

PATIENT INFORMATION ABOUT Metformin Hydrochloride Extended-release Tablets, USP.

Q1. Why do I need to take Metformin hydrochloride extended-release tablets?

Your doctor has prescribed Metformin hydrochloride extended-release tablets to treat your type 2 diabetes, a condition in which blood sugar (blood glucose) is elevated. There are two types of diabetes. Metformin hydrochloride extended-release tablets are indicated for the most common type, known as type 2 diabetes.

Q2. Why is it important to control type 2 diabetes?

Type 2 diabetes has multiple possible complications, including blindness, kidney failure, and circulatory and heart problems. Lowering your blood sugar to a normal level may prevent or delay these complications.

Q3. How is type 2 diabetes usually controlled?

High blood sugar can be lowered by diet and exercise, by a number of oral medications and by insulin injections. Your doctor may recommend that you try lifestyle modifications such as improved diet and exercise before initiating drug treatment for type 2 diabetes. Each patient will be treated individually by his or her physician, and should follow all treatment recommendations.

Q4. Does Metformin hydrochloride extended-release tablet work differently from other glucose control medications?

Yes. Metformin hydrochloride extended-release tablets, as well as other formulations of metformin, lower the amount of sugar in your blood by controlling how much sugar is released by the liver. Metformin hydrochloride extended-release tablet does not cause your body to produce more insulin. Metformin hydrochloride extended-release tablet rarely causes hypoglycemia (low blood sugar) and it does not usually cause weight gain when taken alone. However, if you do not eat enough, if you take other medications to lower blood sugar, or if you drink alcohol, you can develop hypoglycemia. Specifically, when Metformin hydrochloride extended-release tablet is taken together with a sulfonylurea or with insulin, hypoglycemia and weight gain are more likely to occur.

Q5. What happens if my blood sugar is still too high?

If your blood sugar is high, consult your physician. When blood sugar cannot be lowered enough by either Metformin hydrochloride extended-release tablets or a sulfonylurea, the two medications can be effective when taken together. Other alternatives involve switching to other oral antidiabetic drugs (e.g., alpha glucoside inhibitors or glitazones). Metformin hydrochloride extended-release tablets may be stopped and replaced with other drugs and/or insulin. If you are unable to maintain your blood sugar with diet, exercise and glucose- control medications taken orally, then your doctor may prescribe injectable insulin to control your diabetes.

Q6. Why should I take Metformin hydrochloride extended-release tablets in addition to insulin if I am already on insulin alone?

Adding Metformin hydrochloride extended-release tablets to insulin can help you better control your blood sugar while reducing the insulin dose and possibly reducing your weight.

Q7. Can Metformin hydrochloride extended-release tablets cause side effects?

Metformin hydrochloride extended-release tablets, like all blood sugar-lowering medications, can cause side effects in some patients. Most of these side effects are minor and will go away after you've taken Metformin hydrochloride extended-release tablets for a while. However, there are also serious but rare side effects related to Metformin hydrochloride extended-release tablets (see below).

Q8. What kind of side effects can Metformin hydrochloride extended-release tablets cause?

If side effects occur, they usually occur during the first few weeks of therapy. They are normally minor ones such as diarrhea, nausea, abdominal pain and upset stomach. Metformin hydrochloride extended-release tablets are generally taken with meals, which reduce these side effects.

Although these side effects are likely to go away, call your doctor if you have severe discomfort or if these effects last for more than a few weeks. Some patients may need to have their doses lowered or stop taking Metformin hydrochloride extended-release tablets either temporarily or permanently. You should tell your doctor if the problems come back or start later on during the therapy.

WARNING: A rare number of people who have taken metformin have developed a serious condition called lactic acidosis. Properly functioning kidneys are needed to help prevent lactic acidosis. (see Q9-13).

Q9. Are there any serious side effects that Metformin hydrochloride extended-release tablets can cause?

Metformin hydrochloride extended-release tablets rarely cause serious side effects. The most serious side effect that Metformin hydrochloride extended-release tablets can cause is called lactic acidosis.

Q10. What is lactic acidosis and can it happen to me?

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



Q11. Are there other risk factors for lactic acidosis?

Most people who have had lactic acidosis with metformin have other things that, combined with the metformin, led to the lactic acidosis. Tell your doctor if you have any of the following, because you have a higher chance for getting lactic acidosis with Metformin hydrochloride extended-release tablets if you:

- have severe kidney problems or your kidneys are affected by certain x-ray tests that use injectable dye.
- have liver problems
- drink alcohol very often, or drink a lot of alcohol in 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 surgery
- have a heart attack, severe infection, or stroke

The best way to keep from having a problem with lactic acidosis from metformin is to tell your doctor if you have any of the problems in the list above. Your doctor may decide to stop your Metformin hydrochloride extended-release tablets for a while if you have any of these things.

Q12. What are the symptoms of lactic acidosis?

Call your doctor right away if you have any of the following symptoms, which could be signs of lactic acidosis:

- you feel cold in your hands or feet
- you feel dizzy or lightheaded
- you have a slow or irregular heartbeat
- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you feel sleepy or drowsy
- you have stomach pains, nausea or vomiting

Q13. What does my doctor need to know to decrease my risk of lactic acidosis?

Before you take Metformin hydrochloride extended-release tablets, tell your doctor if you:

- have severe kidney problems
 - have liver problems
 - have heart problems, including congestive heart failure
 - drink alcohol very often, or drink a lot of alcohol in short term “binge” drinking
 - are going to get an injection of dye or contrast agents for an x-ray procedure.
- Metformin hydrochloride extended-release tablets may need to be stopped for a short time. Talk to your doctor about when you should stop Metformin hydrochloride extended-release tablets and when you should start Metformin hydrochloride extended-release tablets again. See **“What is the most important information I should know about Metformin hydrochloride extended-release tablets?”**
- have any other medical conditions

Q14. Can I take Metformin hydrochloride extended-release tablets with other medications?

Remind your doctor and/or pharmacist that you are taking Metformin hydrochloride extended-release tablets when any new drug is prescribed or a change is made in how you take a drug already prescribed. Metformin hydrochloride extended-release tablets may interfere with the way some drugs work and some drugs may interfere with the action of Metformin hydrochloride extended-release tablets.

Q15. What if I become pregnant while taking Metformin hydrochloride extended-release tablets?

Tell your doctor if you plan to become pregnant or have become pregnant. As with other oral glucose-control medications, you should not take Metformin hydrochloride extended-release tablets during pregnancy. Usually your doctor will prescribe insulin while you are pregnant.

Q16. How do I take Metformin hydrochloride extended-release tablets?

Metformin hydrochloride extended-release tablets should not be cut, crushed, or chewed and should be taken whole with a full glass of water once daily with the evening meal. Occasionally, the inactive ingredients of Metformin hydrochloride extended-release tablets may be eliminated as a soft mass in your stool that may look like the original tablet; this is not harmful and will not affect the way Metformin hydrochloride extended-release tablets work to control your diabetes. Metformin hydrochloride extended-release tablets should be taken once a day with food. You will be started on a low dose of Metformin hydrochloride extended-release tablets and your dosage will be increased gradually until your blood sugar is controlled.

Q17. Where can I get more information about Metformin hydrochloride extended-release tablets?

This leaflet is a summary of the most important information about Metformin hydrochloride extended-release tablets. If you have any questions or problems, you should talk to your doctor or other healthcare provider about type 2 diabetes as well as Metformin hydrochloride extended-release tablet and its side effects.

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