

Brightside Specialty Pharmacy

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Patient Education for SYNJARDY XR 12.5-1,000 MG TAB



.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

EMPAGLIFLOZIN/METFORMIN EXTENDED-RELEASE - ORAL
(EM-pa-gli-FLOE-zin/met-FOR-min)

COMMON BRAND NAME(S):

Synjardy XR

WARNING:

Rarely, too much metformin can build up in the body and

cause a serious (sometimes fatal) condition called lactic acidosis. Lactic acidosis is more likely if you are an older adult, if you have kidney or liver disease, dehydration, heart failure, heavy alcohol use, if you have surgery, if you have X-ray or scanning procedures that use iodinated contrast, or if you are using certain drugs. For some conditions, your doctor may tell you to stop taking this medication for a short time. Ask your doctor or pharmacist for more details.

Stop taking this medication and get medical help right away if you have any symptoms of lactic acidosis, such as unusual tiredness, dizziness, severe drowsiness, chills, blue/cold skin, muscle pain, fast/difficult breathing, slow/irregular heartbeat, or stomach pain with nausea/vomiting/diarrhea.

USES:

This medication is a combination of 2 drugs: empagliflozin

and metformin. It is used with a proper diet and exercise program to control high blood sugar in people with type 2 diabetes.

Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, loss of limbs, and sexual function problems. Proper control of diabetes may also lessen your risk of a heart attack or stroke. This medication works by helping to

restore your body's proper response to the insulin you naturally produce. It also increases the removal of sugar by your kidneys, decreases how much sugar is made in your liver, and decreases how much sugar your body takes in through your stomach and intestines.

HOW TO USE:

Read the Medication Guide provided by your

pharmacist before you start taking this medication and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth as directed by your doctor, usually once daily with the morning meal. Swallow the tablets whole. Do not crush, dissolve, or chew the tablets. Doing so can release all of the drug at once, increasing the risk of side effects. Take this medication regularly to get the most benefit from it. To help you remember, take it at the same time each day. Drink plenty of fluids while taking this medication unless otherwise directed by your doctor.

The dosage is based on your medical condition, response to treatment, and other medications you may be taking. Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). To reduce your risk of side effects (such as diarrhea, nausea), your doctor may direct you to start this medication at a low dose and gradually increase your dose. Follow your doctor's instructions carefully.

Tell your doctor if your condition does not get better or if it gets worse (your blood sugar is too high or too low).

SIDE EFFECTS:

See also Warning section.

Nausea, vomiting, stomach upset, diarrhea, bloating/gas, headache, or weakness may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. If stomach symptoms return later (after taking the same dose for several days or weeks), tell your doctor right away. Stomach symptoms that occur after the first days of your treatment may be signs of lactic acidosis.

Tell your doctor if you see undissolved tablets in your stool.

Your doctor may check lab tests to make sure the medication is working.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: signs of a urinary tract infection (such as burning/painful/frequent/urgent urination, pink/bloody urine), signs of kidney problems (such as change in the amount of urine).

This medication may cause a new yeast infection in the vagina or the penis. It may also cause a rare but very serious bacterial infection in the genital/anal area (Fournier's gangrene). Tell your doctor right away if you have signs of a yeast infection in the vagina (such as unusual vaginal discharge/burning/itching/odor) or in the penis (such as redness/itching/swelling of the penis, unusual discharge from the penis). However, get medical help right away if you have any pain/redness/swelling in or around the genital/anal area, along with a fever or feeling unwell.

This medication does not usually cause low blood sugar (hypoglycemia). Low blood sugar may occur if this drug is prescribed with other diabetes medications, or if you do not consume enough calories from food, or if you do unusually heavy exercise.

Symptoms of low blood sugar include sudden sweating, shaking, fast heartbeat, hunger, blurred vision, dizziness, or tingling hands/feet. It is a good habit to carry glucose tablets or gel to treat low blood sugar. If you don't have these reliable forms of glucose, rapidly raise your blood sugar by eating a quick source of sugar such as table sugar, honey, or candy, or drink fruit juice or non-diet soda. Tell your doctor right away about the reaction and the use of this product. To help prevent low blood sugar, eat meals on a regular schedule, and do not skip meals. Check with your doctor or pharmacist to find out what you should do if you miss a meal.

Symptoms of high blood sugar (hyperglycemia) include increased thirst/urination. If these symptoms occur, tell your doctor right away. Your doctor may need to adjust your diabetes medications.

