Christine S. Meyer, Ph.D.

AstraZeneca

MYLAN - EXHIBIT 1034
Mylan et al. v. AstraZeneca
IPR2015-01340
PDX-400

ommercial Success Expert Witness Experience

For the Brand

rexo AB and Orexo US, Inc., Actavis Elizabeth LLC.

- United States District Court for the District of Delaware

orizon Pharma AG and agotec AG v. Watson aboratories, Inc., - Florida, ctavis Pharma, Inc., Andrx orporation and Actavis, Inc.

- United States District Court for the District of New Jersey

Against the Brand

Coalition for Affordable Drugs II, LLC v. Cosmo Technologies, Ltd.

- United States Patent and Trademark Office Before the Patent Trial and Appeal Board

Amneal Pharmaceuticals, LLC v. Endo Pharmaceuticals, Inc.

- United States Patent and Trademark Office Before the Patent Trial and Appeal Board

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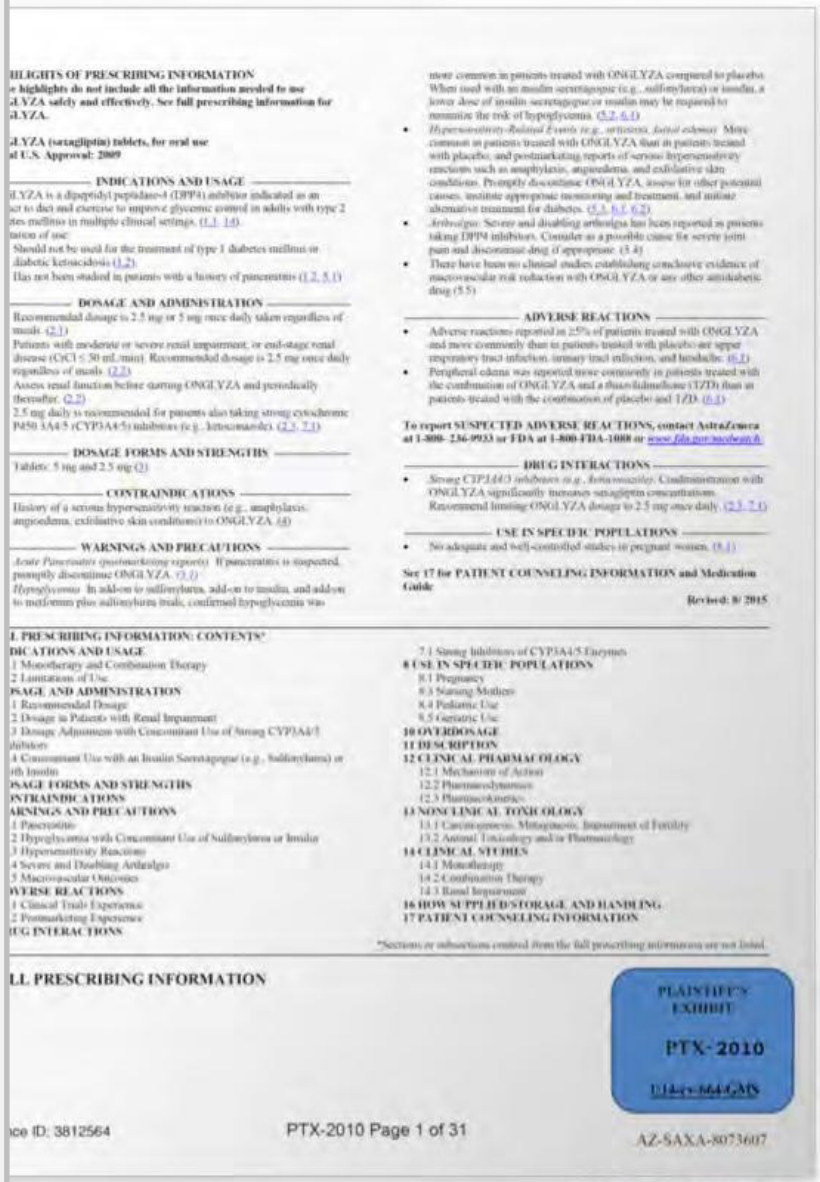
escribing Information



HLIGHTS OF PRESCRIBING INFORMATION
e highlights do not include all the information needed to use
LYZA safely and effectively. See full prescribing information for
LYZA.

