

# iMedix: Your Personal Health Advisor.

## Kombiglyze XR

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### Description

Side Effects Nausea, vomiting, stomach upset, diarrhea, headache, or a metallic taste in the mouth 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. An empty tablet shell may appear in your stool. This effect is harmless because your body has already absorbed the medication.

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: joint pain, unusual skin blisters, signs of heart failure (such as shortness of breath, swelling ankles/feet, unusual tiredness, unusual/sudden weight gain). Although this medication by itself usually does not cause low blood sugar (hypoglycemia), low blood sugar may occur if this drug is prescribed with other diabetes medications. Talk with your doctor or pharmacist about all your diabetes medication(s). 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. Low blood sugar is more likely if you drink large amounts of alcohol, do unusually heavy exercise, or do not consume enough calories from food. To help prevent low blood sugar, eat meals on a regular schedule, and do not skip meals. Talk with your doctor or pharmacist about what to 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 medication, exercise program, or diet. Get medical help right away if you have any very serious side effects, including: signs of disease of the pancreas (such as severe stomach/abdominal pain which may spread to the back, nausea/vomiting that doesn't stop). 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](http://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. Uses Saxagliptin/metformin 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 product contains 2 medications: saxagliptin and metformin. Saxagliptin works by increasing levels of natural substances called incretins. Incretins help to control blood sugar by increasing insulin release, especially after a meal. They also decrease the amount of sugar your liver makes. Metformin lowers blood sugar by helping to restore your body's proper response to the insulin. It also decreases the amount of sugar that your liver makes and that your stomach/intestines absorb. How to use Kombiglyze XR Read the Medication Guide provided by your pharmacist before you start using saxagliptin/metformin 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 a day with the evening meal. Swallow the tablets whole. Do not crush or chew the tablets. Doing so can release all of the drug at once, increasing the risk of side effects. 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 upset stomach), your doctor may direct you to start this medication at a low dose and gradually increase your dose. Follow your doctor's instructions carefully. Take this medication regularly to get the most benefit from it. To help you remember, take it at the same time each day. Carefully follow the medication treatment plan, meal plan, and exercise program your doctor has recommended. Warnings 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. Precautions Before taking this medication, tell your doctor or pharmacist if you are allergic to saxagliptin 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: kidney disease, severe breathing problems (such as obstructive lung disease, severe asthma), blood problems (such as anemia, vitamin B12 deficiency), liver disease, disease of the pancreas (pancreatitis), risk factors for pancreatitis (such as stones in your gallbladder, regular use/abuse of alcohol, high levels of fats/triglycerides in the blood). 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. 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 taking this medication because it can increase your risk of developing lactic acidosis, pancreatitis and low blood sugar. 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). Consult your doctor because this may require a change in your treatment plan, medications, or blood sugar testing. Older adults may be more sensitive to the side effects of this drug, especially low blood sugar or lactic acidosis. Metformin can cause changes in the menstrual cycle (promote ovulation) and increase the chance of pregnancy. Consult your doctor or pharmacist about using reliable birth control while taking this medication. 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 passes into breast milk in small amounts. It is unknown if saxagliptin passes into breast milk. Consult your doctor before breast-feeding. 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. 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 function, liver function, blood sugar, hemoglobin A1c, complete blood counts) 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. 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. 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. 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. Other medications can affect the removal of saxagliptin from your body, which may affect how saxagliptin works. Examples include azole antifungals (such as itraconazole, ketoconazole), HIV protease inhibitors (such as saquinavir), nefazodone, telithromycin, ritonavir, among others. 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 unaffected 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 and share the results with your doctor. Tell your doctor right away if you have symptoms of high or low blood sugar. () Your doctor may need to adjust your diabetes medication, exercise program, or diet.

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## Side Effects

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## Uses

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**Interactions**

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**Other Details**

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