

# Kombiglyze XR

**Generic name:** metformin and saxagliptin [ met-FOR-min-and-SAX-a-GLIP-tin ]

Drug class: Antidiabetic combinations

Medically reviewed by Sanjai Sinha, MD. Last updated on Apr 8, 2024.

## What is Kombiglyze XR?

Kombiglyze XR contains a combination of metformin and saxagliptin. Metformin and saxagliptin are oral diabetes medicines that help control blood sugar levels.

Metformin works by decreasing glucose (sugar) production in the liver and decreasing absorption of glucose by the intestines. Saxagliptin works by regulating the levels of insulin your body produces after eating.

Kombiglyze XR is used together with diet and exercise to improve blood sugar control in adults with type 2 diabetes mellitus.

Kombiglyze XR is not for treating type 1 diabetes.

### Warnings

You should not use Kombiglyze XR if you have severe kidney disease or diabetic ketoacidosis (call your doctor for treatment).

You may develop lactic acidosis, a dangerous build-up of lactic acid in your blood. Call your doctor or get emergency medical help if you have unusual muscle pain, trouble breathing, stomach pain, dizziness, feeling cold, or feeling very weak or tired.

# Before taking this medicine

You should not use Kombiglyze XR if you are allergic to metformin or saxagliptin (Onglyza), or if you have severe kidney disease or diabetic ketoacidosis (call your doctor for treatment with insulin).

Tell your doctor if you have ever had:

- kidney disease (your kidney function may need to be checked before you take Kombiglyze XR);
- · liver disease;
- heart disease;
- · pancreatitis;

- high triglycerides (a type of fat in the blood);
- gallstones; or
- · alcoholism.

You may develop **lactic acidosis**, a dangerous build-up of lactic acid in your blood. This may be more likely if you have other medical conditions, a severe infection, chronic alcoholism, or if you are 65 or older. Ask your doctor about your risk.

If you need to have surgery or any type of x-ray or CT scan using a dye that is injected into your veins, you may need to temporarily stop taking Kombiglyze XR. Be sure your caregivers know ahead of time that you are using this medication.

Follow your doctor's instructions about using Kombiglyze XR **if you are pregnant or breastfeeding a baby.** Blood sugar control is very important during pregnancy, and your dose needs may be different during each trimester of pregnancy. Your dose needs may also be different while you are breastfeeding.

Metformin may stimulate ovulation in a premenopausal woman and may increase the risk of unintended pregnancy. Talk to your doctor about your risk.

Kombiglyze XR is not approved for use by anyone younger than 18 years old.

(1) Kombiglyze XR pregnancy and breastfeeding warnings (more detail)

# How should I take Kombiglyze XR?

Take Kombiglyze XR exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets. Use the medicine exactly as directed.

Take Kombiglyze XR with food.

Swallow the tablet whole and do not crush, chew, or break it.

You may have low blood sugar **(hypoglycemia)** and feel very hungry, dizzy, irritable, confused, anxious, or shaky. To quickly treat hypoglycemia, eat or drink a fast-acting source of sugar (fruit juice, hard candy, crackers, raisins, or non-diet soda).

Your doctor may prescribe a glucagon injection kit in case you have severe hypoglycemia. Be sure your family or close friends know how to give you this injection in an emergency.

Also watch for signs of high blood sugar (hyperglycemia) such as increased thirst or urination.

Blood sugar levels can be affected by stress, illness, surgery, exercise, alcohol use, or skipping meals. Ask your doctor before changing your dose or medication schedule.

Kombiglyze XR is only part of a complete treatment program that may also include diet, exercise, weight control, regular blood sugar testing, and special medical care. Follow your doctor's instructions very closely.

Store Kombiglyze XR at room temperature away from moisture and heat.

#### **Dosing information**

#### **Usual Adult Dose of Kombiglyze XR for Diabetes Type 2:**

Individualize dose based patient's current regimen, effectiveness, and tolerability; gradual dose titration of metformin is advised to reduce gastrointestinal side effects.

#### Saxagliptin-Metformin XR:

Usual dose: 1 tablet orally once a day with the evening meal

Maximum dose: saxagliptin 5 mg-metformin 2000 mg orally once a day

Maximum dose with concomitant strong CYP450 3A4/5 inhibitors: saxagliptin 2.5-metformin 1000 mg orally once a day

- -Patients not currently treated with metformin: Initial dose saxagliptin 5 mg-metformin 500 mg orally once daily
- -Patients currently treated with metformin: Initial dose: saxagliptin 5 mg plus the dose of metformin that is already being taken, or the nearest therapeutically appropriate dose.

#### Comments:

- -Patients requiring saxagliptin 2.5 mg per day AND are either metformin-naive or require a dose of metformin greater than 1000 mg per day should use the individual components.
- -Following a switch from metformin immediate-release to metformin extended release, glycemic control should be closely monitored and dosage adjustments made according.
- -When used in combination with a sulfonylurea or insulin, a lower dose of the sulfonylurea or insulin may be considered to reduce the risk of hypoglycemia.
- -Note: There are saxagliptin-metformin combination products available internationally that contain immediate-release metformin; saxagliptin-metformin products containing immediate-release metformin should be dosed twice a day.

Use: An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes when treatment with both saxagliptin and metformin is appropriate.

1 Detailed Kombiglyze XR dosage information

# What happens if I miss a dose?

Take the medicine (with food) as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not take two doses at one time.

# What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. You may have severely low blood sugar (extreme weakness, nausea, tremors, sweating, confusion, trouble speaking, fast heartbeats, or seizure).

#### What to avoid

Avoid drinking alcohol. It lowers blood sugar and may increase your risk of lactic acidosis.

### Kombiglyze XR side effects

Get emergency medical help if you have **signs of an allergic reaction to Kombiglyze XR:** hives, itching, peeling skin; difficult breathing; swelling of your face, lips, tongue, or throat.

Stop taking this medicine and call your doctor right away if you have **symptoms of pancreatitis**: severe pain in your upper stomach spreading to your back, nausea and vomiting, loss of appetite, or fast heartbeats.

Some people using metformin develop lactic acidosis, which can be fatal. **Get emergency medical** help if you have even mild symptoms such as:

- · unusual muscle pain;
- · feeling cold;
- · trouble breathing;
- feeling dizzy, light-headed, tired, or very weak;
- stomach pain, vomiting; or
- · irregular heart rate.

Call your doctor at once if you have any of these serious side effects:

- severe autoimmune reaction itching, blisters, breakdown of the outer layer of skin;
- severe or ongoing pain in your joints;
- pain or burning when you urinate; or
- **symptoms of heart failure** shortness of breath (even while lying down), swelling in your legs or feet, rapid weight gain.

Common Kombiglyze XR side effects may include:

- · diarrhea, nausea;
- headache; or
- cold symptoms such as runny or stuffy nose, sneezing, sore throat.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Kombiglyze XR side effects (more detail)

### Related/similar drugs

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### What other drugs will affect Kombiglyze XR?

Many drugs can interact with metformin and saxagliptin, making this medicine less effective or increasing your risk of lactic acidosis.

Tell your doctor about all your other medicines, especially:

- an antibiotic or antifungal medicine;
- insulin or oral diabetes medicine; or
- · medicine to treat HIV or AIDS.

This list is not complete. Other drugs may interact with metformin and saxagliptin, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

(more detail)

# Frequently asked questions

What are the ingredient drugs contained in Qternmet XR?

#### **Further information**

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Kombiglyze XR only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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