LYZA (saxagliptin) tablets, for oral use
al U.S. Approval: 2009

INDICATIONS AND USAGE

LYZA is a dipeptidyl peptidase-4 (DPP4) inhibitor indicated as an
ct to diet and exercise to improve glycemic control in adults with type 2
tes mellitus in multiple clinical settings. (1.1, 14)
ation of use:
Should not be used for the treatment of type 1 diabetes mellitus or
diabetic ketoacidosis (1.2)
Has not been studied in patients with a history of pancreatitis (1.2, 5.1)

DOSAGE AND ADMINISTRATION

Recommended dosage is 2.5 mg or 5 mg once daily taken regardless of
meals. (2.1)
Patients with moderate or severe renal impairment, or end-stage renal
disease (CrCl ≤ 50 mL/min): Recommended dosage is 2.5 mg once daily
regardless of meals. (2.2)
Assess renal function before starting ONGLYZA and periodically
thereafter. (2.2)
2.5 mg daily is recommended for patients also taking strong cytochrome
P450 3A4/5 (CYP3A4/5) inhibitors (e.g., ketoconazole). (2.3, 7.1)

DOSAGE FORMS AND STRENGTHS

Tablets: 5 mg and 2.5 mg (3)

CONTRAINDICATIONS

History of a serious hypersensitivity reaction (e.g., anaphylaxis,
angioedema, exfoliative skin conditions) to ONGLYZA. (4)

WARNINGS AND PRECAUTIONS

Acute Pancreatitis (postmarketing reports): If pancreatitis is suspected,
promptly discontinue ONGLYZA. (5.1)
Hypoglycemia: In add-on to sulfonylurea, add-on to insulin, and add-on
to metformin plus sulfonylurea trials, confirmed hypoglycemia was
more common in patients treated with ONGLYZA compared to placebo.
When used with an insulin secretagogue (e.g., sulfonylurea) or insulin, a
lower dose of insulin secretagogue or insulin may be required to
minimize the risk of hypoglycemia. (5.2, 6.1)
- *Hypersensitivity-Related Events (e.g., urticaria, facial edema):* More common in patients treated with ONGLYZA than in patients treated with placebo, and postmarketing reports of serious hypersensitivity reactions such as anaphylaxis, angioedema, and exfoliative skin conditions. Promptly discontinue ONGLYZA, assess for other potential causes, institute appropriate monitoring and treatment, and initiate alternative treatment for diabetes. (5.3, 6.1, 6.2)
- *Arthralgia:* Severe and disabling arthralgia has been reported in patients taking DPP4 inhibitors. Consider as a possible cause for severe joint pain and discontinue drug if appropriate. (5.4)
- There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with ONGLYZA or any other antidiabetic drug (5.5)

ADVERSE REACTIONS

- Adverse reactions reported in ≥5% of patients treated with ONGLYZA and more commonly than in patients treated with placebo are upper respiratory tract infection, urinary tract infection, and headache. (6.1)
- Peripheral edema was reported more commonly in patients treated with the combination of ONGLYZA and a thiazolidinedione (TZD) than in patients treated with the combination of placebo and TZD. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact AstraZeneca at 1-800- 236-9933 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- *Strong CYP3A4/5 inhibitors (e.g., ketoconazole):* Coadministration with ONGLYZA significantly increases saxagliptin concentrations. Recommend limiting ONGLYZA dosage to 2.5 mg once daily. (2.3, 7.1)

USE IN SPECIFIC POPULATIONS

- No adequate and well-controlled studies in pregnant women. (8.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