This medication may cause you to become dehydrated. This can lead to serious kidney damage. Drink plenty of fluids to prevent dehydration. Tell your doctor or pharmacist right away if you are not able to drink fluids as usual, or losing fluid (such as due to vomiting, diarrhea, or heavy sweating). Also, tell your doctor right away if you have any signs of dehydration, such as urinating less than usual, unusual dry mouth/thirst, fast heartbeat, or dizziness/lightheadedness/fainting. To reduce the risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

See also Warning section.

Before taking this medication, tell your doctor or pharmacist if you are allergic to empagliflozin or metformin; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: breathing problems (such as asthma, obstructive lung disease), blood problems (such as anemia, vitamin B12 deficiency), dehydration, heart disease (such as heart failure, recent heart attack), kidney disease, liver problems, use/abuse of alcohol, yeast infections in the vagina or penis.

You may experience blurred vision, dizziness, or drowsiness due to extremely low or high blood sugar. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely.

Limit alcohol while using this medication because it can increase your risk of developing lactic acidosis, low blood sugar, or a high ketone level.

High fever, "water pills" (diuretics such as hydrochlorothiazide), too much sweating, diarrhea, or vomiting may cause dehydration and increase your risk of lactic acidosis. Stop taking this medication and tell your doctor right away if you have prolonged diarrhea or vomiting. Be sure to drink enough fluids to prevent dehydration unless your doctor directs you otherwise.

It may be harder to control your blood sugar when your body is stressed (such as due to fever, infection, injury, or surgery). Also, if you are eating less or not able to eat due to these conditions or any illness, this can lead to a high ketone level while you are taking this medication. Consult your doctor because this may require a change in your treatment plan, medications, or blood sugar or ketone testing.

Before having surgery or any X-ray/scanning procedure using iodinated contrast, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). You may need to stop this medication for a short time for the surgery/procedure. Ask your doctor or dentist for instructions before your surgery/procedure.

Older adults may be at greater risk for side effects such as low blood sugar, dehydration, lactic acidosis, kidney problems, and low blood pressure.

During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.

Pregnancy may cause or worsen diabetes. Discuss a plan with your doctor for managing your blood sugar while pregnant. Your doctor may change your diabetes treatment during your pregnancy

(such as diet and medications including insulin).

Metformin can cause changes in the menstrual cycle (promote ovulation) and increase the risk of becoming pregnant. Consult your doctor or pharmacist about the use of reliable birth control while using this medication.

Metformin passes into breast milk in small amounts. It is unknown if empagliflozin passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Drug interactions may change how your

medications work or increase your risk for serious side effects.

This document does not contain all possible drug interactions.

Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Beta blocker medications (such as metoprolol, propranolol, glaucoma eye drops such as timolol) may prevent the fast/pounding heartbeat you would usually feel when your blood sugar falls too low (hypoglycemia). Other symptoms of low blood sugar, such as dizziness, hunger, or sweating, are not affected by these drugs.

Many drugs can affect your blood sugar, making it harder to control. Before you start, stop, or change any medication, talk with your doctor or pharmacist about how the medication may affect your blood sugar. Check your blood sugar regularly as directed by your doctor. Tell your doctor about the results and of any symptoms of high or low blood sugar. (See also Side Effects section.) Your doctor may need to adjust your diabetes medication, exercise program, or diet.

Your urine will test positive for glucose. Make sure lab personnel and all your doctors know you use this drug.

OVERDOSE:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Overdose can cause lactic acidosis. Symptoms of overdose may include: severe drowsiness, severe nausea/vomiting/diarrhea, rapid breathing, slow/irregular heartbeat.

NOTES:

Do not share this medication with others.

Attend a diabetes education program to learn more about how to manage your diabetes with medications, diet, exercise, and regular medical exams.

Learn the symptoms of high and low blood sugar and how to treat low blood sugar. Check your blood sugar regularly as directed.

Lab and/or medical tests (such as kidney/liver function, blood sugar, hemoglobin A1c, complete blood counts, cholesterol, vitamin B12) should be done before you start taking this medication and while you are taking it. Keep all medical and lab appointments. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, take it as soon as you

remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

MEDICAL ALERT:

Your condition can cause complications in a

medical emergency. For information about enrolling in MedicAlert, call 1-888-633-4298 (US) or 1-800-668-1507 (Canada).

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