



Boehringer Ingelheim and Lilly's new oral type 2 diabetes treatment for adults, Jentadueto™ (linagliptin/metformin hydrochloride) tablets, now available in U.S. pharmacies

JENTADUETO, available in three dosage strengths, further expands treatment options for people living with diabetes

RIDGEFIELD, Conn. and INDIANAPOLIS, March 7, 2012 /PRNewswire/ --

Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company (NYSE: LLY) today announced Jentadueto™ (linagliptin/metformin hydrochloride) tablets are now available by prescription in many leading chain and independent pharmacies across the U.S.

JENTADUETO is a new prescription medication for patients who need to control their blood sugar. Taken twice daily, it combines two diabetes medicines — the dipeptidyl peptidase-4 (DPP-4) inhibitor, linagliptin and metformin — in one tablet. Linagliptin is marketed in the U.S. as Tradjenta™ 5mg once-daily tablets. JENTADUETO was approved by the U.S. Food and Drug Administration (FDA) on January 30, 2012, as a prescription medicine used along with diet and exercise to improve glycemic control in adults with type 2 diabetes when treatment with both linagliptin and metformin is appropriate. JENTADUETO is not for the treatment of type 1 diabetes or diabetic ketoacidosis (increased ketones in the blood or urine) and it has not been studied in combination with insulin. The product 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.

"By combining two important diabetes medicines in a single tablet, JENTADUETO provides people with type 2 diabetes another option to control their blood sugar," said David Pass, PharmD, vice president, cardiovascular and metabolic disorders marketing, Boehringer Ingelheim Pharmaceuticals, Inc. "Making JENTADUETO available quickly following its approval further demonstrates Boehringer Ingelheim and Lilly's shared commitment to address the needs of the millions of Americans living with type 2 diabetes."

JENTADUETO provides physicians with options to adjust the metformin dosing based on effectiveness and tolerability. It is available in three dosage strengths, taken twice daily: 2.5 mg linagliptin/500 mg metformin hydrochloride; 2.5 mg linagliptin/850 mg metformin hydrochloride; and 2.5 mg linagliptin/1000 mg metformin hydrochloride. Boehringer Ingelheim and Lilly are actively working with insurance companies on formulary coverage to have JENTADUETO reimbursed at a co-pay level similar to other preferred branded products.

In addition, the Boehringer Ingelheim Cares Foundation Patient Assistance Programs make Boehringer Ingelheim medicines, including JENTADUETO, available free of charge to patients who are without pharmaceutical insurance coverage, and who meet certain household income levels and eligibility requirements.

To learn more about JENTADUETO visit www.JENTADUETO.com. For full prescribing information, visit <http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&folderPath=/Prescribing+Information/Pis/Jentadueto/Jentadueto.pdf> or call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257.

Please report any unexpected effects or product problems to the Boehringer Ingelheim Drug Information Unit by calling 1-800-542-6257.

Savings Card Program Available for Qualifying Patients

Along with the availability of JENTADUETO, Boehringer Ingelheim and Lilly also announced today that a Savings Card Program is available for patients who qualify.

Under the program, most commercially insured eligible patients at least 18 years of age will pay as little as \$10 per month, with savings of up to \$150 per monthly prescription. An eligible patient is responsible for any additional cost beyond the \$150 maximum covered by this offer for each monthly prescription. Eligible cash-paying patients will receive up to \$150 in savings per 30-day supply of JENTADUETO.

Savings Card Program key points:

- Eligible patients can activate their JENTADUETO Savings Card by visiting www.JENTADUETO.com or calling 1-888-232-8458.
- If activated by May 31, 2012, the card is valid for prescriptions filled during 24 consecutive months from date of activation. If activated between June 1, 2012 and May 31, 2013, the card is valid for prescriptions filled during 12 consecutive months from date of activation.
- Once activated, patients must present the Savings Card to the pharmacist along with a signed prescription for JENTADUETO to receive savings. Patients are not eligible if prescriptions are paid in part or full by any state or federally funded programs, including but not limited to Medicare or Medicaid, Medigap, VA, DOD, or TriCare and where prohibited by law.
- This offer will be valid in the United States including the District of Columbia and Puerto Rico. This card is not valid for residents of Massachusetts or where otherwise prohibited by law.
- The offer is limited to one per patient. By accepting this offer, patients agree that if they are required to do so under the terms of their insurance coverage for this prescription or are otherwise required to do so by law, they should notify their insurance carrier of their redemption of the Savings Card.
- For questions regarding eligibility or benefits or to discontinue participation, call the JENTADUETO Savings Card Program at 1-877-512-4246 (8:00 AM - 8:00 PM EST, Monday - Friday).
- Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company reserve the right to rescind, revoke or amend this offer at any time without notice.

