

KOMBIGLYZE® XR TABLET

Saxagliptin / Metformin Hydrochloride (5/1000 mg)

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What KOMBIGLYZE XR is used for

- 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.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems.

The main goal of treating diabetes is to lower your blood sugar so that it is as close to normal as possible. High blood sugar can be lowered by diet and exercise, and by certain medicines when necessary.

How KOMBIGLYZE XR works

- Saxagliptin lowers blood sugar by helping the body increase the level of insulin after meals.

- Metformin helps in improving insulin sensitivity by increasing glucose uptake and utilization in the body.

Before you use KOMBIGLYZE XR

- When you must not use it

Do not take KOMBIGLYZE XR if you:

- have kidney problems.
- are allergic to metformin hydrochloride, saxagliptin, or any of the ingredients in KOMBIGLYZE XR. See the end of this Patient Information Leaflet for a complete list of ingredients in KOMBIGLYZE XR. Symptoms of a serious allergic reaction to KOMBIGLYZE XR may include:
 - swelling of your face, lips, throat, and other areas on your skin
 - raised, red areas on your skin (hives)
 - difficulty with swallowing or breathing
 - skin rash, itching, flaking, or peeling

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

- have a condition called metabolic acidosis or diabetic ketoacidosis (increased ketones in your blood or urine).

KOMBIGLYZE XR is not for people with type 1 diabetes.

KOMBIGLYZE XR is not for people with diabetic ketoacidosis (increased ketones in your blood or urine).

It is not known if KOMBIGLYZE XR is safe and effective in children younger than 18 years old.

- Before you start to use it

Before taking KOMBIGLYZE XR, tell your healthcare provider about all your medical conditions, including if you:

- have type 1 diabetes, KOMBIGLYZE XR should not be used to treat type 1 diabetes.
- have a history or risk for diabetes ketoacidosis (high levels of certain acids, known as ketones, in the blood or urine). KOMBIGLYZE XR should not be used for the treatment of diabetic ketoacidosis.
- have kidney problems.
- have liver problems.
- have heart problems, including congestive heart failure.
- are older than 80 years. If you are over 80 years old you should not take KOMBIGLYZE XR unless your kidneys have been checked and they are normal.
- drink alcohol very often, or drink a lot of alcohol in short-term “binge” drinking.
- are going to get an injection of dye or contrast agents for an x-ray procedure or if you are going to have surgery and will not be able to eat or drink much. In these situations, KOMBIGLYZE XR may need to be stopped for a short time. Talk to your healthcare provider about when you should stop KOMBIGLYZE XR and when you should start KOMBIGLYZE XR again. See “Side effects”
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if KOMBIGLYZE XR 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. It is not known if KOMBIGLYZE XR passes into your breast milk. Talk with your

healthcare provider about the best way to feed your baby while you take KOMBIGLYZE XR.

- Taking other medicines

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 them to show your healthcare provider and pharmacist when you get a new medicine.

KOMBIGLYZE XR may affect the way other medicines work, and other medicines may affect how KOMBIGLYZE XR works.

Tell 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 KOMBIGLYZE XR might need to be changed.

How to use KOMBIGLYZE XR

- How much to use

Take KOMBIGLYZE XR exactly as your healthcare provider tells you.

- When to use it

- KOMBIGLYZE XR should be taken with meals to help lessen an upset stomach side effect.
- Swallow KOMBIGLYZE XR whole. Do not crush, cut, or chew KOMBIGLYZE XR.
- You may sometimes pass a soft mass in your stools (bowel movement) that looks like KOMBIGLYZE XR tablets.

- How long to use it

- Take KOMBIGLYZE XR exactly as your healthcare provider tells you.
- Do not stop your dose without talking to your healthcare provider.

- If you forget to use it

If you miss a dose of KOMBIGLYZE XR, take your next dose as prescribed unless your healthcare provider tells you differently. Do not take an extra dose the next day.

- If you use too much (overdose)

If you take too much KOMBIGLYZE XR, call your healthcare provider or go to the nearest hospital emergency room right away.

While you are using KOMBIGLYZE XR

- Things you must do

- Follow your healthcare provider's instructions for treating blood sugar that is too low (hypoglycemia). Talk to your healthcare provider if low blood sugar is a problem for you. See "*Side effects*".
- Check your blood sugar as your healthcare provider tells you to.
- Stay on your prescribed diet and exercise program while taking KOMBIGLYZE XR.
- Talk to your healthcare provider about how to prevent, recognize, and take care of low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and problems you have because of your diabetes.

