For the use of a registered medical practitioner or a hospital or laboratory only

Saxagliptin film-coated tablets
ONGLYZA® 2.5 mg & 5 mg
Abbreviated Prescribing Information

INDICATIONS AND USAGE:
Monotherapy and Combination Therapy
ONGLYZA® is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes.
Important Limitations of Use
ONGLYZA® should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
ONGLYZA® has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using ONGLYZA®.
DOSAGE AND ADMINISTRATION:
Recommended Dosing
The recommended dose of ONGLYZA® is 2.5 mg or 5 mg once daily taken regardless of meals.
Patients with Renal Impairment
No dosage adjustment for ONGLYZA® is recommended for patients with mild renal impairment (creatinine clearance [CrCl] >50 mL/min.
The dose of ONGLYZA® is 2.5 mg once daily for patients with moderate or severe renal impairment, or with end-stage renal disease (ESRD) requiring haemodialysis (CrCl≤50
mL/min, approximately corresponding to serum creatinine levels of ≥1.7 mg/dl in men and ≥1.5 mg/dl in women).
Strong CYP3A4/5 Inhibitors
The dose of ONGLYZA® is 2.5 mg once daily when coadministered with strong cytochrome P450 3A4/5 (CYP3A4/5) inhibitors.
Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin
When ONGLYZA® is used in combination with an insulin secretagogue (e.g., sulfonylurea) or with insulin, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycaemia. [See *Warnings and Precautions*]
CONTRAINDICATIONS:
History of a serious hypersensitivity reaction to ONGLYZA®, such as anaphylaxis, angioedema, or exfoliative skin conditions.
WARNINGS & PRECAUTION:
Pancreatitis
There have been post marketing reports of acute pancreatitis in patients taking ONGLYZA®. After initiation of ONGLYZA, observe patients for signs and symptoms of pancreatitis. If pancreatitis is suspected, ONGLYZA® should promptly be discontinued and appropriate management should be initiated. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using ONGLYZA
Heart Failure
Consider the risks and benefits of ONGLYZA prior to initiating treatment in patients at a higher risk for heart failure. Observe patients for signs and symptoms of heart failure during therapy. Advise patients of the characteristic symptoms of heart failure and to immediately report such symptoms. If

heart failure develops, evaluate and manage according to current standards of care and consider discontinuation of ONGLYZA.

Hypersensitivity Reactions

There have been post marketing reports of serious hypersensitivity reactions (including anaphylaxis, angioedema, and exfoliative skin conditions) in patients treated with ONGLYZA®. If a serious hypersensitivity reaction is suspected, discontinue ONGLYZA®, assess for other potential causes for the event, and institute alternative treatment for diabetes.

Use with Medications Known to Cause Hypoglycemia

Insulin or Insulin secretagogues, such as sulfonylureas, cause hypoglycemia. Therefore, a lower dose of the insulin or insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with ONGLYZA®.

Macrovascular Outcomes

The cardiovascular risk of ONGLYZA was evaluated in SAVOR, a multicenter, multinational, randomized, double-blind study comparing ONGLYZA (N=8280) to placebo (N=8212), both administered in combination with standard of care, in adult patients with type 2 diabetes at high risk for atherosclerotic cardiovascular disease. The incidence rate of MACE was similar in both treatment arms: 3.8 MACE per 100 patient-years on placebo vs. 3.8 MACE per 100 patient-years on ONGLYZA. The estimated hazard ratio of MACE associated with ONGLYZA relative to placebo was 1.00 with a 95.1% confidence interval of (0.89, 1.12)

USE IN SPECIAL POPULATION

Pregnancy (Category B):

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, ONGLYZA® should be used during pregnancy only if clearly needed.

Nursing mothers

Saxagliptin is secreted in the milk of lactating rats. It is not known whether saxagliptin is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when ONGLYZA® is administered to a nursing woman.

Paediatric Use

Safety and effectiveness of ONGLYZA® in paediatric patients have not been established.

Geriatric Use

Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in the elderly based on renal function.

ADVERSE REACTIONS:

The more common adverse reactions reported in patients treated with ONGLYZA® 5 mg were upper respiratory tract infection, urinary tract infection, nasopharyngitis & headache. The less common adverse reactions that were reported in patients treated with ONGLYZA® 2.5 mg or 5 mg included the following: sinusitis, abdominal pain, gastroenteritis, vomiting, hypersensitivity reactions, and dose related mean decrease in absolute lymphocyte count, which was clinically irrelevant. Hypoglycemia was seen in patients on insulin, insulin secretagogues such as sulphonylureas, and in renally impaired patients. Vital signs- No clinically meaningful changes in vital signs have been observed in patients treated with ONGLYZA®.

OVERDOSE:

In a controlled clinical trial, once-daily, orally-administered ONGLYZA® in healthy subjects at doses up to 400 mg daily for 2 weeks (80 times the MRHD) had no dose-related clinical adverse reactions and no clinically meaningful effect on QTc interval or heart rate. In the event of an overdose, appropriate supportive treatment should be initiated as dictated by the patient's clinical status. Saxagliptin and its active metabolite are removed by haemodialysis (23% of dose over 4 hours).

PATIENT COUNSELING INFORMATION

Heart Failure

Patients should be informed of the signs and symptoms of heart failure. Before initiating ONGLYZA, patients should be asked about a history of heart failure or other risk factors for heart failure including moderate to severe renal impairment. Patients should be instructed to contact their healthcare provider as soon Heart Failure Patients should be informed of the signs and symptoms of heart failure. Before initiating ONGLYZA, patients should be asked about a history of heart failure or other risk factors for heart failure including moderate to severe renal impairment. Patients should be instructed to contact their healthcare provider as soon as possible if they experience symptoms of heart failure, including increasing shortness of breath, rapid increase in weight or swelling of the feet's possible if they experience symptoms of heart failure, including increasing shortness of breath, rapid increase in weight or swelling of the feet.

STORAGE: Store below 30°C.

ONGLYZA® is an applied trademark of AstraZeneca group of companies.

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For more information, refer full prescribing information Version 10, dated 1st June 2016.