

DPP-4 Inhibitors: **ONGLYZA® (saxagliptin)** **KOMBIGLYZE® XR**
 (saxagliptin and metformin HCl extended-release) tablets

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Important Safety Information for ONGLYZA® (saxagliptin)

Contraindications

- History of a serious hypersensitivity reaction to ONGLYZA ...[Read More](#)(eg, anaphylaxis, angioedema, or exfoliative skin conditions)...[Read More](#)...[Read More](#)

ONGLYZA IS A DIPEPTIDYL PEPTIDASE-4 (DPP4) INHIBITOR INDICATED AS AN ADJUNCT TREATMENT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS. ONGLYZA IS NOT INDICATED FOR THE TREATMENT OF TYPE 1 DIABETES MELLITUS OR DIABETIC KETOACIDOSIS.

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MECHANISM OF ACTION

Learn how ONGLYZA prolongs the activity of incretin gut hormones¹

FORMULARY COVERAGE »

Important Safety Information for ONGLYZA® (saxagliptin)

Contraindications

- History of a serious hypersensitivity reaction to ONGLYZA (eg, anaphylaxis, angioedema, or exfoliative skin conditions)

Warnings and Precautions

- **Pancreatitis:** There have been postmarketing reports of acute pancreatitis in patients taking ONGLYZA, and in the SAVOR cardiovascular outcomes trial after initiating ONGLYZA. After initiating ONGLYZA, observe patients carefully for signs and symptoms of pancreatitis. If pancreatitis is

using ONGLYZA

- **Heart Failure:** In SAVOR, a cardiovascular outcomes trial enrolling participants with established or multiple risk factors for atherosclerotic cardiovascular disease (ASCVD), more patients treated with ONGLYZA were hospitalized for heart failure compared to placebo. Patients with a prior history of heart failure or renal impairment had a higher risk for hospitalization for heart failure. Consider the risks and benefits of ONGLYZA in patients who have known risk factors for heart failure. Monitor for signs and symptoms. If heart failure develops, initiate appropriate management and consider discontinuation of ONGLYZA
- **Hypoglycemia with Concomitant Use of Sulfonylurea or Insulin:** When ONGLYZA was used in combination with a sulfonylurea or with insulin, medications known to cause hypoglycemia, the incidence of confirmed hypoglycemia was increased over that of placebo used in combination with a sulfonylurea or with insulin. Therefore, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycemia when used in combination with ONGLYZA
- **Hypersensitivity Reactions:** There have been postmarketing reports of serious hypersensitivity reactions in patients treated with ONGLYZA, including anaphylaxis, angioedema, and exfoliative skin conditions. Onset of these reactions occurred within the first 3 months after initiation of treatment with ONGLYZA, with some reports occurring after the first dose. If a serious hypersensitivity reaction is suspected, discontinue ONGLYZA, assess for other potential causes for the event, and institute alternative treatment for diabetes. Use caution in patients with a history of angioedema to another DPP-4 inhibitor as it is unknown whether they will be predisposed to angioedema with ONGLYZA
- **Severe and Disabling Arthralgia:** There have been postmarketing reports of severe and disabling arthralgia in patients taking DPP-4 inhibitors. The time to onset of symptoms following initiation of drug therapy varied from one day to years. Patients experienced relief of symptoms upon discontinuation of the medication. A subset of patients experienced a recurrence of symptoms when restarting the same drug or a different DPP-4 inhibitor. Consider DPP-4 inhibitors as a possible cause for severe joint pain and discontinue drug if appropriate
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with ONGLYZA or any other antidiabetic drug

Most Common Adverse Reactions

- Most common adverse reactions reported in $\geq 5\%$ of patients treated with ONGLYZA and more commonly than in patients treated with control were upper respiratory tract infection (7.7%, 7.6%), urinary tract infection (6.8%, 6.1%), and headache (6.5%, 5.9%)
- When used as add-on combination therapy with a thiazolidinedione, the incidence of peripheral edema for ONGLYZA 2.5 mg, 5 mg, and placebo was 3.1%, 8.1% and 4.3%, respectively
- Confirmed hypoglycemia was reported more commonly in patients treated with ONGLYZA 2.5 mg and ONGLYZA 5 mg compared to placebo in the add-on to glyburide trial (2.4%, 0.8% and 0.7%, respectively), with ONGLYZA 5 mg compared to placebo in the add-on to insulin (with or without metformin) trial (5.3% and 3.3%, respectively), with ONGLYZA 2.5 mg compared to placebo in the renal impairment trial (4.7% and 3.5%, respectively), and with ONGLYZA 5 mg compared to placebo in the add-on to metformin plus sulfonylurea trial (1.6% and 0.0%, respectively)

Drug Interactions

atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, and telithromycin)

Use in Specific Populations

- **Patients with Renal Impairment:** The dose of ONGLYZA is 2.5 mg once daily for patients with moderate or severe renal impairment, or with end-stage renal disease requiring hemodialysis (creatinine clearance [CrCl] ≤50 mL/min). ONGLYZA should be administered following hemodialysis. ONGLYZA has not been studied in patients undergoing peritoneal dialysis. Assessment of renal function is recommended prior to initiation of ONGLYZA and periodically thereafter
- **Pregnant and Nursing Women:** There are no adequate and well-controlled studies in pregnant women. ONGLYZA, like other antidiabetic medications, should be used during pregnancy only if clearly needed. 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
- **Pediatric Patients:** Safety and effectiveness of ONGLYZA in pediatric patients have not been established

Indication and Limitations of Use for ONGLYZA® (saxagliptin)

ONGLYZA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

ONGLYZA is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

Please see accompanying US Full [Prescribing Information](#) and [Medication Guide](#) for ONGLYZA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-10881-800-FDA-1088.

Reference:

1. ONGLYZA [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2016.

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