







KOMBIGLYZE XR can cause serious side effects, including:

Lactic Acidosis: Metformin hydrochloride, one of the medicines in KOMBIGLYZE XR, can cause a rare, but serious, side effect called lactic acidosis (a build-up of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in a hospital. Stop taking KOMBIGLYZE XR and call your doctor right away if you get any of the following symptoms of lactic acidosis: feel very weak and tired, unusual (not normal) muscle pain, trouble breathing, unusual sleepiness or sleep longer than usual, unexplained stomach or intestinal problems with nausea and vomiting or diarrhea, feel cold (especially in your arms and legs), dizzy or lightheaded, or have a slow or irregular heartbeat.

You have a higher chance of getting lactic acidosis if you have kidney or liver problems, have congestive heart failure that requires treatment with medicines, drink a lot of alcohol (very often or short-term "binge" drinking), get dehydrated (lose a large amount of body fluids), have certain x-ray tests with injectable dyes or contrast agents, have surgery, have a heart attack, severe infection, or stroke, or are 80 years of age or older and have not had your kidney function tested.

Please see Important Safety Information on page 9.
Click <u>here</u> for Medication Guide and click <u>here</u> for full
Prescribing Information for KOMBIGLYZE XR (5/500,
5/1000_25/1000 ma tablets)_including Boxed WARNING



Managing type 2 diabetes can be challenging. Especially if you're taking metformin and finding that it isn't doing enough to get your A1C numbers to goal. For some, combining metformin with another kind of type 2 medicine may work better. This combination pill could be the kickstart you need.

What is KOMBIGLYZE XR?

KOMBIGLYZE XR is a prescription medicine that contains saxagliptin and metformin hydrochloride. KOMBIGLYZE XR is used with diet and exercise to help control high blood sugar (hyperglycemia) in adults with type 2 diabetes. Your doctor will decide if treatment with both saxagliptin and metformin is right for you.

KOMBIGLYZE XR should not be used to treat people with type 1 diabetes or diabetic ketoacidosis (increased ketones in the blood or urine).

Because managing type 2 diabetes takes more than just medicine, there's the Fit2Me diet and lifestyle support program custom-fit to you. Learn more about Fit2Me on page 8.





PROVEN TO LOWER A1C LEVELS

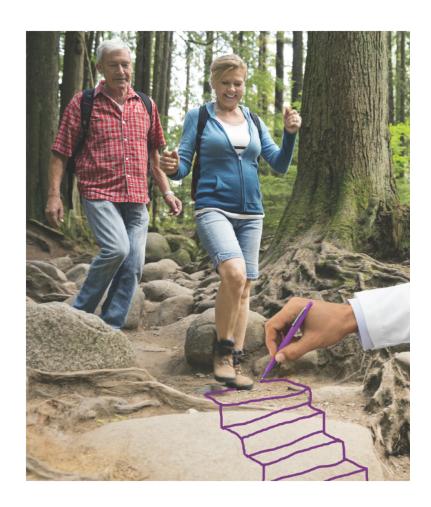
for patients whose blood sugar was not controlled with metformin alone

One very important goal in managing type 2 diabetes is lowering your A1C level to a number agreed upon by you and your healthcare provider.

The combination of saxagliptin and metformin hydrochloride, the two medicines that make up KOMBIGLYZE XR, has been tested in multiple clinical studies in thousands of adult patients with type 2 diabetes. In all of these studies, KOMBIGLYZE XR, in addition to diet and exercise, has been shown to lower A1C levels.

These results are the average responses from the total population in these studies. Your personal results may vary.

Your healthcare provider will determine if KOMBIGLYZE XR could give you the kickstart you need to reach your A1C goals.



Talk to your healthcare provider to see if KOMBIGLYZE XR is right for you.

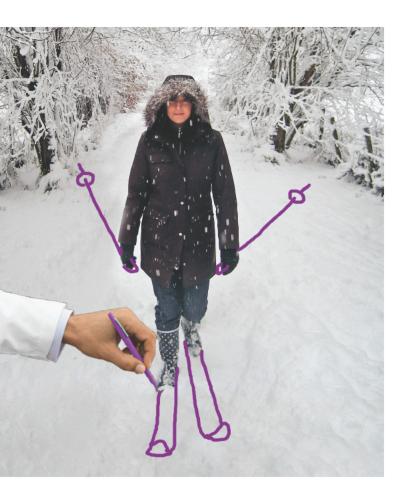
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Who should not take KOMBIGLYZE XR?

Do not take KOMBIGLYZE XR if you have kidney problems, have a condition called metabolic acidosis or diabetic ketoacidosis (increased ketones in the blood or urine), or are allergic to metformin hydrochloride, saxagliptin, or any of the ingredients in KOMBIGLYZE XR. Serious allergic reactions can occur with KOMBIGLYZE XR and may include swelling of the face, lips or throat, difficulty swallowing or breathing, swelling of the skin, hives, rash, itching, flaking, or peeling. If you have these symptoms, stop taking



kombiglyze°xR (saxagliptin and metformin HCl extended-release) tablets



24-WEEK CLINICAL STUDY

A 24-week clinical study involved 1,306 adult type 2 diabetes patients whose blood sugar was not controlled enough by diet and exercise. Of these patients, 643 were given saxagliptin plus metformin IR, 335 were given saxagliptin plus placebo and 328 were given a placebo plus metformin IR.

The patients started the study with an A1C of 9.4% to 9.6%, on average.

After 24 weeks, results showed significant A1C reduction.

Patients who took sax agliptin plus metformin IR:

- · lowered their A1C by 2.5% on average
- 60% of patients reached an A1C goal of less than 7%

*Your results may vary

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What is the most important information you should know about KOMBIGLYZE XR?

Serious side effects can happen to people taking KOMBIGLYZE XR, including inflammation of the pancreas (pancreatitis) which may be severe and lead to death. Before taking KOMBIGLYZE XR, tell your doctor if you ever had pancreatitis, gallstones, history of alcoholism, or high triglyceride levels. Stop taking KOMBIGLYZE XR and contact your doctor 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





KOMBIGLYZE XR IS BELIEVED TO WORK IN 4 DIFFERENT WAYS

to help control blood sugar

Not all medicines for type 2 diabetes work the same way. The graphic below demonstrates how **KOMBIGLYZE XR** is believed to work in four different ways to help control blood sugar.

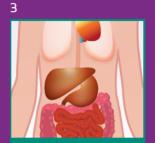




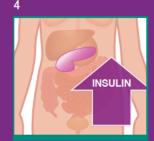
works to decrease the amount of sugar absorbed by the gut



works to reduce the amount of sugar made by the liver



helps the body respond better to its own insulin



helps your body make more insulin when you eat

What is the most important information you should know about KOMBIGLYZE XR?

Heart Failure. Before taking KOMBIGLYZE XR tell your doctor if you have ever had heart failure or problems with your kidneys. Contact your doctor right away if you have any of the following symptoms of heart failure: increasing shortness of breath or trouble breathing, especially when

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