Patient Assistance Program Available

For more than 125 years, Boehringer Ingelheim has been focused on improving the lives of patients. In keeping with the company commitment to do the most good for the most people, Boehringer Ingelheim works hard to ensure its medicines are accessible to patients, including senior citizens and families on limited incomes. The Boehringer Ingelheim Cares Foundation Patient Assistance Programs (BI-PAP) make Boehringer Ingelheim medicines available free of charge to patients who are without pharmaceutical insurance coverage and who meet certain household income levels and eligibility requirements.

To receive an application or inquire about the BI-PAP, please call 1-800-556-8317. Please note, while people of all ages are eligible for the program, applications can be sent only to people at least 18 years of age.

About Diabetes

Approximately 25.8 million Americans⁽¹⁾ and an estimated 366 million people worldwide⁽²⁾ have type 1 and type 2 diabetes.

Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diabetes cases.⁽¹⁾ Diabetes is a chronic disease that occurs when the body either does not properly produce, or use, the hormone insulin.⁽³⁾

What is JENTADUETO?

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

It is not known if JENTADUETO is safe and effective when used with insulin.

IMPORTANT SAFETY INFORMATION

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

WARNING: RISK OF LACTIC ACIDOSIS

Serious side effects can happen in people taking JENTADUETO. Metformin, one of the medicines in JENTADUETO, 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.

Stop taking JENTADUETO and call your doctor right away if you feel very weak or tired, have unusual muscle pain, have trouble breathing, are very sleepy, have sudden nausea and vomiting or diarrhea, feel cold, especially in your arms or legs, feel dizzy or lightheaded, or have a slow or irregular heartbeat, as these could be symptoms of lactic acidosis.

You have a higher chance of getting lactic acidosis with JENTADUETO if you have kidney problems, liver problems, congestive heart failure that requires medicines, 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 certain x-ray tests with dyes or contrast agents that are injected into your body, have surgery, have a heart attack, severe infection, or stroke, and are 80 years of age or older and have not had your kidneys tested.

Who should not take JENTADUETO?

Do not take JENTADUETO 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. Symptoms of any allergic reaction are rash, raised red patches on your skin (hives), and swelling of your face, lips, and throat that may cause difficulty breathing or swallowing. If you have any symptoms of a serious allergic reaction, stop taking JENTADUETO and call your doctor right away.

What should I tell my doctor before using JENTADUETO?

Before you take JENTADUETO, tell your doctor if you:

- have kidney problems
- are going to get an injection of dye or contrast agents for an x-ray procedure. JENTADUETO will need to be stopped for a short time. Talk to your doctor about when you should stop JENTADUETO and when you should start JENTADUETO again.
- 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
- have any other medical conditions
- are pregnant or planning to become pregnant. It is not known if JENTADUETO will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.
- are breast-feeding or plan to breast-feed. It is not known if JENTADUETO passes into your breast milk. Talk with your doctor about the best way to feed your baby if you take JENTADUETO.

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

Especially tell your doctor if you take:

- other medicines that can lower your blood sugar. JENTADUETO may cause serious side effects, including low blood sugar (hypoglycemia), which may become worse in people who already take another medication to treat diabetes, such as a sulfonylurea or insulin. Tell your healthcare provider if you take other diabetes medicines. Your doctor may prescribe lower doses of the sulfonylurea medicine.

If you have symptoms of low blood sugar, you should check your blood sugar and treat it if it is low, then call your healthcare provider. Symptoms of low blood sugar include shaking, rapid heartbeat, hunger, headache, sweating, change in vision, and change in mood.

- rifampin (Rifadine®, Rimactane®, Rifater®, Rifamate®), an antibiotic that is used to treat tuberculosis.

Ask your doctor or pharmacist for a list of these medicines if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

What are the possible side effects of JENTADUETO tablets?

The most common side effects of JENTADUETO include:

- stuffy or runny nose and sore throat
- diarrhea

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.

Please see Important Safety Information for Warning about the Risk of Lactic Acidosis, and full Prescribing Information, including Patient Information for additional safety information.

To learn more about JENTADUETO visit www.JENTADUETO.com. For full prescribing information visit <http://bidocs.boehringer->

[ingelheim.com/BIWebAccess/ViewServlet.ser?](http://ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renentnt&folderPath=/Prescribing+Information/PIs/Jentadueto/Jentadueto.pdf)

[docBase=renentnt&folderPath=/Prescribing+Information/PIs/Jentadueto/Jentadueto.pdf](http://ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renentnt&folderPath=/Prescribing+Information/PIs/Jentadueto/Jentadueto.pdf) or call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257, or (TTY) 1-800-459-9906.

