

PATIENT INFORMATION ABOUT FORTAMET® (metformin hydrochloride) Extended-Release Tablets

Rx only

Q1. Why do I need to take FORTAMET®?

Your doctor has prescribed FORTAMET® to treat your type 2 diabetes, a condition in which blood sugar (blood glucose) is elevated. There are two types of diabetes. FORTAMET® is 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 FORTAMET® work differently from other glucose control medications?

Yes. FORTAMET®, as well as other formulations of metformin, lowers the amount of sugar in your blood by controlling how much sugar is released by the liver. FORTAMET® (metformin hydrochloride) does not cause your body to produce more insulin. FORTAMET® 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 FORTAMET® 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 FORTAMET® (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). FORTAMET™ 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 FORTAMET® in addition to insulin if I am already on insulin alone?

Adding FORTAMET® to insulin can help you better control your blood sugar while reducing the insulin dose and possibly reducing your weight.

Q7. Can FORTAMET® cause side effects?

FORTAMET®, 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 FORTAMET® for a while. However, there are also serious but rare side effects related to FORTAMET®(see below).

Q8. What kind of side effects can FORTAMET® 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. FORTAMET® is 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 FORTAMET®, 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. You should not take FORTAMET® if you have impaired kidney function, as measured by a blood test (see Q9-13).

Q9. Are there any serious side effects that FORTAMET® can cause?

FORTAMET® rarely causes serious side effects. The most serious side effect that FORTAMET® can cause is called lactic acidosis.

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

Lactic acidosis is caused by a build-up of lactic acid in the blood. Lactic acidosis associated with metformin 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 over the course of a year. Although rare, if lactic acidosis does occur, it can be fatal in up to half the cases.

It is also important for your liver to be working normally when you take FORTAMET® . Your liver helps to remove lactic acid from your bloodstream. Your doctor will monitor your diabetes and may perform blood tests on you from time to time to make sure your kidneys and your liver are functioning normally. There is no evidence that FORTAMET® causes harm to the kidneys or liver.

Q11. Are there other risk factors for lactic acidosis?

Your risk of developing lactic acidosis from taking FORTAMET® is very low as long as your kidneys and liver are healthy. However, some factors can increase your risk because they can affect kidney and liver function. You should discuss your risk with your physician. You should not take FORTAMET® if:

- You have some forms of kidney or liver problems
- You have congestive heart failure which is treated with medications, e.g., digoxin (Lanoxin®) or furosemide (Lasix®)
- You drink alcohol excessively (all the time or short-term “binge” drinking)
- You are seriously dehydrated (have lost a large amount of body fluids)
- You are going to have, within a few days, certain x-ray tests with injectable contrast agents

- You are going to have surgery
- You develop a serious condition such as a heart attack, severe infection, or a stroke
- You are 80 years of age or older and have NOT had your kidney function tested

Q12. What are the symptoms of lactic acidosis?

Some of the symptoms include feeling very weak, tired or uncomfortable, unusual muscle pain, trouble breathing, unusual or unexpected stomach discomfort, feeling cold, feeling dizzy or lightheaded, or suddenly developing a slow or irregular heartbeat. If you notice these symptoms, or if your medical condition has suddenly changed, stop taking FORTAMET® and call your doctor right away. Lactic acidosis is a medical emergency that must be treated in a hospital.

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

Tell your doctor if you have an illness that results in severe vomiting, diarrhea and/or fever, or if your intake of fluids is generally reduced. These situations can lead to severe dehydration, and it may be necessary to stop taking FORTAMET® temporarily. You should let your doctor know if you are going to have any surgery or specialized x-ray procedures that require injection of contrast agents. FORTAMET® therapy will need to be stopped temporarily in such instances.

Q14. Can I take FORTAMET® with other medications?

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

Q15. What if I become pregnant while taking FORTAMET®?

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

Q16. How do I take FORTAMET®?

FORTAMET® 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 FORTAMET® may be eliminated as a soft mass in your stool that may look like the original tablet; this is not harmful and will not effect the way FORTAMET® works to control diabetes. FORTAMET® should be taken once a day with food. You will be started on a low dose of FORTAMET® and your dosage will be increased gradually until your blood sugar is controlled.

Q17. Where can I get more information about FORTAMET®?

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

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