



May 31, 2016

U.S. FDA Approves Once-daily Jentadueto® XR (linagliptin and metformin hydrochloride extended-release) Tablets for Adults with Type 2 Diabetes

New formulation of medicines that helps lower blood sugar in type 2 diabetes can be taken once a day

RIDGEFIELD, Conn. and INDIANAPOLIS, May 31, 2016 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) has approved Jentadueto® XR (linagliptin and metformin hydrochloride extended-release) tablets for the treatment of type 2 diabetes (T2D) in adults. JENTADUETO XR, which is marketed by Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY), is the seventh new treatment from the Boehringer Ingelheim-Lilly Diabetes alliance to be approved by the FDA in the last five years.

JENTADUETO XR combines 2.5 mg or 5 mg of linagliptin with 1000 mg of metformin. Linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, works by increasing hormones that stimulate the pancreas to produce more insulin and the liver to produce less glucose. Metformin, a commonly prescribed initial treatment for T2D, lowers glucose production by the liver and its absorption in the intestine.

"Adults with type 2 diabetes are often required to take more than one medication to manage their condition, including some that have to be taken multiple times a day," said Paul Fonteyne, president and CEO, Boehringer Ingelheim Pharmaceuticals, Inc. "JENTADUETO XR, the first extended-release therapy to emerge from our alliance with Lilly, offers adults with type 2 diabetes the convenience of a combination pill taken once a day to help lower blood sugar levels."

JENTADUETO XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2D when treatment with both linagliptin and metformin is appropriate. JENTADUETO XR should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, and has not been studied in people with a history of pancreatitis.

The JENTADUETO XR label contains a boxed warning for the risk of lactic acidosis, a serious metabolic complication that can occur due to metformin accumulation during treatment with JENTADUETO XR.

The safety and efficacy of JENTADUETO XR have been established based on adequate and well-controlled studies of linagliptin and metformin co-administered in patients with T2D inadequately controlled on diet and exercise and in combination with sulfonylurea.

About Diabetes

Approximately 29 million Americans and an estimated 415 million people worldwide have diabetes, and nearly 28 percent of Americans with diabetes—totaling 8 million people—are undiagnosed. In the U.S., approximately 12 percent of those aged 20 and older have diabetes. Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diagnosed adult diabetes cases in the U.S. Diabetes is a chronic condition that occurs when the body either does not properly produce, or use, the hormone insulin.

What is JENTADUETO XR?

JENTADUETO XR is a prescription medicine that contains 2 diabetes medicines, linagliptin and metformin. JENTADUETO XR can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes when treatment with both linagliptin and metformin is appropriate.

JENTADUETO XR is not for people with type 1 diabetes or for people with diabetic ketoacidosis (increased ketones in the blood or urine).

If you have had inflammation of the pancreas (pancreatitis) in the past, it is not known if you have a higher chance of getting pancreatitis while you take JENTADUETO XR.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about JENTADUETO XR?

Serious side effects can happen in people taking JENTADUETO XR, including lactic acidosis. Metformin, one of the medicines in JENTADUETO XR, can cause a rare but serious condition 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.

Call your doctor right away if you have any of the following symptoms, which could be signs of lactic acidosis: feel cold in your hands or feet, feel dizzy or lightheaded, have a slow or irregular heart beat, feel very weak or tired, have unusual muscle pain, have trouble breathing, feel sleepy or drowsy, have stomach pains, nausea or vomiting.

You have a higher chance of getting lactic acidosis with JENTADUETO XR if you have severe kidney problems or your kidneys are affected by certain x-ray tests that use injectable dye, liver problems, drink alcohol very often, or drink a lot of alcohol in short term ("binge" drinking), get dehydrated (lose a large amount of body fluids), have surgery, have a heart attack, severe infection, or stroke.

Inflammation of the pancreas (pancreatitis) is another serious side effect that can happen to people taking JENTADUETO XR. Pancreatitis may be severe and lead to death. Before you start taking JENTADUETO XR tell your doctor if you have ever had pancreatitis, gallstones, a history of alcoholism, or high triglyceride levels. Stop taking JENTADUETO XR and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

Who should not take JENTADUETO XR?

Do not take JENTADUETO XR if you:

- | have kidney problems.
- | have a condition called metabolic acidosis or diabetic ketoacidosis (increased ketones in the blood or urine).
- | are allergic to linagliptin, metformin or any of the ingredients in JENTADUETO XR. Symptoms of an allergic reaction may include rash, itching, flaking or peeling; raised red patches on your skin (hives); and swelling of your face, lips, tongue and throat that may cause difficulty breathing or swallowing. If you have any symptoms of a serious allergic reaction, stop taking JENTADUETO XR and call your doctor or go to the emergency room right away.

What should I tell my doctor before using JENTADUETO XR?