Please report any unexpected effects or product problems to the Boehringer Ingelheim Drug Information Unit by calling 1-800-542-6257.

What are TRADJENTA tablets?

TRADJENTA is a prescription medicine that is used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.

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

It is not known if TRADJENTA is safe and effective when used with insulin.

Important Safety Information

Who should not take TRADJENTA?

Do not take TRADJENTA if you are allergic to linagliptin or any of the ingredients in TRADJENTA.

Symptoms of a serious allergic reaction to TRADJENTA are rash, raised red patches on your skin (hives), swelling of your face, lips, and throat that may cause difficulty breathing or swallowing. If you have any symptoms of a serious allergic reaction, stop taking TRADJENTA and call your doctor right away.

What should I tell my doctor before taking TRADJENTA?

Tell your doctor if you take other medicines that can lower your blood sugar, such as a sulfonylurea or insulin.

TRADJENTA may cause serious side effects, including low blood sugar (hypoglycemia). If you take TRADJENTA 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 medicine or insulin may need to be lowered while you take TRADJENTA.

Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, or feeling jittery.

Also tell your doctor if you take rifampin (Rifadin®, Rimactane®, Rifater®, Rifamate®), an antibiotic that is used to treat tuberculosis.

TRADJENTA may affect the way other medicines work, and other medicines may affect how TRADJENTA works.

Tell your doctor if you are pregnant or planning to become pregnant or are breast-feeding or plan to breast-feed.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

What are the possible side effects of TRADJENTA?

The most common side effects of TRADJENTA include stuffy or runny nose and sore throat.

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 safety information, please see Patient Information and full Prescribing Information.

To learn more about TRADJENTA visit: www.TRADJENTA.com. For full prescribing information visit: <http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renentnt&folderPath=/Prescribing+Information/PIs/Tradjenta/Tradjenta.pdf> or call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257

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Boehringer Ingelheim and Eli Lilly and Company

In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance in the field of diabetes that centers on four pipeline compounds representing several of the largest treatment classes. This alliance leverages the companies' strengths as two of the world's leading pharmaceutical companies, combining Boehringer Ingelheim's solid track record of research-driven innovation and Lilly's innovative research, experience, and pioneering history in diabetes. 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 Pharmaceuticals, Inc.

Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT, is the largest U.S. subsidiary of Boehringer Ingelheim Corporation (Ridgefield, CT) and a member of the Boehringer Ingelheim group of companies.

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 145 affiliates and more than 42,000 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.

As a central element of its culture, Boehringer Ingelheim pledges to act socially responsible. Involvement in social projects, caring for employees and their families, and providing equal opportunities for all employees form the foundation of the global operations. Mutual cooperation and respect, as well as environmental protection and sustainability are intrinsic factors in all of Boehringer Ingelheim's endeavors.

In 2010, Boehringer Ingelheim posted net sales of approximately \$16.7 billion (about 12.6 billion euro) while spending almost 24 percent of net sales in its largest business segment, Prescription Medicines, on research and development.

For more information, please visit us.boehringer-ingelheim.com and follow us on Twitter at twitter.com/boehringerus.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, IN, Lilly provides answers — through medicines and information — for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

About Lilly Diabetes

For more than 85 years, Lilly has been a worldwide leader in pioneering industry-leading solutions to support people living with and treating diabetes. Lilly introduced the world's first commercial insulin in 1923, and remains at the forefront of medical and delivery device innovation to manage diabetes. Lilly is also committed to providing solutions beyond therapy — practical tools, education, and support programs to help overcome barriers to success along the diabetes journey. At Lilly, the journeys of each person living with or treating diabetes inspire ours. For more information, visit www.lillydiabetes.com.

This press release contains forward-looking statements about JENTADUETO for the treatment of type 2 diabetes. It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that JENTADUETO will be commercially successful. For further discussion of these and other risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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(1) Centers for Disease Control and Prevention. National Diabetes Fact Sheet 2011. http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf. Accessed on: February 22, 2012.

(2) International Diabetes Federation. Diabetes Atlas, 5th Edition: Fact Sheet. 2011.

(3) International Diabetes Federation. Diabetes Atlas, 5th Edition: What is Diabetes? <http://www.idf.org/diabetesatlas/5e/what-is-diabetes>. Accessed on: February 22, 2012.

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