

KOMBIGLYZE® XR

Saxagliptin/metformin hydrochloride modified release

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about KOMBIGLYZE XR. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking KOMBIGLYZE XR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What KOMBIGLYZE XR is used for

KOMBIGLYZE XR is used to lower blood sugar levels in patients with type 2 diabetes mellitus along with diet and exercise. KOMBIGLYZE XR may also be used in combination with other medicines including insulin, a sulfonylurea (such as gliclazide) or a SGLT2 inhibitor (such as

dapagliflozin) along with diet and exercise to treat type 2 diabetes.

Type 2 diabetes mellitus

Type 2 diabetes mellitus 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 and can lead to serious medical problems.

The main goal of treating diabetes is to lower your blood sugar to a normal level. Lowering and controlling blood sugar may help prevent or delay complications of diabetes, such as heart disease, kidney disease, blindness and amputation.

KOMBIGLYZE XR contains two active ingredients, saxagliptin and metformin hydrochloride (modified release). Saxagliptin is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors), and metformin belongs to a class of medicines called biguanides. Saxagliptin and metformin work together to lower blood sugar levels in patients with type 2 diabetes mellitus.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why KOMBIGLYZE XR has been prescribed for you.

This medicine is only available with a doctor's prescription.

KOMBIGLYZE XR is not addictive.

Before you take KOMBIGLYZE XR

When you must not take it

Do not take KOMBIGLYZE XR if you have an allergy to:

- Saxagliptin or metformin, the active ingredients in KOMBIGLYZE XR, or any of the other ingredients listed at the end of this leaflet.
- any other medicine in the same class as saxagliptin (ie a DPP-4 inhibitor).

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin or you may feel faint.

Do not take KOMBIGLYZE XR if you have any of the following conditions:

- type 1 diabetes mellitus that is well controlled by insulin alone
- type 2 diabetes that is already well controlled by diet alone
- diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood - you may notice this as an unusual fruity odour on your breath, difficulty breathing, confusion and frequent urination)
- severe liver disease

- excessive alcohol intake, binge drinking, alcohol dependence
- kidney failure or severe kidney disease
- dehydration, severe blood loss, shock
- a severe infection
- certain heart or blood vessel problems, including a recent heart attack or severe heart failure (when the heart fails to pump blood effectively)
- severe breathing difficulties
- blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
- gangrene
- inflammation of the pancreas (pancreatitis), symptoms include severe upper stomach pain, often with nausea and vomiting

Do not take KOMBIGLYZE XR if you need to have major surgery or an examination such as an X-ray or a scan requiring an injection of iodinated contrast (dye).

You must stop taking KOMBIGLYZE XR for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Do not take this medicine if you are pregnant or plan to become pregnant.

The safety of KOMBIGLYZE XR in pregnant women has not been established. Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace KOMBIGLYZE XR with insulin while you are pregnant.

Do not take KOMBIGLYZE XR if you are breastfeeding.

KOMBIGLYZE XR is not recommended while you are breastfeeding. Your doctor will discuss the options available to you.

Do not take KOMBIGLYZE XR after the use by (expiry) date printed on the pack.

Do not take KOMBIGLYZE XR if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

KOMBIGLYZE XR is not recommended for use in children.

There is not enough information on its effects in children.

If you are not sure whether you should start taking KOMBIGLYZE XR, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have any allergies to:

- any other medicines
- any other substances such as foods, dyes or preservatives

Tell your doctor or pharmacist if you have, or have had, any medical conditions, especially the following:

- heart failure
- liver problems
- kidney problems

Your doctor will do some tests for kidney function at the start of treatment and regularly while you are on treatment.

Tell your doctor if you drink alcohol.

Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with KOMBIGLYZE XR may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

KOMBIGLYZE XR may affect how well other medicines work and some medicines can affect how well KOMBIGLYZE XR works.

