PATIENT & CAREGIVER EDUCATION

Empagliflozin and Metformin

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Synjardy; Synjardy XR

Brand Names: Canada

Synjardy

Warning

- Rarely, metformin may cause too much lactic acid in the blood (lactic acidosis). The risk is higher in people who have kidney problems, liver problems, heart failure, mitochondrial disease, use alcohol, or take certain other drugs, including topiramate. The risk is also higher in people who are 65 or older and in people who are having surgery, an exam or test with contrast, or other procedures. If lactic acidosis happens, it can lead to other health problems and can be deadly. Kidney tests may be done while taking this drug.
- Do not take this drug if you have a very bad infection, low oxygen, or a lot of fluid loss (dehydration).
- Call your doctor right away if you have signs of too much lactic acid in the blood (lactic acidosis) like confusion; fast breathing; fast or slow heartbeat; a heartbeat that does not feel normal; very bad stomach pain, upset stomach, or throwing up; feeling very sleepy; shortness of breath; feeling very tired or weak; very bad dizziness; feeling cold; or muscle pain or cramps.

What is this drug used for?

- It is used to help control blood sugar in people with type 2 diabetes.
- It is used to lower the chance of death from heart disease in certain people.
- It is used in certain people to lower the risk of death and having to go to the hospital because of heart failure.
- It is used in people with certain kidney problems to lower the risk of worsening kidney problems, hospital stays, and death.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have type 1 diabetes. Do not use this drug to treat type 1 diabetes.
- If you do NOT have type 2 diabetes.
- If you have any of these health problems: Acidic blood problem, kidney disease, or liver disease.
- If you have had a recent heart attack or stroke.
- If you have a mitochondrial disease like MELAS syndrome (mitochondrial encephalomyopathy with lactic acidosis and stroke-like episodes) or MIDD (maternally inherited diabetes and deafness).
- If you are dehydrated, talk with your doctor.
- If you are taking or have recently taken drugs that suppress your immune system to treat kidney disease.
- If you are not able to eat or drink like normal, talk with your doctor. This includes if you are sick, fasting, or you are having certain procedures or surgery.
- If you are having an exam or test with contrast or have had one within the past 48 hours, talk with your doctor.
- If you are pregnant or may be pregnant. Do not take this drug if you are in the second or third trimester of pregnancy.
- If you are breast-feeding. Do not breast-feed while you take this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists. This drug may need to be stopped before certain types of surgery as your doctor has told you. If this drug is stopped, your doctor will tell you when to start taking this drug again after your surgery or procedure.
- To lower the chance of feeling dizzy or passing out, rise slowly if you have been sitting or lying down. Be careful going up and down stairs.
- Do not drive if your blood sugar has been low. There is a greater chance of you having a crash.
- Check your blood sugar as you have been told by your doctor.
- Talk with your doctor about which glucose tests are best to use.
- It may be harder to control blood sugar during times of stress such as fever, infection, injury, or surgery. A change in physical activity, exercise, diet, or weight may also affect blood sugar.
- Talk with your doctor before you drink alcohol.
- Have your blood work and other lab tests checked as you have been told by your doctor.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- If you are on a low-salt or salt-free diet, talk with your doctor.
- Follow the diet and exercise plan that your doctor told you about.
- Be careful in hot weather or while being active. Drink lots of fluids to stop fluid loss.
- If you cannot drink liquids by mouth or if you have upset stomach, throwing up, or diarrhea that does not go away, you need to avoid getting dehydrated. Contact your doctor to find out what to do. Dehydration may lead to low blood pressure or to new or worsening kidney problems.

- Too much acid in the blood or urine (ketoacidosis) has happened with this drug. This may need to be treated in the hospital and can be deadly. This can happen even when blood sugar is less than 250. People with diabetes or pancreas problems have a higher risk of ketoacidosis. The risk of ketoacidosis is also higher in people who are sick or dehydrated, cannot eat or drink like normal, skip meals, are on a ketogenic diet, or have surgery. The risk is also higher in people who use insulin and take less than the normal insulin dose or miss the dose. Check your ketones as you have been told by the doctor. If you have questions, talk with your doctor.
- High cholesterol has happened with this drug. If you have questions, talk with the doctor.
- Long-term treatment with metformin may lead to low vitamin B-12 levels. If you have ever had low vitamin B-12 levels, talk with your doctor.
- Severe urinary tract infections (UTIs) have happened with this drug. Sometimes, this needed to be treated in a hospital.
- Kidney problems have happened. Sometimes, these may need to be treated in the hospital or with dialysis.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Use this drug with care in children. They may have more chance of low blood sugar.
- There is a chance of pregnancy in people of childbearing age who have not been ovulating. If you want to avoid pregnancy, use birth control while taking this drug.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. If you are pregnant or you get pregnant while taking this drug, call your doctor right away.

Extended-release tablets:

- You may see something that looks like the tablet in your stool. If this happens, talk with your doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of fluid and electrolyte problems like mood changes, confusion, muscle pain or weakness, fast or abnormal heartbeat, severe dizziness or passing out, increased thirst, seizures, feeling very tired or weak, decreased appetite, unable to pass urine or change in the amount of urine produced, dry mouth, dry eyes, or severe upset stomach or throwing up.
- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Vaginal yeast infection. Report itching, bad odor, or discharge.
- Yeast infection of the penis. Report pain, swelling, rash, or discharge.
- It is common to have stomach problems like upset stomach, throwing up, or diarrhea when you start taking this drug. If you have stomach problems later during treatment, call your doctor right away. This may be a sign of an acid health problem in the blood (lactic acidosis).
- Low blood sugar can happen when this drug is used with other drugs for diabetes. Signs may be dizziness, headache, feeling sleepy or weak, shaking, fast heartbeat, confusion, hunger, or sweating. Call your doctor right away if you have any of these signs. Follow what you have been told to do for low blood sugar. This may include taking glucose tablets, liquid glucose, or some

fruit juices.

- A rare but severe infection has happened with drugs like this one. This infection may be deadly. Get medical help right away if your genitals or the area between your genitals and rectum becomes red, swollen, tender, or painful, and you have a fever or do not feel well.
- This drug may raise the risk of lower limb amputations. Toe and foot amputations have happened most often. Talk to your doctor about how to take care of your feet. Tell your doctor if you have ever had an amputation, blood vessel disease, nerve disease, or a foot ulcer caused by diabetes. Call your doctor right away if you have new pain or tenderness, sores or ulcers, or infections in your legs or feet.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Nose or throat irritation.
- Gas.
- Diarrhea, upset stomach, or throwing up.
- Stomach pain.
- Heartburn.
- Feeling tired or weak.
- Headache.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

Regular-release tablets:

- Take with meals.
- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

Extended-release tablets:

- Take with the first meal of the day, if taking once a day.
- Swallow whole. Do not chew, break, crush, or dissolve.
- If you have trouble swallowing, talk with your doctor.
- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- If you are not sure what to do if you miss a dose, call your doctor.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical

advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

Last Reviewed Date

2026-09-09

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

Empagliflozin and Metformin - Last updated on December 12, 2022
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