

Medication Guide
Saxagliptin
(SAX-a-GLIP-tin)
Tablets, for oral use

What is the most important information I should know about saxagliptin tablets?

Serious side effects can happen to people taking saxagliptin tablets, including:

1) Inflammation of the pancreas (pancreatitis) which may be severe and lead to death.

Certain medical problems make you more likely to get pancreatitis.

Before you start taking saxagliptin tablets:

Tell your healthcare provider if you have ever had

- inflammation of your pancreas (pancreatitis)
- stones in your gallbladder (gallstones)
- a history of alcoholism
- high blood triglyceride levels

Stop taking saxagliptin tablets and contact your healthcare provider right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back.

The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

2) Heart failure. Heart failure means your heart does not pump blood well enough.

Before you start taking saxagliptin tablets:

Tell your healthcare provider if you

- have ever had heart failure or have problems with your kidneys.

Contact your healthcare provider right away if you have any of the following symptoms:

- increasing shortness of breath or trouble breathing, especially when you lie down
- an unusually fast increase in weight
- swelling or fluid retention, especially in the feet, ankles or legs
- unusual tiredness

These may be symptoms of heart failure.

What are saxagliptin tablets?

- Saxagliptin tablets are a prescription medicine used along with diet and exercise to help control high blood sugar (hyperglycemia) in adults with type 2 diabetes mellitus.
- Saxagliptin tablets are not recommended for people with type 1 diabetes mellitus.
- Saxagliptin tablets are not recommended for people with diabetic ketoacidosis (increased ketones in your blood or urine).

It is not known if saxagliptin tablets are safe and effective in children.

Who should not take saxagliptin tablets?

Do not take saxagliptin tablets if you:

- are allergic to any ingredients in saxagliptin tablets. See the end of this Medication Guide for a complete list of ingredients in saxagliptin tablets. Symptoms of a serious allergic reaction to saxagliptin tablets may include:
 - swelling of your face, lips, throat, and other areas on your skin
 - difficulty with swallowing or breathing
 - raised, red areas on your skin (hives)
 - skin rash, itching, flaking, or peeling

If you have these symptoms, stop taking saxagliptin tablets and contact your healthcare provider right away.

Before taking saxagliptin tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have heart failure
- have or have had inflammation of your pancreas (pancreatitis)
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if saxagliptin tablets will harm your unborn baby. If you are pregnant, talk with your healthcare provider about the best way to control your blood sugar while you are pregnant.
- are breast-feeding or plan to breast-feed. Saxagliptin may be passed in your milk to your baby. Talk with your healthcare provider about the best way to feed your baby while you take saxagliptin tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

Saxagliptin tablets may affect the way other medicines work, and other medicines may affect how saxagliptin tablets work. Contact your healthcare provider if you will be starting or stopping certain other types of medicines, such as antibiotics, or medicines that treat fungus or HIV/AIDS, because your dose of saxagliptin tablets might need to be changed.

How should I take saxagliptin tablets?

- Take saxagliptin tablets by mouth 1 time each day exactly as directed by your healthcare provider. Do not change your dose without talking to your healthcare provider.
- Saxagliptin tablets can be taken with or without food.
- Do not cut, crush, or chew saxagliptin tablets.
- Your healthcare provider should test your blood to measure how well your kidneys are working before and during your treatment with saxagliptin tablets. You may need a lower dose of saxagliptin tablets if your kidneys are not working well.
- If you miss a dose of saxagliptin tablets, Just take the next dose at your regular time. Do not take two doses at the same time.
- In case of an overdose contact the Poison Help line at 1-800-222-1222 or get medical help right away. Advice is also available online at poisonhelp.org.

What are the possible side effects of saxagliptin tablets?

Saxagliptin tablets can cause serious side effects, including:

- See “**What is the most important information I should know about saxagliptin tablets?**” **Low blood sugar (hypoglycemia)** If you take saxagliptin tablets with another medicine that can cause low blood sugar, such as a sulfonylureas or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine
- or insulin may need to be lowered while you take ONGLYZA. Symptoms of low blood sugar include:
 - shaking
 - sweating
 - rapid heartbeat
 - change in vision
 - hunger
 - headache
 - change in mood
- **Allergic (hypersensitivity) reactions**, such as:
 - swelling of your face, lips, throat, and other areas on your skin
 - difficulty with swallowing or breathing
 - raised, red areas on your skin (hives)
 - skin rash, itching, flaking, or peelingIf you have these symptoms, stop taking saxagliptin tablets and contact your healthcare provider right away.

• **Joint pain.** Some people who take medicines called DPP-4 inhibitors like saxagliptin tablets, may develop joint pain that can be severe. Call your healthcare provider if you have severe joint pain.

• **Skin reaction.** Some people who take medicines called DPP-4 inhibitors, like saxagliptin tablets, may develop a skin reaction called bullous pemphigoid that can require treatment in a hospital. Tell your healthcare provider right away if you develop blisters or the breakdown of the outer layer of your skin (erosion). Your healthcare provider may tell you to stop taking saxagliptin tablets.

The most common side effects of saxagliptin tablets include:

- upper respiratory tract infection
- urinary tract infection
- headache
- Swelling or fluid retention in your hands, feet, or ankles (peripheral edema) may become worse in people who also take a thiazolidinedione to treat diabetes. If you do not know whether you are already on this type of medication, ask your healthcare provider.

These are not all of the possible side effects of saxagliptin tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store saxagliptin tablets?

Store saxagliptin tablets between 68°F to 77°F (20°C to 25°C).

Keep saxagliptin tablets and all medicines out of the reach of children.

General information about the use of saxagliptin tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guides. Do not use saxagliptin tablets for a condition for which it was not prescribed. Do not give saxagliptin tablets to other people, even if they have the same symptoms you have. It may harm them.

You can ask your healthcare provider for additional information about saxagliptin tablets that is written for health professionals.

What are the ingredients of saxagliptin tablets?

Active ingredient: saxagliptin

Inactive ingredients: croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose. In addition, the film-coating contains the following inactive ingredients: hypromellose, iron oxide yellow (2.5 mg tablet only), iron oxide red (5 mg tablet only), polyethylene glycol and titanium dioxide. The imprinting ink contains the following: ammonium hydroxide, n-butyl alcohol, FD&C blue #2, isopropyl alcohol, propylene glycol and shellac.

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For more information about saxagliptin tablets, call Glenmark Pharmaceuticals Inc., USA at 1 (888) 721-7115.

Medication Guide available at:

www.glenmarkpharma-us.com/medguides

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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