PATIENT INFORMATION
Metformin Hydrochloride
(met for' min hye'' droe klor' ide)
Extended-Release Tablets, for oral use

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 buildup of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in the hospital.
Stop taking metformin hydrochloride extended-release tablets and call your doctor 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
- 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.
- 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 or other procedure for which you need to restrict the amount of food and liquid you eat and drink.
- have congestive heart failure.
- have a heart attack, severe infection, or stroke.
- are 65 years of age or older.
- have a genetically inherited disease affecting mitochondria (the energy-producing parts within the cells) such as mitochondrial encephalomyopathy with lactic acidosis, and stroke-like episodes (MELAS) syndrome and maternally inherited diabetes and deafness (MIDD).

Tell your doctor if you have any of the problems in the list above.
Tell your doctor that you are taking metformin hydrochloride extended-release tablets before you have surgery or x-ray tests. Your doctor 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 is 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.

Do not take metformin hydrochloride extended-release tablets if you:
- have severe kidney problems.
- are allergic to metformin hydrochloride 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 doctor about all of 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 can harm your unborn baby. If you are pregnant, talk with your doctor 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 doctor about the best way to feed your baby while you take metformin hydrochloride extended-release tablets.
- have a genetically inherited disease affecting mitochondria (the energy-producing parts within the cells) such as MELAS syndrome and MIDD.

Tell your doctor 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 doctor and pharmacist. Talk to your doctor before you start any 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 doctor tells you.
- Metformin hydrochloride extended-release tablets should be taken 1 time each day with your evening meal 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 normal and will not affect the way metformin hydrochloride extended-release tablets works.
- When your body is under some type 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 doctor right away if you have any of these problems.
- Your doctor should do blood tests to check how well your kidneys are working before and during your treatment with metformin hydrochloride extended-release tablets.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.
- Low blood sugar (hypoglycemia) can happen more often when metformin hydrochloride extended-release tablets are taken with certain other diabetes medicines. Talk to your doctor 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 doctor tells you to.
- Stay on your prescribed diet and exercise program while taking metformin hydrochloride extended-release tablets.
- If you miss a dose of metformin hydrochloride extended-release tablets, take your next dose at the normal schedule.

Do not take 2 doses of metformin hydrochloride extended-release tablets on the same day.

- If you take too much metformin hydrochloride extended-release tablets, call your doctor 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 can cause serious side effects, including:

- See **"What is the most important information I should know about metformin hydrochloride extended-release tablets?"**
- **Low vitamin B_{12} (vitamin B_{12} deficiency).** Using metformin hydrochloride extended-release tablets may cause a decrease in the amount of vitamin B_{12} in your blood, especially if you have had low vitamin B_{12} levels before. Your doctor may do blood tests to check your vitamin B_{12} levels.
- **Low blood sugar (hypoglycemia). Low blood sugar is a serious, but common, side effect of metformin hydrochloride extended-release tablets.** If you take metformin hydrochloride extended-release tablets with another medicine that can cause low blood sugar, such as sulfonylureas or insulin, you have a higher risk of getting low blood sugar. 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

The most common side effects of metformin hydrochloride extended-release tablets include:

- diarrhea
- nausea

These are not all of 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 20° to 25°C (68° to 77°F).

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 you have. It may harm them.

You can ask your pharmacist or doctor 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 Ingredient: metformin hydrochloride

Inactive Ingredients: ammonio methacrylate copolymer type A, hypromellose, magnesium stearate, povidone, talc, triethyl citrate.

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Manufactured by:
Granules India Limited
Hyderabad-500084, India

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Chantilly, VA 20151

For more information Call 1-877-770-3183.

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