

## PART III: CONSUMER INFORMATION

### **Ⓡ** KOMBOGLYZE<sup>®</sup>

saxagliptin and metformin hydrochloride tablets  
(as saxagliptin hydrochloride and metformin hydrochloride)

This leaflet is part III of a three-part "Product Monograph" published when KOMBOGLYZE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about KOMBOGLYZE. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### WHAT THE MEDICATION IS USED FOR:

KOMBOGLYZE is used in addition to diet and exercise to improve blood sugar levels in adult patients with type 2 diabetes, who are already treated with:

- saxagliptin (ONGLYZA<sup>®</sup>) and metformin or who are not controlled on metformin alone.
- saxagliptin (ONGLYZA<sup>®</sup>), metformin and sulfonylurea or who are not controlled on metformin and sulfonylurea alone.
- saxagliptin (ONGLYZA<sup>®</sup>), metformin and insulin or who are not controlled on metformin and insulin alone.

##### WHAT IT DOES:

KOMBOGLYZE contains saxagliptin and metformin hydrochloride.

Saxagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). Saxagliptin helps to improve blood sugar levels in response to a meal. Saxagliptin also lowers blood sugar levels between meals, and helps to decrease the amount of sugar made by your body.

Metformin is a member of the biguanide class of medicines, it helps to lower the amount of sugar made by the liver.

##### What is Type 2 Diabetes?

Insulin is a hormone that helps control the level of sugar (glucose) in your blood. Type 2 diabetes is a condition in which your body does not make enough insulin and/or the insulin that your body produces does not work as well as it should. When this happens, glucose can build up in the blood. This can lead to serious problems.

##### WHEN IT SHOULD NOT BE USED:

Do not take KOMBOGLYZE if you:

- Have unstable and/or insulin-dependent (Type 1) diabetes mellitus.
- Have metabolic acidosis [including diabetic ketoacidosis (increased ketones in the blood or urine) or lactic acidosis (too much acid in the blood), or history of ketoacidosis or lactic acidosis]
- Have or have had a liver or kidney problem
- Have heart failure or cardiovascular collapse (abrupt failure of blood circulation) or cardiorespiratory insufficiency
- Drink a lot of alcohol
- Are stressed, have severe infections, are experiencing trauma, prior to surgery or during the recovery phase
- Suffer from severe dehydration (have lost a lot of water from your body)
- Are breastfeeding
- Are pregnant or planning to become pregnant
- Are going to get or receive an injection of dye or contrast agent for an x-ray procedure. Talk to your physician or pharmacist about when to stop KOMBOGLYZE and when to start again
- Are allergic (including angioedema / anaphylaxis) to saxagliptin, metformin or any of the ingredients in KOMBOGLYZE (see "WHAT THE NONMEDICINAL INGREDIENTS ARE") or if you are allergic to other drugs belonging to the DPP-4 class.

##### WHAT THE MEDICINAL INGREDIENT IS:

Saxagliptin (as saxagliptin hydrochloride) and metformin hydrochloride.

##### WHAT THE NONMEDICINAL INGREDIENTS ARE:

Magnesium stearate, polyvinyl alcohol, polyethylene glycol 3350, povidone, titanium dioxide, talc, and red iron oxide (2.5mg/500mg strength) or yellow iron oxide (2.5mg/1000mg strength) or a combination of red and yellow iron oxides (2.5mg/850mg strength).

##### WHAT DOSAGE FORMS IT COMES IN:

KOMBOGLYZE is supplied as tablets containing saxagliptin / metformin hydrochloride 2.5mg/500mg, 2.5mg/850mg or 2.5mg/1000mg.

#### WARNINGS AND PRECAUTIONS

##### Serious Warnings and Precautions

KOMBOGLYZE contains metformin and it can rarely cause lactic acidosis. Lactic acidosis can cause death and must be treated in the hospital. Alcohol may increase the risk of lactic acidosis. Do not drink a lot of alcohol while taking KOMBOGLYZE.

