

KOMBIGLYZE XR®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking KOMBIGLYZE XR?

KOMBIGLYZE XR contains two active ingredients, saxagliptin and metformin hydrochloride. KOMBIGLYZE XR is used to lower blood sugar levels in patients with type 2 diabetes mellitus along with diet and exercise.

For more information, see Section [1. Why am I taking KOMBIGLYZE XR?](#) in the full CMI.

2. What should I know before I take KOMBIGLYZE XR?

Do not use if you have ever had an allergic reaction to saxagliptin or metformin hydrochloride, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or drink alcohol.

For more information, see Section [2. What should I know before I take KOMBIGLYZE XR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KOMBIGLYZE XR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take KOMBIGLYZE XR?

- Your doctor will tell you how many KOMBIGLYZE XR tablets to take and how often you should take them.
- KOMBIGLYZE XR should be taken with or immediately after food in the evening. Swallow tablet whole with a full glass of water.

More instructions can be found in Section [4. How do I take KOMBIGLYZE XR?](#) in the full CMI.

5. What should I know while taking KOMBIGLYZE XR?

Things you should do	<ul style="list-style-type: none">• Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia (low blood sugar) and hyperglycaemia (high blood sugar) and know how to treat them.• Talk to your doctor if you need to have any medical tests while taking KOMBIGLYZE XR.• Remind any doctor, dentist or pharmacist you visit for any new medicine that you are taking KOMBIGLYZE XR.• If you become pregnant while taking KOMBIGLYZE XR, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how KOMBIGLYZE XR affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your KOMBIGLYZE XR tablets in the blister until it is time to take them.• Keep your tablets in a cool dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while taking KOMBIGLYZE XR?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Some can be minor and temporary. However, some side effects may be serious and could require urgent medical attention or hospitalisation. Tell your doctor immediately or go to the nearest hospital if you notice any of the following symptoms: trouble breathing, feeling weak or tired, unusual muscle pain, dizziness, shivering, feeling extremely cold, slow heartbeat, swelling of the face, lips, tongue or other parts of the body, skin rash, itching or hives on the skin.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

KOMBIGLYZE XR®

Active ingredient(s): saxagliptin/metformin hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about taking KOMBIGLYZE XR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking KOMBIGLYZE XR.**

Where to find information in this leaflet:

1. [Why am I taking KOMBIGLYZE XR?](#)
2. [What should I know before I take KOMBIGLYZE XR?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take KOMBIGLYZE XR?](#)
5. [What should I know while taking KOMBIGLYZE XR?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking KOMBIGLYZE XR?

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.

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.

2. What should I know before I take KOMBIGLYZE XR?

Warnings

Do not take KOMBIGLYZE XR if you:

- are allergic to saxagliptin or metformin hydrochloride, or any of the ingredients listed at the end of this leaflet.
- are taking any other medicine in the same class as saxagliptin (ie a DPP-4 inhibitor). Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin or
 - o you may feel faint
- have type 1 diabetes mellitus that is well controlled by insulin alone
- have type 2 diabetes that is already well controlled by diet alone
- have 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)
- have severe liver disease
- drink excessive alcohol, binge drink, have alcohol dependence
- have kidney failure or severe kidney disease
- have dehydration, severe blood loss, shock
- have a severe infection
- have certain heart or blood vessel problems, including a recent heart attack or severe heart failure (when the heart fails to pump blood effectively)
- have severe breathing difficulties
- have blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
- have gangrene
- have inflammation of the pancreas (pancreatitis), symptoms include severe upper stomach pain, often with nausea and vomit

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.

Check with your doctor if you:

- have any allergies to any other medicines, foods, dyes or preservatives.
- have or may have mitochondrial diseases such as Mitochondrial Encephalomyopathy with Lactic Acidosis, and Stroke-like episodes (MELAS) syndrome and Maternally Inherited Diabetes and Deafness (MIDD)
- have or have had any other medical conditions:
 - Kidney or liver problems
 - heart failure
 - an underactive thyroid gland known as hypothyroidism, whether you are being treated for it or not
 - 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.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

Children

KOMBIGLYZE XR is not recommended for use in children.

