

PATIENT INFORMATION

Metformin Hydrochloride (met for' min hye'' droe klor' ide) Extended-release Tablets USP

What is the most important information I should know about Metformin hydrochloride extended-release tablets?

Metformin hydrochloride extended-release tablets can cause serious side effects including:

Lactic Acidosis. Metformin hydrochloride, the medicine in Metformin hydrochloride extended-release tablets, can cause a rare, but serious side effect called lactic acidosis (a build-up of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in a hospital.

Stop taking Metformin hydrochloride extended-release tablets and call your healthcare provider right away if you get any of the following symptoms of lactic acidosis:

- feel very weak and tired
- have unusual (not normal) muscle pain
- have trouble breathing
- have unexplained stomach or intestinal problems with nausea and vomiting, or diarrhea
- have unusual sleepiness or sleep longer than usual
- feel cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a slow or irregular heartbeat

You have a higher chance of getting lactic acidosis if you:

- have severe kidney problems. See “**Do not take Metformin hydrochloride extended-release tablets if you:**”
- have liver problems.
- have congestive heart failure that requires treatment with medicines.
- drink a lot of alcohol (very often or short-term “binge” drinking).
- get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids.
- have certain x-ray tests with injectable dyes or contrast agents.
- have surgery.
- have a heart attack, severe infection, or stroke.
- are 65 years of age or older.

Tell your healthcare provider if you have any of the problems in the list above.

Tell your healthcare provider that you are taking Metformin hydrochloride extended-release tablets before you have surgery or x-ray tests. Your healthcare provider may need to stop Metformin hydrochloride extended-release tablets for a while if you have surgery or certain x-ray tests).

Metformin hydrochloride extended-release tablets can have other serious side effects. See “**What are the possible side effects of Metformin hydrochloride extended-release tablets?**”

What are Metformin hydrochloride extended-release tablets?

- Metformin hydrochloride extended-release tablets are a prescription medicine that contains metformin hydrochloride. Metformin hydrochloride extended-release tablets are used with diet and exercise to help control high blood sugar (hyperglycemia) in adults with type 2 diabetes.
- It is not known if Metformin hydrochloride extended-release tablets are safe and effective in children under 18 years of age.

Do not take Metformin hydrochloride extended-release tablets if you:

- have severe kidney problems
- are allergic to metformin HCl or any of the ingredients in Metformin hydrochloride extended-release tablets. See the end of this Patient Information leaflet for a complete list of ingredients in Metformin hydrochloride extended-release tablets.
- have a condition called metabolic acidosis including diabetic ketoacidosis (high levels of certain acids called “ketones” in your blood or urine).

Before taking Metformin hydrochloride extended-release tablets, tell your healthcare provider about all your medical conditions, including if you:

- have a history or risk for diabetic ketoacidosis. See “**Do not take Metformin hydrochloride extended-release tablets if you:**”
- have kidney problems.
- have liver problems.
- have heart problems, including congestive heart failure.
- are 65 years of age or older.
- drink alcohol very often or drink a lot of alcohol in short-term “binge” drinking.
- are taking insulin or a sulfonylurea medicine.
- are pregnant or plan to become pregnant. It is not known if Metformin hydrochloride extended-release tablets will harm your unborn baby. If you are pregnant, talk with your healthcare provider about the best way to control your blood sugar while you are pregnant.
- are a woman who has not gone through menopause (premenopausal) who does not have periods regularly or at all. Metformin hydrochloride extended-release tablets can cause the release of an egg from an ovary in a woman (ovulation). This can increase your chance of getting pregnant.
- are breastfeeding or plan to breastfeed. Metformin hydrochloride can pass into your breast milk. Talk with your healthcare provider about the best way to feed your baby while you take Metformin hydrochloride extended-release tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Metformin hydrochloride extended-release tablets may affect the way other medicines work, and other medicines may affect how Metformin hydrochloride extended-release tablets works.

How should I take Metformin hydrochloride extended-release tablets?

