You should not take or receive REGLAN for more than 12 weeks.

What should I avoid while receiving REGLAN?

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

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

- **Abnormal muscle movements.** See the section “What is the most important information I should know about REGLAN?”
- **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 REGLAN become depressed. You may have thoughts about hurting or killing yourself. Some people who take REGLAN have ended their own lives (suicide).
- **Neuroleptic Malignant Syndrome (NMS).** NMS is a very rare but very serious condition that can happen with REGLAN. 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.

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 of REGLAN include:

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

Infusion related side effects can happen if REGLAN is given too fast. You may feel very anxious and restless for a short time, and then become sleepy while you are receiving a dose of REGLAN. Tell your doctor or nurse right away if this happens.

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

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.

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

General information about REGLAN

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about REGLAN. If you would like more information about REGLAN, talk with your doctor. You can ask your doctor or pharmacist for information about REGLAN that is written for healthcare professionals. For more information, call Baxter Healthcare at 1-800-933-3030.

What are the ingredients in REGLAN?

Active ingredient: metoclopramide

Inactive ingredients: sodium chloride, water, hydrochloric acid or sodium hydroxide

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