##### Lactic Acidosis

Stop taking KOMBOGLYZE and tell your doctor if you get the following symptoms of lactic acidosis:

- 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 diarrhea
- You feel cold, especially in your arms and legs
- You feel dizzy or lightheaded
- You feel unusual fatigue and drowsiness
- You have a slow or irregular heart beat
- Your medical condition suddenly changes

BEFORE you use KOMBOGLYZE talk to your doctor or pharmacist if:

- You have or have had any kidney problems
- You have or have had liver problems
- You have or have had heart failure
- You consume large quantities of alcohol all the time or short term “binge”
- You are dehydrated (have lost 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 don’t drink enough fluids.)
- You will have certain x-ray tests with injectable dyes or contrast agents
- You will be having surgery
- You have had a heart attack, severe infection, or stroke
- You feel very weak and tired
- You have had an allergic reaction to other DPP-4 inhibitors
- You have or have had diabetic ketoacidosis (increased ketones in the blood or urine)
- You are pregnant or planning to become pregnant
- You are breast-feeding or plan to breast-feed
- You are 80 years of age or older and have not had your kidney function tested
- You have or have had pancreas problems such as inflammation of the pancreas (pancreatitis)
- You have low B<sub>12</sub> levels

**Heart Failure** has been seen in patients treated with KOMBOGLYZE. **Heart Failure** is when your heart is unable to pump enough blood to meet the needs of the body. You are at greater risk of **Heart Failure** if you have or have had:

- heart or blood vessel disease including heart failure and heart attack
- kidney disease
- several risk factors of getting heart disease

Symptoms of heart failure include one or more of the following: tiredness, swollen ankles, a fast increase in weight and increased shortness of breath especially when lying down. This is serious. You must talk to your physician immediately or go to the hospital if this happens to you.

KOMBOGLYZE is not recommended for use in children under 18 years of age.

### INTERACTIONS WITH THIS MEDICATION

Some drugs may interact with KOMBOGLYZE. Tell your doctor if you are taking:

- Other diabetes drugs such as glyburide
- Furosemide
- Nifedipine
- Cationic drugs (e.g. amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim and vancomycin)
- Other drugs tend to produce hyperglycemia (high blood sugar) and may lead to a loss of blood sugar control. Some example of drugs that can increase the blood sugar include:
  - Thiazide and other diuretics (water pills)
  - Corticosteroids
  - Phenothiazines
  - Thyroid products
  - Estrogens or estrogens plus progestogen
  - Oral contraceptives
  - Phenytoin
  - Nicotinic Acid
  - Sympathomimetics
  - Calcium channel blocking drugs
  - Isoniazid
  - Beta-2-agonists
- ACE inhibitor drugs (may lower blood glucose)

Talk to your doctor or pharmacist about all the drugs you take. This includes prescription drugs, as well as those you buy yourself, and herbal supplements.

### PROPER USE OF THIS MEDICATION

Follow the directions given to you by your doctor. Your doctor will tell you how many KOMBOGLYZE tablets to take and how often you need to take them.

KOMBOGLYZE is to be taken twice a day with meals.

### OVERDOSE:

If you think you, or a person you are caring for, have taken too much KOMBOGLYZE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

### MISSED DOSE:

If you miss a dose of KOMBOGLYZE, take it with food as soon as you remember. If you do not remember until it is almost time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Common side effects: upper respiratory tract infection, urinary tract infection, headache, diarrhea, nausea, upset stomach, abdominal bloating, gas, and loss of appetite.

Hypoglycemia may occur more frequently in people who already take a sulfonylurea or insulin. 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, and change in mood.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
<b>Uncommon</b>			
Pancreatitis (inflammation of the pancreas): prolonged severe abdominal pain which may be accompanied by vomiting.		X	X
Severe disabling joint pain.		X	
<b>Rare</b>			
Lactic Acidosis (build up of lactic acid in your blood): <ul style="list-style-type: none"> <li>• feeling very weak, tired or uncomfortable</li> <li>• unusual muscle pain</li> <li>• trouble breathing</li> <li>• unusual or unexpected stomach discomfort</li> <li>• feeling cold</li> <li>• feeling dizzy or lightheaded</li> <li>• unusual fatigue and drowsiness</li> <li>• suddenly develop a slow or irregular heartbeat.</li> </ul>			X
<b>Very rare</b>			
Allergic (hypersensitivity) reactions (angioedema / anaphylaxis): swelling of the face, lips or throat, difficulty breathing, rash, hives, itching, peeling, or flaking skin.		X	X
Bullous pemphigoid (serious skin reaction): blistering of the skin, redness, peeling skin.		X	
Rhabdomyolysis (breakdown of damaged muscle): muscle spasms, weakness, red-brown (tea-coloured) urine.			X
<b>Unknown</b>			
Heart failure (a weakness of the heart): tiredness, swollen ankles, increasing shortness of breath especially when lying down and a fast increase in weight.			X

This is not a complete list of side effects. For any unexpected effects while taking KOMBOGLYZE, contact your doctor or pharmacist.

**HOW TO STORE IT**

Store at room temperature (15-25°C).

Keep KOMBOGLYZE well out of reach of children.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Call toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing.

The most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: [www.astrazeneca.ca](http://www.astrazeneca.ca) or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries 1-800-668-6000, Renseignements 1-800-461-3787.

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