

Diabetes Update: Important News For Adults With Type 2 Diabetes

(NAPSA)—The Centers for Disease Control and Prevention (CDC) estimate that about one in every 11 adults in the United States has diagnosed diabetes.¹ Type 2 diabetes accounts for approximately 90 to 95% of all cases of diagnosed diabetes in adults.² Despite trying to maintain a healthy lifestyle through diet and exercise, nearly half of adult patients with type 2 diabetes remain uncontrolled on their current treatment regimen and thus may require additional medicines.³

Now there's good news for these patients—the U.S. Food and Drug Administration has recently approved KOMBIGLYZE™ XR (saxagliptin and metformin HCl extended-release) tablets, the first and only once-a-day combination tablet of extended-release (XR) metformin (a long-acting form of metformin) plus saxagliptin. KOMBIGLYZE XR is now available by prescription. KOMBIGLYZE XR is used with diet and exercise to help control high blood sugar (hyperglycemia) in adults with type 2 diabetes. Your doctor will decide if treatment with both saxagliptin and metformin is right for you. KOMBIGLYZE XR should generally be taken once a day with the evening meal to help lessen an upset stomach side effect.

Important Safety Information about KOMBIGLYZE™ XR (saxagliptin and metformin HCl extended-release) tablets

Lactic Acidosis: Metformin hydrochloride, one of the medicines in KOMBIGLYZE XR, can cause a rare, but serious, side effect called lactic acidosis (a build-up of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in a hospital. Stop taking KOMBIGLYZE XR and call your healthcare provider right away if you get any of the following symptoms of lactic acidosis: feel very weak and tired, unusual (not normal) muscle pain, trouble breathing, unusual sleepiness or sleep longer than usual, unexplained stomach or intestinal problems with nausea and vomiting or diarrhea, feel cold (especially in your arms and legs), dizzy or lightheaded, or have a slow or irregular heartbeat.

You have a higher chance of getting lactic acidosis if you have kidney or liver problems, have congestive heart failure that requires treatment with medicines, drink a lot of alcohol (very often or short-term “binge” drinking), get dehydrated (lose a large amount of body fluids), have certain x-ray tests with injectable dyes or contrast agents, have surgery, have a heart attack, severe infection, or stroke, or are 80 years of age or older and have not had your kidney function tested.

Do not take KOMBIGLYZE XR if you have kidney problems, are allergic to metformin hydrochloride or any of the ingredients in KOMBIGLYZE XR, or have a condition called metabolic acidosis or diabetic ketoacidosis (increased ketones in your blood or urine). Do not take KOMBIGLYZE XR if you are going to get an injection of dye or contrast agents for an x-ray procedure or will have surgery and not be able to eat or drink much. In these situations, KOMBIGLYZE XR will need to be stopped for a short time. Talk to your healthcare provider about when you should stop and restart KOMBIGLYZE XR.

Your healthcare provider should do blood tests to check how well your kidneys are working before and during your treatment with KOMBIGLYZE XR.

If you take KOMBIGLYZE XR with another medicine that can cause low blood sugar (hypoglycemia), such as sulfonylureas or insulin, you have a higher risk of having low blood sugar. Symptoms of low blood sugar include, shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood. Follow your healthcare provider's instructions for treating low blood sugar.

The most common side effects of KOMBIGLYZE XR include upper respiratory tract infection, stuffy or runny nose and sore throat, urinary tract infection, headache, diarrhea, and nausea and vomiting.

If you have allergic (hypersensitivity) reactions, such as rash, hives, and swelling of the face, lips, and throat, stop taking KOMBIGLYZE XR and call your healthcare provider right away.

Tell your healthcare provider if you will be starting or stopping certain other types of medicines, such as antibiotics, or medicines that treat fungus or HIV/AIDS, as your healthcare provider may need to change your dose of KOMBIGLYZE XR.

Tell your healthcare provider if you are pregnant or breast-feeding, or plan to become pregnant or breast-feed.

Swallow KOMBIGLYZE XR whole; do not crush, cut, or chew.

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

For more information about KOMBIGLYZE XR, or type 2 diabetes, talk to your doctor. Please see the US Full Prescribing Information including **Boxed WARNING** about lactic acidosis, and Patient Information at www.kombiglyzextr.com or call 1-800-664-5992.

KOMBIGLYZE XR is a trademark of Bristol-Myers Squibb.

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Dr. Matthew Mintz, The George Washington University School of Medicine



KOMBIGLYZE XR should not be used to treat people with type 1 diabetes or to treat diabetic ketoacidosis (increased ketones in your blood or urine). KOMBIGLYZE XR has not been studied with insulin. Metformin hydrochloride, one of the medicines in KOMBIGLYZE XR, can cause a rare, but serious, side effect called lactic acidosis (a build up of lactic acid in the blood) that can cause death.

“Patients with type 2 diabetes in the United States can be taking four or five medications for various diseases and conditions, which can lead to complicated medication schedules,”⁴ said Dr. Matthew Mintz, from The George Washington University School of Medicine, and a consultant for Bristol-Myers Squibb and AstraZeneca, the makers of KOMBIGLYZE XR. “KOMBIGLYZE XR combines two effective diabetes medications in a simple once-a-day dose for adult patients to help control their high blood sugar levels.”

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By combining complementary therapies of saxagliptin with metformin, the most widely prescribed oral antidiabetic treatment, KOMBIGLYZE XR offers strong blood sugar control across three key measures used by physicians to monitor type 2 diabetes. These key measures are fasting plasma glucose or FPG (morning blood sugar), postprandial glucose or PPG (after-meal blood sugar) and glycosylated hemoglobin levels or A1C (the test your doctor does every 3 months).

KOMBIGLYZE XR was developed through an ongoing collaboration between Bristol-Myers Squibb and AstraZeneca.

¹Centers for Disease Control and Prevention, National Health Interview Survey, 1997-March 2010. Available at: http://www.cdc.gov/nchs/data/nhis/earlyrelease/201009_14.pdf. Accessed November 10, 2010.

²National Diabetes Statistics, 2007. National Diabetes Information Clearinghouse. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/statistics/>. Accessed October 21, 2010.

³Ong, et al. Prevalence, Treatment, and Control of Diagnosed Diabetes in the U.S. National Health and Nutrition Examination Survey 1999-2004. *Ann Epidemiol.* 2008; 18:222-229.

⁴Leichter SB, Faulkner S, Camp J: On the cost of being a diabetic patient: variables for physician prescribing behavior. *Clin Diabetes.* 18:42-44, 2000.

Editor's Note:

Please [click here](#) for the KOMBIGLYZE XR US Full Prescribing Information, including **Boxed WARNING** about lactic acidosis, and [click here](#) for Patient Information

or

Please visit http://packageinserts.bms.com/pi/pi_kombiglyze_xr.pdf for the KOMBIGLYZE XR US Full Prescribing Information, including **Boxed WARNING** about lactic acidosis, and Patient Information