These include:

- other medicines used to treat diabetes
- medicines that contain alcohol, such as cough and cold syrups
- tetracosactrin, a medicine used in people with multiple sclerosis, and in young children to treat some types of seizures (fits)
- danazol, a medicine used to treat endometriosis
- some medicines used to treat high blood pressure and some heart conditions, including beta-blockers, calcium channel blockers and ACE inhibitors
- medicines used to prevent blood clots, such as warfarin
- diuretics, also called fluid tablets
- chlorpromazine, a medicine used to treat schizophrenia and other mental illnesses
- NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to relieve pain, swelling and other symptoms of inflammation, such as aspirin, diclofenac, ibuprofen, meloxicam, naproxen or piroxicam
- cimetidine, a medicine used to treat reflux and ulcers
- corticosteroids such as prednisone or cortisone

- some medicines used to treat asthma such as salbutamol or terbutaline

If you have not told your doctor about any of these things, tell them before you take any KOMBIGLYZE XR.

How to take KOMBIGLYZE XR

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack ask your doctor or pharmacist for help.

How to take it

Swallow your KOMBIGLYZE XR tablets whole with a full glass of water.

KOMBIGLYZE XR tablets must not be chewed or crushed.

How much to take

Your Doctor will tell you how many KOMBIGLYZE XR tablets to take and how often you should take them. The dose varies from person to person. Your doctor will decide the right dose for you.

When to take it

Take KOMBIGLYZE XR during or immediately after food in the evening.

This will reduce the chance of a stomach upset.

KOMBIGLYZE XR should be taken at approximately the same time each day.

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

How long to take it

Continue taking the tablets for as long as your doctor tells you. Make sure you keep enough KOMBIGLYZE XR to last over weekends and holidays.

KOMBIGLYZE XR helps control your condition, but does not cure it. Therefore you must take KOMBIGLYZE XR every day.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much KOMBIGLYZE XR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking KOMBIGLYZE XR

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking KOMBIGLYZE XR.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking KOMBIGLYZE XR.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

Attend your doctor or diabetes centre for regular check-ups about your diabetes.

HYPOGLYCAEMIA

KOMBIGLYZE XR does not normally cause hypoglycaemia, although you may experience it if you take certain other medicines.

Hypoglycaemia can occur suddenly. Initial signs may include:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose immediately.

You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 2 to 3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

HYPERGLYCAEMIA

If you notice the return of any of the signs of hyperglycaemia, contact your doctor immediately.

Your doctor may need to consider additional or other treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less KOMBIGLYZE XR than prescribed
- taking certain other medicines

- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if you:

- become ill
- become dehydrated
- are injured
- have a fever
- have a serious infection
- are having surgery (including dental surgery)

Your blood glucose may become difficult to control at these times. You may also be more at risk of developing a serious condition called lactic acidosis. At these times, your doctor may temporarily replace KOMBIGLYZE XR with insulin.

If you become pregnant while taking KOMBIGLYZE XR, tell your doctor immediately.

If you need to have any medical tests while you are taking KOMBIGLYZE XR, tell your doctor.

KOMBIGLYZE XR may affect the results of some tests.

Visit your doctor regularly for check ups.

Your doctor may want to perform blood tests to check your kidneys, liver, heart and vitamin B12 level while you are taking KOMBIGLYZE XR.

Things you must not do

Do not take KOMBIGLYZE XR to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar or they have the same condition as you.

Do not skip meals while taking KOMBIGLYZE XR.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how KOMBIGLYZE XR affects you.

KOMBIGLYZE XR may cause dizziness in some people. Low blood sugar levels may also slow your reaction time and affect your ability to drive or operate machinery. Do not drive a car if you have signs of low blood sugar.

Make sure you know how you react to KOMBIGLYZE XR before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking KOMBIGLYZE XR.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache
- signs of an infection in the breathing passages including runny nose, sore throat and cough
- soreness in the back of the nose and throat and discomfort when swallowing
- difficulty breathing or tightness in the chest
- vomiting or diarrhoea
- stomach pain or discomfort
- swelling of hands, ankles or feet

- signs of urinary tract infection such as an urge to urinate frequently and in small amounts, and painful burning when passing urine
- rash
- feeling depressed or anxious
- signs of anaemia such as tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- loss of appetite
- loss of taste
- increased blood pressure
- back pain.
- joint pain

These side effects are usually mild.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- signs of hypoglycaemia (low blood sugar) that persist despite administering sugar as described under 'While you are taking Kombiglyze XR' in this leaflet . Signs of hypoglycaemia may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, lack of concentration, tearfulness or crying, irritability,

hunger and numbness around the lips and fingers. Do not drive a car if you have signs of low blood sugar.