Before you take JENTADUETO XR, tell your doctor about all of your medical conditions, including if you:

- | have or have had inflammation of your pancreas (pancreatitis).
- | have severe kidney problems.
- | have liver problems.
- | have heart problems, including congestive heart failure.
- | drink alcohol very often, or drink a lot of alcohol in short term "binge" drinking.
- | are going to get an injection of dye or contrast agents for an x-ray procedure. JENTADUETO XR may need to be stopped for a short time. Talk to your doctor about when you should stop JENTADUETO XR and when you should start JENTADUETO XR again.
- | have type 1 diabetes.
- | have any other medical conditions.
- | are pregnant or planning to become pregnant. It is not known if JENTADUETO XR will harm your unborn baby.
- | **are a premenopausal woman (before the "change of life"), who does not have periods regularly or at all.** Talk to your doctor about birth control choices while taking JENTADUETO XR if you are not planning to become pregnant since JENTADUETO XR may increase your chance of becoming pregnant. Tell your doctor right away if you become pregnant while taking JENTADUETO XR.
- | are breast-feeding or plan to breast-feed. It is not known if JENTADUETO XR passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. JENTADUETO XR may affect the way other medicines work, and other medicines may affect how JENTADUETO XR works. Especially tell your doctor if you take:

- | other medicines that can lower your blood sugar. If you take JENTADUETO XR with another medicine that can cause low blood sugar, such as sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea or insulin may need to be lowered while you take JENTADUETO XR.
- | rifampin (Rifadin®, Rimactane®, Rifater®, Rifamate®), an antibiotic that is used to treat tuberculosis.

What are the possible side effects of JENTADUETO XR?

JENTADUETO XR may cause serious side effects, including:

- | Lactic acidosis (a build-up of lactic acid in the blood).
- | Inflammation of the pancreas (pancreatitis).
- | Low blood sugar (hypoglycemia), especially if you take JENTADUETO XR with another medicine that can cause low blood sugar. Signs and symptoms of low blood sugar may include headache, irritability, drowsiness, hunger, weakness, fast heart beat, dizziness, sweating, confusion, or feeling jittery.
- | Allergic (hypersensitivity) reactions can happen after your first dose or up to 3 months after starting JENTADUETO XR. Symptoms may include swelling of your face, lips, throat, and other areas on your skin; difficulty with swallowing or breathing; raised, red areas on your skin (hives); skin rash, itching, flaking, or peeling.
- | Joint pain. Some people who take medicines called DPP-4 inhibitors, one of the medicines in JENTADUETO XR, may develop joint pain that can be severe. Call your doctor if you have severe joint pain.

The most common side effects of JENTADUETO XR include stuffy or runny nose, sore throat, **and** diarrhea.

These are not all the possible side effects of JENTADUETO XR. For more information, ask your doctor or pharmacist. **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.**

JDXR CONS ISI 27MAY16

Please see [Prescribing Information](#), including Boxed Warning regarding lactic acidosis, and [Medication Guide](#).

Boehringer Ingelheim and Eli Lilly and Company

In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance in diabetes that centers on compounds representing several of the largest diabetes treatment classes. This alliance leverages the strengths of two of the world's leading pharmaceutical companies. By joining forces, the companies demonstrate commitment in the care of patients with diabetes and stand together to focus on patient needs. Find out more about the alliance at www.boehringer-ingelheim.com or www.lilly.com.

About Boehringer Ingelheim

Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT, is the largest U.S. subsidiary of Boehringer Ingelheim Corporation.

Boehringer Ingelheim is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, the company operates globally with 145 affiliates and more than 47,000 employees. Since its founding in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel treatments for human and veterinary medicine.

Boehringer Ingelheim is committed to improving lives and providing valuable services and support to patients and families. Our employees create and engage in programs that strengthen our communities. To learn more about how we make more health for more people, visit our [Corporate Social Responsibility Report](#).

In 2015, Boehringer Ingelheim achieved net sales of about \$15.8 billion dollars (14.8 billion euros). R&D expenditure corresponds to 20.3 percent of its net sales.

For more information please visit www.us.boehringer-ingelheim.com, or follow us on Twitter @BoehringerUS.

About Lilly Diabetes

Lilly has been a global leader in diabetes care since 1923, when we introduced the world's first commercial insulin. Today we are building upon this heritage by working to meet the diverse needs of people with diabetes and those who care for them. Through research and collaboration, a broad and growing product portfolio and a continued determination to provide real solutions—from medicines to support programs and more—we strive to make life better for all those affected by diabetes around the world. For more information, visit www.lillydiabetes.com.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and

newsroom.lilly.com/social-channels.

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about JENTADUETO XR as a treatment for patients with type 2 diabetes along with diet and exercise and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with the results to date or that JENTADUETO XR will receive additional regulatory approvals. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

Jentaduetto® XR is a registered trademark of Boehringer Ingelheim

P-LLY
PR-JD-0001

CONTACT:

Jennifer Forsyth

Director, Public Relations

Boehringer Ingelheim Pharmaceuticals, Inc.

Email: jennifer.forsyth@boehringer-ingelheim.com

Phone: (203) 791-5889

Gregory Kueterman

Director of Communications

Lilly Diabetes

Email: kueterman_gregory_andrew@lilly.com

Phone: (317) 277-4021



Logo - <http://photos.prnewswire.com/prnh/20110825/DE57898LOGO>

Logo - <http://photos.prnewswire.com/prnh/20031219/LLYLOGO>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/us-fda-approves-once-daily-jentaduetto-xr-linagliptin-and-metformin-hydrochloride-extended-release-tablets-for-adults-with-type-2-diabetes->

[300276894.html](https://www.sec.gov/edgar/data/1373291/000137329119000001/300276894.html)

SOURCE Eli Lilly and Company

News Provided by Acquire Media