PATIENT INFORMATION
METFORMIN HYDROCHLORIDE TABLETS, USP
(met for’ min hye’ droe klor’ ide)
500 mg, 850 mg and 1000 mg

Read this information carefully before you start taking this medicine and each time you refill your prescription. There may be new information. This information does not take the place of your doctor’s advice. Ask your doctor or pharmacist if you do not understand some of this information or if you want to know more about this medicine.

What are metformin hydrochloride tablets?
Metformin hydrochloride tablets are used to treat type 2 diabetes. This is also known as non-insulin-dependent diabetes mellitus. People with type 2 diabetes are not able to make enough insulin or respond normally to the insulin their bodies make. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems including kidney damage, amputations, and blindness. Diabetes is also closely linked to heart disease. The main goal of treating diabetes is to lower your blood sugar to a normal level.

High blood sugar can be lowered by diet and exercise, by a number of medicines taken by mouth, and by insulin shots. Before you take metformin hydrochloride tablets, try to control your diabetes by exercise and weight loss. While you take your diabetes medicine, continue to exercise and follow the diet advised for your diabetes. No matter what your recommended diabetes management plan is, studies have shown that maintaining good blood sugar control can prevent or delay complications of diabetes, such as blindness.

Metformin hydrochloride tablets help control your blood sugar in a number of ways. These include helping your body respond better to the insulin it makes naturally, decreasing the amount of sugar your liver makes, and decreasing the amount of sugar your intestines absorb. Metformin hydrochloride tablets do not cause your body to make more insulin. Because of this, when taken alone, they rarely cause hypoglycemia (low blood sugar), and usually do not cause weight gain. However, when they are taken with a sulfonylurea or with insulin, hypoglycemia is more likely to occur, as is weight gain.

WARNING: A small number of people who have taken metformin hydrochloride tablets have developed a serious condition called lactic acidosis. Lactic acidosis is caused by a buildup of lactic acid in the blood. This happens more often in people with kidney problems. Most people with kidney problems should not take metformin hydrochloride tablets. (See “What are the side effects of metformin hydrochloride tablets?”)

Who should not take metformin hydrochloride tablets?
Some conditions increase your chance of getting lactic acidosis, or cause other problems if you take either of these medicines. Most of the conditions listed below can increase your chance of getting lactic acidosis.

Do not take metformin hydrochloride tablets if you:
• have kidney problems
• have liver problems
• have heart failure that is treated with medicines, such as Lasix® (furosemide)
• drink a lot of alcohol. This means you binge drink for short periods of time or drink all the time
• are seriously dehydrated (have lost a lot of water from your body)
• are going to have an x-ray procedure with injection of dyes (contrast agents)
• are going to have surgery
• develop a serious condition, such as heart attack, severe infection or a stroke
• are 80 years or older and you have NOT had your kidney function tested

Tell your doctor if you are pregnant or plan to become pregnant. Metformin hydrochloride tablets may not be right for you.

Talk with your doctor about choices. You should also discuss your choices with your doctor if you are nursing a child.

Can metformin hydrochloride tablets be used in children?
Metformin hydrochloride tablets have been shown to effectively lower glucose levels in children (ages 10 to 16 years) with type 2 diabetes. Metformin hydrochloride tablets have not been studied in children younger than 10 years old. Metformin hydrochloride tablets have not been studied in combination with other oral glucose-control medicines or insulin in children. If you have any questions about the use of metformin hydrochloride tablets in children, talk with your doctor or healthcare provider.

How should I take metformin hydrochloride tablets?
Your doctor will tell you how much medicine to take and when to take it. You will probably start out with a low dose of the medicine. Your doctor may slowly increase your dose until your blood sugar is better controlled. You should take metformin hydrochloride tablets with meals.

Your doctor may have you take other medicines along with metformin hydrochloride tablets to control your blood sugar. These medicines may include insulin shots. Taking metformin hydrochloride tablets with insulin may help you better control your blood sugar while reducing the insulin dose.

Continue your exercise and diet program and test your blood sugar regularly while taking metformin hydrochloride tablets. Your doctor will monitor your diabetes and may perform blood tests on you from time to time to make sure your kidneys and liver are functioning normally. There is no evidence that metformin...
hydrochloride tablets causes harm to the liver or kidneys. Tell your doctor if you:
- have an illness that causes severe vomiting, diarrhea or fever, or if you drink a much lower amount of liquid than normal. These conditions can lead to severe dehydration (loss of water in your body). You may need to stop taking metformin hydrochloride tablets for a short time.
- plan to have surgery or an X-ray procedure with injection of dye (contrast agent). You may need to stop taking metformin hydrochloride tablets for a short time.
- start to take other medicines or change how you take a medicine. Metformin hydrochloride tablets can affect how well other drugs work, and some drugs can affect how well metformin hydrochloride tablets work. Some medicines may cause high blood sugar.

What should I avoid while taking metformin hydrochloride tablets?
Do not drink a lot of alcoholic drinks while taking metformin hydrochloride 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 side effects of metformin hydrochloride tablets?

**Lactic Acidosis:** In rare cases, metformin hydrochloride tablets can cause a serious side effect called lactic acidosis. This is caused by a buildup of lactic acid in your blood. This buildup can cause serious damage. Lactic acidosis caused by metformin hydrochloride tablets is rare and has occurred mostly in people whose kidneys were not working normally. Lactic acidosis has been reported in about one in 33,000 patients taking metformin hydrochloride tablets over the course of a year. Although rare, if lactic acidosis does occur, it can be fatal in up to half the people who develop it.

It is also important for your liver to be working normally when you take metformin hydrochloride tablets. Your liver helps remove lactic acid from your blood. Make sure you tell your doctor before you use metformin hydrochloride tablets and call your doctor right away if you have signs of lactic acidosis. Lactic acidosis is a medical emergency that must be treated in a hospital.

Signs of lactic acidosis are:
- feeling very weak, tired, or uncomfortable
- unusual muscle pain
- trouble breathing
- unusual or unexpected stomach discomfort
- feeling cold
- feeling dizzy or lightheaded
- suddenly developing a slow or irregular heartbeat

If your medical condition suddenly changes, stop taking metformin hydrochloride tablets and call your doctor right away if you have signs of lactic acidosis. Lactic acidosis is a medical emergency that must be treated in a hospital.

Other Side Effects: Common side effects of metformin hydrochloride tablets include diarrhea, nausea, and upset stomach. These side effects generally go away after you take the medicine for a while. Taking your medicine with meals can help reduce these side effects. Tell your doctor if the side effects bother you a lot, last for more than a few weeks, come back after they’ve gone away, or start later in therapy. You may need a lower dose or need to stop taking the medicine for a short period or for good.

About 3 out of every 100 people who take metformin hydrochloride tablets have an unpleasant metallic taste when they start taking the medicine. It lasts for a short time.

Metformin hydrochloride tablets rarely cause hypoglycemia (low blood sugar) by themselves. However, hypoglycemia can happen if you do not eat enough, if you drink alcohol, or if you take other medicines to lower blood sugar.

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

**General advice about prescription medicines**
If you have questions or problems, talk with your doctor or other healthcare provider. You can ask your doctor or pharmacist for the information about metformin hydrochloride tablets that is written for health care professionals. Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use metformin hydrochloride tablets for a condition for which it was not prescribed. Do not share your medicine with other people.

*Lanoxin® is a registered trademark of GlaxoSmithKline.
*Lasix® is a registered trademark of Aventis Pharmas.