- severe allergic reaction (may include shortness of breath, wheezing or severe difficulty in breathing, shock, swelling of the face, lips, tongue or other parts of the body, skin rash, itching or hives on the skin hayfever, or you may feel faint)
- severe upper stomach pain, often with nausea and vomiting
- signs and symptoms of heart failure. Signs of heart failure may include, increasing shortness of breath, rapid increase in weight and swelling of the feet.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

IN RARE CASES, METFORMIN, ONE OF THE MEDICINES IN KOMBIGLYZE XR, CAN CAUSE A SERIOUS SIDE EFFECT CALLED LACTIC ACIDOSIS.

LACTIC ACIDOSIS IS A MEDICAL EMERGENCY THAT CAN CAUSE DEATH AND MUST BE TREATED IN THE HOSPITAL. LACTIC ACIDOSIS IS CAUSED BY A BUILD-UP OF LACTIC ACID IN YOUR BLOOD.

STOP TAKING KOMBIGLYZE XR IF YOU GET ANY OF THE FOLLOWING SYMPTOMS OF LACTIC ACIDOSIS AND SEE YOUR DOCTOR IMMEDIATELY:

- You feel very weak and tired.
- You have unusual (not normal) muscle pain.
- You have trouble breathing.
- You have stomach pain with nausea and vomiting, or diarrhoea.
- You feel cold, especially in your arms and legs.
- You feel dizzy or lightheaded.
- You have a slow or irregular heart beat
- Your medical condition suddenly changes.

The risk of lactic acidosis is higher in the elderly, those whose diabetes is poorly controlled, those with prolonged fasting, those with certain heart conditions, those who drink alcohol and those with kidney or liver problems.

Occasionally, KOMBIGLYZE XR may be associated with changes in your blood. These can only be found when your doctor does tests from time to time to check your progress.

Other side effects not listed here may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking KOMBIGLYZE XR

Storage

Keep your KOMBIGLYZE XR tablets in the blister pack until it is time to take them.

If you take KOMBIGLYZE XR out of the blister pack it will not keep well.

Keep it in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking KOMBIGLYZE XR or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What KOMBIGLYZE XR looks like

KOMBIGLYZE XR tablets are available in three strengths:

- 5mg/500mg, light brown to brown, biconvex, capsule shaped, film-coated tablets, with "5/500" printed on one side and "4221" printed on the other side, in blue ink. Available in blister packs of 7 and 28 tablets

- 5mg/1000mg, pink, biconvex, capsule shaped, film-coated tablets, with "5/1000" printed on one side and "4223" printed on the other side, in blue ink. Available in blister packs of 7 and 28 tablets

- 2.5mg/1000mg, pale yellow to light yellow, biconvex, capsule shaped, film-coated tablets, with "2.5/1000" printed on one side and "4222" printed on the other side, in blue ink. Available in blister packs of 14 and 56 tablets

Ingredients

Active ingredients

Each KOMBIGLYZE XR tablet contains the active ingredients:

- Saxagliptin 5 mg and metformin hydrochloride 500mg;
- Saxagliptin 5 mg and metformin hydrochloride 1000mg;
or

- Saxagliptin 2.5mg and metformin hydrochloride 1000mg

Plus the following inactive ingredients:

- carmellose sodium
- magnesium stearate
- hypromellose
- microcrystalline cellulose
- macrogol 3350
- titanium dioxide
- purified talc
- iron oxide red CI77491 (5 mg/500 mg and 5 mg/1000 mg tablets)
- iron oxide yellow CI77492 (5 mg/500 mg and 2.5 mg/1000 mg tablets)
- Opacode Blue (printing ink).

KOMBIGLYZE XR tablets do not contain lactose, gluten or sucrose.

Supplier

KOMBIGLYZE XR[®] is sponsored and supplied in Australia by

AstraZeneca Pty Ltd

ABN 54 009 682 311

66 Talavera Road

MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

This leaflet was prepared in July 2017.

KOMBIGLYZE XR Australian Registration Numbers:

5 mg/500 mg - AUST R 202209

5 mg/1000 mg - AUST R 202208

2.5 mg/1000 mg - AUST R 202207

KOMBIGLYZE XR is a registered trademark of the AstraZeneca group of companies.

Doc ID-002379897 V 6.0