- Things you must not do

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

- Things to be careful of

- When your body is under some types of stress, such as fever, trauma (such as a car accident), infection, or surgery, the amount

of diabetes medicine that you need may change. Tell your healthcare provider right away if you have any of these problems.

- Your healthcare provider should do blood tests to check how well your kidneys are working before and during your treatment with KOMBIGLYZE XR.
- Your healthcare provider will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.

Side effects

Serious side effects can happen in people taking KOMBIGLYZE XR, including:

1. Lactic Acidosis. Metformin, one of the medicines in KOMBIGLYZE XR, can cause a rare, but serious condition 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 the hospital.

Call your doctor right away if you get any of the following symptoms, which could be signs of lactic acidosis:

- you feel cold in your hands or feet
- you feel dizzy or lightheaded
- you have a slow or irregular heartbeat
- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you feel sleepy or drowsy
- you have stomach pains, nausea or vomiting

Most people who have had lactic acidosis with metformin have other things that, combined with the metformin, led to the lactic acidosis. Tell your doctor if you have any of the following, because you have a higher chance for getting lactic acidosis with KOMBIGLYZE XR if you:

- have severe kidney problems or your kidneys are affected by certain x-ray tests that use injectable dye

- have liver problems
- drink alcohol very often, or drink a lot of alcohol in short-term “binge” drinking
- get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids
- have surgery
- have a heart attack, severe infection, or stroke

The best way to keep from having a problem with lactic acidosis from metformin is to tell your doctor if you have any of the problems in the list above. Your doctor may decide to stop your KOMBIGLYZE XR for a while if you have any of these things.

KOMBIGLYZE XR can have other serious side effects. See other serious side effects below.

2. 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 KOMBIGLYZE XR:
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

It is not known if having these medical problems will make you more likely to get pancreatitis with KOMBIGLYZE XR.

Stop taking KOMBIGLYZE XR 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.

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

Before you start taking KOMBIGLYZE XR:
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
- swelling or fluid retention, especially in the feet, ankles or legs
- an unusually fast increase in weight
- unusual tiredness

These may be symptoms of heart failure.

KOMBIGLYZE XR can cause other serious side effects, including:

- **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 peeling

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

- **Low blood sugar (hypoglycemia).** May become worse in people who also take another medication to treat diabetes, such as sulfonylureas or insulin. Tell your healthcare provider if you take other diabetes medicines. If you have symptoms of low blood sugar, you should check your blood

sugar and treat if low, then call your healthcare provider.

Symptoms of low blood sugar include:

- shaking
- sweating
- rapid heartbeat
- change in vision
- hunger
- headache
- change in mood

- **Joint pain.** Some people who take medicines called DPP-4 inhibitors, one of the medicines in KOMBIGLYZE XR, 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, one of the medicines in KOMBIGLYZE XR, 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 KOMBIGLYZE XR.

Common side effects of KOMBIGLYZE XR include:

- upper respiratory tract infection
- stuffy or runny nose and sore throat
- urinary tract infection
- headache
- diarrhea
- nausea and vomiting
- decreased or low vitamin B₁₂ levels in the blood
 - Symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin. Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

Taking KOMBIGLYZE XR with meals can help lessen the common stomach side effects of metformin. If you have unexplained stomach problems, tell your healthcare provider. Stomach problems that start later during treatment may be a sign of something more serious.

These are not all of the possible side effects of KOMBIGLYZE XR. Call your doctor for medical advice about side effects.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of KOMBIGLYZE XR

- Storage

Store below 30°C.

Keep KOMBIGLYZE XR and all medicines out of the reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- What it looks like

KOMBIGLYZE XR 5/1000 mg
Tablet: pink, biconvex, capsule-shaped, marked “5/1000” on one side and “4223” on the reverse, in blue ink

Pack size of 28 tablets in blisters.

- Ingredients

- Active ingredients

- Saxagliptin
- Metformin hydrochloride

- Inactive ingredients

- Carboxymethylcellulose sodium
- Hypromellose 2208
- Magnesium stearate

Tablet film coat contains:
polyvinyl alcohol, polyethylene glycol 3350, titanium dioxide, talc, and iron oxides.

- MAL number

5/1000 mg: MAL11115004AZ

Manufacturer

AstraZeneca Pharmaceuticals LP
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Product Registration Holder

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