There is not enough information on its effects in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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
- levothyroxine, a medicine used to treat hypothyroidism and acts to replace the hormone your thyroid gland normally makes

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KOMBIGLYZE XR

4. How do I take 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.

- **Swallow your KOMBIGLYZE XR tablet 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 KOMBIGLYZE XR

- **KOMBIGLYZE XR should be taken with 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

- **Continue taking your medicine 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 use KOMBIGLYZE XR

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 you missed.

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

If you take too much KOMBIGLYZE XR

If you think that you have used too much KOMBIGLYZE XR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking KOMBIGLYZE XR?

Things you should 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.

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 or diabetic

ketoacidosis. At these times, your doctor may temporarily replace KOMBIGLYZE XR with insulin.

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.

Metformin may reduce Vitamin B12 levels. Periodic monitoring may be necessary in patients at risk for Vitamin B12 deficiency.

If you have hypothyroidism, your doctor may monitor your thyroid function. If you are taking levothyroxine, it may reduce the blood glucose lowering effect of this medicine and your doctor may want to monitor your blood glucose more closely.

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
- light-headedness, 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.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

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.

Looking after your medicine

- **Keep your KOMBIGLYZE XR tablets in the blister until it is time to take them.** If you take KOMBIGLYZE XR out of the blister, it will not keep well.
- **Keep your tablets 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 young children cannot reach it.

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

Getting rid of any unwanted medicine

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.

6. Are there any 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gut-related: <ul style="list-style-type: none">• nausea, vomiting or diarrhoea• stomach pain or discomfort Nervous system-related: <ul style="list-style-type: none">• loss of appetite• loss of taste• headache Others: <ul style="list-style-type: none">• 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• signs of urinary tract infection such as an urge to urinate frequently and in small amounts, and painful burning when passing urine• feeling depressed or anxious• signs of anaemia such as tiredness, headaches, being short of breath when exercising, dizziness and looking pale• increased blood pressure• back pain.• joint pain• rash	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reaction: <ul style="list-style-type: none">• 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	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
<p>hives on the skin hayfever, or you may feel faint)</p> <p>Hypoglycaemia:</p> <ul style="list-style-type: none"> 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. <p>Heart problems:</p> <ul style="list-style-type: none"> signs and symptoms of heart failure such as increasing shortness of breath, rapid increase in weight and swelling of the feet. <p>Gut related:</p> <ul style="list-style-type: none"> severe upper stomach pain, often with nausea and vomiting. <p>Skin related:</p> <ul style="list-style-type: none"> develop blisters or the breakdown of your skin (erosion). These symptoms could be a sign of a skin reaction called bullous pemphigoid that can require treatment in a hospital. <p>Lactic Acidosis</p> <p>IN RARE CASES, METFORMIN, ONE OF THE MEDICINES IN KOMBIGLYZE XR, CAN CAUSE A SERIOUS SIDE EFFECT CALLED LACTIC ACIDOSIS.</p> <p>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.</p> <p>STOP TAKING KOMBIGLYZE XR IF YOU GET ANY OF THE FOLLOWING SYMPTOMS OF LACTIC ACIDOSIS AND SEE YOUR DOCTOR IMMEDIATELY:</p> <ul style="list-style-type: none"> You feel very weak and tired. You have unusual (not normal) muscle pain. You have trouble breathing. 	<p>notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> You have stomach pain with nausea and vomiting, or diarrhoea. You feel cold, especially in your arms and legs. You feel dizzy or light-headed. You have a slow or irregular heart beat Your medical condition suddenly changes. <p>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.</p>	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Other side effects not listed here may occur in some people.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What KOMBIGLYZE XR contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> saxagliptin 5 mg and metformin hydrochloride 500 mg saxagliptin 5 mg and metformin hydrochloride 1000 mg saxagliptin 2.5 mg and metformin hydrochloride 1000 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> carmellose sodium magnesium stearate hypromellose microcrystalline cellulose

	<ul style="list-style-type: none"> • 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).
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

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

What KOMBIGLYZE XR looks like

- KOMBIGLYZE XR 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 (AUST R 202209).
- KOMBIGLYZE XR 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 (AUST R 202208).
- KOMBIGLYZE XR 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. Available in blister packs of 14 and 56 tablets. (AUST R 202207).

Who distributes KOMBIGLYZE XR

AstraZeneca Pty Ltd
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