- Take Metformin hydrochloride extended-release tablets exactly as your healthcare provider tells you.
- Metformin hydrochloride extended-release tablets should be taken with your evening meals to help decrease an upset stomach.
- Swallow Metformin hydrochloride extended-release tablets whole. Do not crush, cut, or chew the tablets.
- You may sometimes pass a soft mass in your stools (bowel movement) that looks like Metformin hydrochloride extended-release tablets. This is not harmful and will not affect the way Metformin hydrochloride extended-release tablets works.
- When your body is under some types of stress, such as fever, trauma (such as a car accident), infection, or surgery, the amount of diabetes medicine that you need may change. Tell your healthcare provider right away if you have any of these problems.
- Your healthcare provider should do blood tests to check how well your kidneys are working before and during your treatment with Metformin hydrochloride extended-release tablets.
- Your healthcare provider will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A_{1c}.
- Low blood sugar (hypoglycemia) can happen more often when Metformin hydrochloride extended-release tablets are taken with certain other diabetes medicines.

Talk to your healthcare provider about how to prevent, recognize and manage low blood sugar. See “**What are the possible side effects of Metformin hydrochloride extended-release tablets?**”

- Check your blood sugar as your healthcare provider tells you to.
- Stay on your prescribed diet and exercise program while taking Metformin hydrochloride extended-release tablets.
- If you take too much Metformin hydrochloride extended-release tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking Metformin hydrochloride extended-release tablets?

Do not drink a lot of alcoholic drinks while taking Metformin hydrochloride extended-release tablets. This means you should not binge drink for short periods, and you should not drink a lot of alcohol on a regular basis. Alcohol can increase the chance of getting lactic acidosis.

What are the possible side effects of Metformin hydrochloride extended-release tablets?

Metformin hydrochloride extended-release tablets may cause serious side effects, including:

- See “**What is the most important information I should know about Metformin hydrochloride extended-release tablets?**”
- **Low vitamin B₁₂ (vitamin B₁₂ deficiency).** Using Metformin hydrochloride extended-release tablets may cause a decrease in the amount of vitamin B₁₂ in your blood, especially if you have had low vitamin B₁₂ levels before. Your healthcare provider may do blood tests to check your vitamin B₁₂ levels.
- **Low blood sugar (hypoglycemia).** If you take Metformin hydrochloride extended-release tablets with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take Metformin hydrochloride extended-release tablets. Signs and symptoms of low blood sugar may include:
 - headache
 - drowsiness
 - weakness
 - irritability
 - hunger
 - fast heartbeat
 - confusion
 - shaking or feeling jittery
 - dizziness
 - sweating

Common side effects of Metformin hydrochloride extended-release tablets include:

- diarrhea
- indigestion
- headache
- nausea and vomiting
- stomach-area (abdominal) pain and swelling
- taste disturbance (unpleasant metallic taste)
- gassiness (flatulence)

These are not all the possible side effects of Metformin hydrochloride extended-release tablets.

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 Metformin hydrochloride extended-release tablets?

Store Metformin hydrochloride extended-release tablets at room temperature between 68° to 77°F (20° to 25°C). See insert.

Keep bottle tightly closed between each use to protect the Metformin hydrochloride extended-release tablets from moisture.

Protect from light.

Keep Metformin hydrochloride extended-release tablets and all medicines out of the reach of children.

General information about the safe and effective use of Metformin hydrochloride extended-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Metformin hydrochloride extended-release tablets for a condition for which it was not prescribed. Do not give Metformin hydrochloride extended-release tablets 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 Metformin hydrochloride extended-release tablets that is written for health professionals.

What are the ingredients in Metformin hydrochloride extended-release tablets?

Active ingredients: metformin hydrochloride.

Inactive ingredients: ammonium hydroxide, ethylcellulose, hypromellose, lactose monohydrate, medium chain triglycerides, oleic acid, polyethylene glycol, povidone, silicified microcrystalline cellulose, stearic acid, titanium dioxide, talc, triacetin and xanthan gum.

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Manufactured by:

Nostrum Laboratories Inc.

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This Patient Information has been approved by the U.S. Food and Drug Administration.