Revised: 8/ 2015

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LL PRESCRIBING INFORMATION

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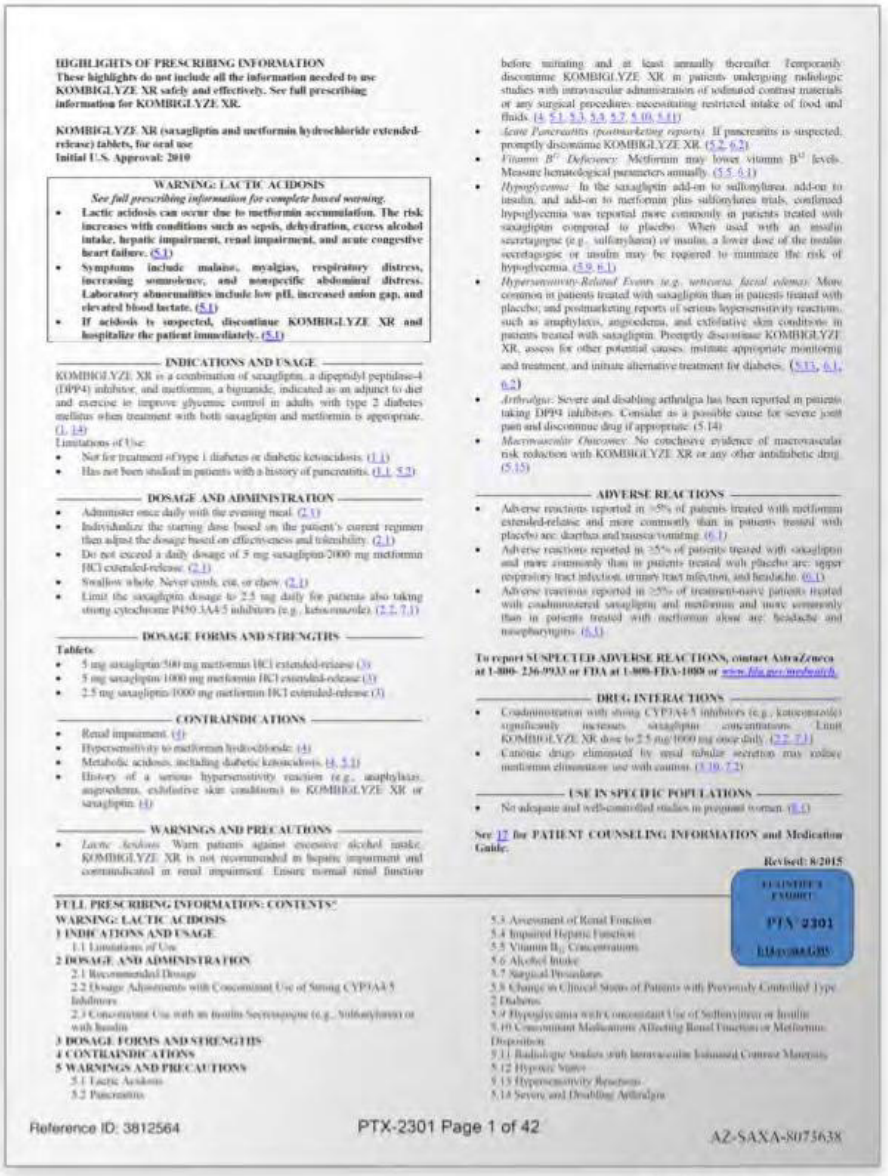

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use KOMBIGLYZE XR safely and effectively. See full prescribing information for KOMBIGLYZE XR.

KOMBIGLYZE XR (saxagliptin and metformin hydrochloride extended-release) tablets, for oral use
Initial U.S. Approval: 2010

WARNING: LACTIC ACIDOSIS
See full prescribing information for complete boxed warning.
- **Lactic acidosis can occur due to metformin accumulation. The risk increases with conditions such as sepsis, dehydration, excess alcohol intake, hepatic impairment, renal impairment, and acute congestive heart failure. (5.1)**
- **Symptoms include malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate. (5.1)**
- **If acidosis is suspected, discontinue KOMBIGLYZE XR and hospitalize the patient immediately. (5.1)**

INDICATIONS AND USAGE

KOMBIGLYZE XR is a combination of saxagliptin, a dipeptidyl peptidase-4 (DPP4) inhibitor, and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate. (1, 14)
Limitations of Use:
- Not for treatment of type 1 diabetes or diabetic ketoacidosis. (1.1)
- Has not been studied in patients with a history of pancreatitis. (1.1, 5.2)

DOSAGE AND ADMINISTRATION

- Administer once daily with the evening meal. (2.1)
- Individualize the starting dose based on the patient's current regimen then adjust the dosage based on effectiveness and tolerability. (2.1)
- Do not exceed a daily dosage of 5 mg saxagliptin/2000 mg metformin HCl extended-release. (2.1)
- Swallow whole. Never crush, cut, or chew. (2.1)
- Limit the saxagliptin dosage to 2.5 mg daily for patients also taking strong cytochrome P450 3A4/5 inhibitors (e.g., ketoconazole). (2.2, 7.1)

DOSAGE FORMS AND STRENGTHS

Tablets:
- 5 mg saxagliptin/500 mg metformin HCl extended-release (3)
- 5 mg saxagliptin/1000 mg metformin HCl extended-release (3)
- 2.5 mg saxagliptin/1000 mg metformin HCl extended-release (3)

CONTRAINDICATIONS

- Renal impairment. (4)
- Hypersensitivity to metformin hydrochloride. (4)
- Metabolic acidosis, including diabetic ketoacidosis. (4, 5.1)
- History of a serious hypersensitivity reaction (e.g., anaphylaxis, angioedema, exfoliative skin conditions) to KOMBIGLYZE XR or saxagliptin. (4)

