

PART III: CONSUMER INFORMATION

ONGLYZA®

saxagliptin tablets

(as saxagliptin hydrochloride)

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

ABOUT THIS MEDICATION

WHAT THE MEDICATION IS USED FOR:

ONGLYZA is used to improve blood sugar levels in adult patients with type 2 diabetes, in combination with;

- metformin,
- sulfonylurea,
- metformin and a sulfonylurea or
- insulin (with or without metformin)

when diet and exercise and metformin, sulfonylurea, metformin and a sulfonylurea or insulin (with or without metformin) alone have failed to adequately control blood sugar levels.

WHAT IT DOES:

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

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 ONGLYZA if you are allergic to any of the ingredients in ONGLYZA or if you are allergic to the other drugs belonging to DPP-4 class.

- Do not take ONGLYZA if you have diabetic ketoacidosis (accumulation of ketones in the blood and urine), diabetic pre-coma or diabetic coma.
- Do not take ONGLYZA if you have Type 1 diabetes.

WHAT THE MEDICINAL INGREDIENT IS:

ONGLYZA contains saxagliptin (as saxagliptin hydrochloride) the active ingredient.

WHAT THE NONMEDICINAL INGREDIENTS ARE:

ONGLYZA tablets contain the following non-medicinal ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, titanium dioxide, talc, and iron oxides. The printing ink contains FD&C Blue #2 and shellac glaze.

WHAT DOSAGE FORMS IT COMES IN:

ONGLYZA is supplied in 2.5 mg and 5 mg saxagliptin (as saxagliptin hydrochloride) tablets.

WARNINGS AND PRECAUTIONS

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

- you have had an allergic reaction to other DPP-4 inhibitors
- you have or have had any kidney problems
- you have or have had liver problems
- you have or have had heart failure
- you have been told you have a reduced immune system [e.g. you have had organ transplantation or have been diagnosed with human immunodeficiency syndrome (HIV/AIDS)]
- you are pregnant or planning to become pregnant
- you are breast-feeding or plan to breast-feed
- you have or have had pancreas problems such as inflammation of the pancreas (pancreatitis)

Heart Failure has been seen in patients treated with ONGLYZA. **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.

ONGLYZA should not be used in patients with end-stage renal disease (ESRD) who require dialysis.

Lactose monohydrate is a non-medicinal ingredient in ONGLYZA. Do not take ONGLYZA if a doctor has told you that you have one of the following hereditary diseases: galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption.

Your blood sugar may get too high (hyperglycemia) if you have fever, infection, surgery, or trauma (stress conditions). In such cases contact your doctor as your medication may need to be adjusted.

INTERACTIONS WITH THIS MEDICATION

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.

USUAL DOSE:

The usual recommended adult dose is 5 mg, once daily, taken with or without food.

You may need a lower dose of ONGLYZA if your kidneys are not working well.

ONGLYZA tablets must not be split or cut.

OVERDOSE:

If you think you have taken too much ONGLYZA, call your doctor or pharmacist right away, or contact your local poison control centre immediately.

MISSED DOSE:

If you miss a dose of ONGLYZA, take it 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

The common side effects of ONGLYZA include: upper respiratory tract infection, urinary tract infection and headache. Hypoglycemia may occur more frequently in people who already take a sulfonyleurea 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. Tell your physician or pharmacist if you develop any unusual side effects, or if any of the above side effects do not go away or get worse.

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	
Uncommon			
Pancreatitis (inflammation of the pancreas): prolonged severe abdominal pain which may be accompanied by vomiting		X	X
Severe disabling joint pain		X	
Very rare			
Allergic (hypersensitivity) reactions: rash, hives, swelling of the face, lips, and throat that may cause difficulty in breathing or swallowing		X	X
Bullous pemphigoid (serious skin reaction): blistering of the skin, redness, peeling skin		X	
Unknown			
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 ONGLYZA, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15-30°C).

Keep ONGLYZA well out of reach of children and pets.

Medicines should not be disposed of down the drain or in household garbage. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.canada.ca/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. 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 or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries 1-800-668-6000, Renseignements 1-800-461-3787.

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