

PRONUNCIATION: (SAX-a-GLIP-tin)

COMMON BRAND NAME(S): Onglyza

HOW TO USE: Read the Patient Information Leaflet provided by your pharmacist before you start using saxagliptin and each time you get a refill. If you have any questions, consult your doctor or pharmacist. Take this medication by mouth with or without food, usually once daily or as directed by your doctor. The dosage is based on your medical condition, response to treatment, and other medications you may be taking. 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. Tell your doctor if your condition persists or worsens (such as blood sugar levels remaining high or increasing).

USES: Saxagliptin is used either alone or with other medications, and with a proper diet and exercise program, to control high blood sugar. It is used in people with type 2 (non-insulin-dependent) 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 drug 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. This medication should not be used to treat people with type 1 diabetes (insulin-dependent diabetes).

SIDE EFFECTS: Remember that your doctor has prescribed this medication because he or she 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. Although saxagliptin by itself usually does not cause low blood sugar (hypoglycemia), low blood sugar may occur if this drug is prescribed with other anti-diabetes medications. Talk with your doctor or pharmacist about whether the dose(s) of your other diabetic medication(s) needs to be lowered. Consuming large quantities of alcohol, not getting enough calories from food, or doing unusually heavy exercise may also lead to low blood sugar. Symptoms may include sudden sweating, shaking, fast heartbeat, hunger, blurred vision, dizziness, headache, 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, raise your blood sugar quickly by eating a quick source of sugar such as table sugar, honey, candy, or drinking a glass of fruit juice or non-diet soda. 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 thirst, increased urination, confusion, drowsiness, flushing, rapid breathing, and fruity breath odor. If these symptoms occur, tell your doctor immediately. Your doctor may need to adjust your diabetes medication(s). A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: 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. 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: Before taking saxagliptin, tell your doctor or pharmacist if you are allergic to it; 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. You may experience blurred vision, dizziness, or drowsiness due to extremely low or high blood sugar levels. 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 low blood sugar. 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 increased stress may require a change in your treatment plan, medications, or blood sugar testing. Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). During pregnancy, this medication should be used only when clearly needed. 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. Discuss the risks and benefits of different treatments (such as diet, exercise, and medications including insulin). It is unknown if this medication passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS: The effects of some drugs can change if you take other drugs or herbal products at the same time. This can increase your risk for serious side effects or may cause your medications not to work correctly. These drug interactions are possible, but do not always occur. Your doctor or pharmacist can often prevent or manage interactions by changing how you use your medications or by close monitoring. To help your doctor and pharmacist give you the best care, be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products) before starting treatment with this product. While using this product, do not start, stop, or change the dosage of any other medicines you are using without your doctor's approval. Other medications can affect the removal of saxagliptin from your body, which may affect how saxagliptin works. Examples include nefazodone, azole antifungals (such as ketoconazole), macrolide antibiotics (such as clarithromycin), HIV protease inhibitors (such as ritonavir), among others. Many drugs can affect your blood sugar levels, making it more difficult to control your blood sugar. Examples include corticosteroids (such as prednisone), psychiatric medicines (such as olanzapine), quinolone antibiotics (such as ciprofloxacin), among others. Ask your doctor or pharmacist how often to check your blood sugar. 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. Beta blocker medications such as metoprolol may mask the fast/pounding heartbeat you would usually feel when your blood sugar levels falls too low (hypoglycemia). Other symptoms of low blood sugar such as dizziness or sweating are unaffected by these drugs. Check the labels on all your medicines (such as cough-and-cold products) carefully. Some products may contain sugar or alcohol and may affect your blood sugar levels. Ask your doctor or pharmacist about using these products safely. This document does not contain all possible interactions. Keep a list of all the products you use. Share this list with your doctor and pharmacist to lessen your risk for serious medication problems.

OVERDOSE: If overdose is suspected, contact a poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center.

NOTES: Do not share this medication with others. Attend a diabetes education program to learn more about diabetes and the important aspects of its treatment, including medications, diet, exercise, and getting regular eye/foot/medical exams. Learn the symptoms of high and low blood sugar and how to treat low blood sugar. Check your blood sugar levels regularly as directed. Keep track of the results, and share them with your doctor. Keep all medical appointments. Laboratory and/or medical tests (such as kidney function, fasting blood glucose, hemoglobin A1c) should be performed periodically to monitor your progress or check for side effects. 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 and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE: Store at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines 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 for more details about how to safely discard your product.

WARNING: No Information Available. Please Consult Your Health Care Provider or Pharmacist.