WARNINGS AND PRECAUTIONS

- *Lactic Acidosis:* Warn patients against excessive alcohol intake. KOMBIGLYZE XR is not recommended in hepatic impairment and contraindicated in renal impairment. Ensure normal renal function before initiating and at least annually thereafter. Temporarily discontinue KOMBIGLYZE XR in patients undergoing radiologic studies with intravascular administration of iodinated contrast materials or any surgical procedures necessitating restricted intake of food and fluids. (4, 5.1, 5.3, 5.4, 5.7, 5.10, 5.11)
- *Acute Pancreatitis (postmarketing reports):* If pancreatitis is suspected, promptly discontinue KOMBIGLYZE XR. (5.2, 6.2)
- *Vitamin B^{12} Deficiency:* Metformin may lower vitamin B^{12} levels. Measure hematological parameters annually. (5.5, 6.1)
- *Hypoglycemia:* In the saxagliptin add-on to sulfonylurea, add-on to insulin, and add-on to metformin plus sulfonylurea trials, confirmed hypoglycemia was reported more commonly in patients treated with saxagliptin compared to placebo. When used with an insulin secretagogue (e.g., sulfonylurea) or insulin, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycemia. (5.9, 6.1)
- *Hypersensitivity-Related Events (e.g., urticaria, facial edema):* More common in patients treated with saxagliptin than in patients treated with placebo, and postmarketing reports of serious hypersensitivity reactions, such as anaphylaxis, angioedema, and exfoliative skin conditions in patients treated with saxagliptin. Promptly discontinue KOMBIGLYZE XR, assess for other potential causes, institute appropriate monitoring and treatment, and initiate alternative treatment for diabetes. (5.13, 6.1, 6.2)
- *Arthralgia:* Severe and disabling arthralgia has been reported in patients taking DPP4 inhibitors. Consider as a possible cause for severe joint pain and discontinue drug if appropriate. (5.14)
- *Macrovascular Outcomes:* No conclusive evidence of macrovascular risk reduction with KOMBIGLYZE XR or any other antidiabetic drug. (5.15)

ADVERSE REACTIONS

- Adverse reactions reported in ≥5% of patients treated with metformin extended-release and more commonly than in patients treated with placebo are: diarrhea and nausea/vomiting. (6.1)
- Adverse reactions reported in ≥5% of patients treated with saxagliptin and more commonly than in patients treated with placebo are: upper respiratory tract infection, urinary tract infection, and headache. (6.1)
- Adverse reactions reported in ≥5% of treatment-naive patients treated with coadministered saxagliptin and metformin and more commonly than in patients treated with metformin alone are: headache and nasopharyngitis. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact AstraZeneca at 1-800- 236-9933 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Coadministration with strong CYP3A4/5 inhibitors (e.g., ketoconazole) significantly increases saxagliptin concentrations. Limit KOMBIGLYZE XR dose to 2.5 mg/1000 mg once daily. (2.2, 7.1)
- Cationic drugs eliminated by renal tubular secretion may reduce metformin elimination via renal tubular transporters. (5.10, 7.2)

USE IN SPECIFIC POPULATIONS

- No adequate and well-controlled studies in pregnant women. (8.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

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PLAINTIFF'S EXHIBIT
PTX-2301
1:14-cv-844-GMS

Reference ID: 3812564

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AZ-SAXA-8073638

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octor Discussion Guide

This information is intended for US consumers only.

onglyza (saxagliptin) 5 mg tablets

Participating in the Fit2Me™ Diet and Lifestyle Support Program

Get ready for your doctor appointment—your input is important.

Voicing your opinions is an important part of having a discussion with your doctor. Together you can decide on a treatment that's best for you. Ask your doctor if ONGLYZA may be the right option for you.

How ONGLYZA has been shown to help

Talk to your doctor about
Read this guide, print it ou
next doctor visit.

What is ONGLYZA?

ONGLYZA is a prescription medicine used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.
ONGLYZA should not be used to treat people with type 1 diabetes or diabetic ketoacidosis (increased ketones in the blood or urine).
you have had inflammation of the pancreas (pancreatitis), it is not known if you have a higher chance of getting pancreatitis while taking ONGLYZA.

PLAINTIFF'S EXHIBIT
PTX-2272
1:14-cv-664-GMS

Who should not take ONGLYZA?

o not take ONGLYZA if you are allergic to any of its ingredients. Serious allergic reactions can occur with ONGLYZA and may include swelling of the face, lips or throat, difficulty swallowing or breathing, swelling of the skin, hives, rash, itching, flaking, or peeling. If you have these symptoms, stop taking ONGLYZA and contact your doctor right away.

Please see Important Safety Information on page 4.
Click here for Medication Guide and click here for full Prescribing Information.

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ONGLYZA has been tested in multiple clinical studies including thousands of adult patients with type 2 diabetes. In all of these studies, ONGLYZA in addition to diet and exercise has been shown to lower A1C. Your results may vary.

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