



August 26, 2014

## **New type 2 diabetes treatment Jardiance® (empagliflozin) tablets for adults now available in U.S. pharmacies**

### **New JARDIANCE Simple Savings program currently offered in doctors' offices and online**

RIDGEFIELD, Conn. and INDIANAPOLIS, Aug. 26, 2014 /PRNewswire/ -- Jardiance® (empagliflozin) tablets are now available by prescription in pharmacies across the United States, including Walgreens, Rite Aid, Kroger and many other leading chain and independent retailers, according to Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) and Eli Lilly and Company (NYSE: LLY). The U.S. Food and Drug Administration (FDA) approved JARDIANCE on August 1, 2014 as an adjunct to diet and exercise to improve glycemic control, or blood glucose levels, in adults with type 2 diabetes (T2D). JARDIANCE is not for people with type 1 diabetes or for people with diabetic ketoacidosis (increased ketones in the blood or urine).

"As a testament to the joint commitment by Boehringer Ingelheim and Lilly to improve care for people with diabetes, our alliance is proud to make JARDIANCE available so quickly following its approval by the FDA," said Kathleen Dowd, senior vice president, marketing, Boehringer Ingelheim Pharmaceuticals, Inc. "We believe JARDIANCE is an exciting new treatment option with the potential to help many of the millions of adults with type 2 diabetes who have difficulty controlling their blood sugar levels."

JARDIANCE, a once-daily, 10 mg or 25 mg tablet, is a sodium glucose co-transporter-2 (SGLT2) inhibitor. JARDIANCE works by blocking the reabsorption of glucose in the kidney, increasing glucose excretion and lowering blood glucose levels in adults with type 2 diabetes who have elevated blood glucose levels.

Patients should not take JARDIANCE if they have severe kidney problems or are on dialysis, or if they are allergic to empagliflozin or any ingredient in JARDIANCE. JARDIANCE can cause some people to have dehydration (the loss of body water and salt), which may lead to a drop in blood pressure, and may cause patients to feel dizzy or faint.

The JARDIANCE Simple Savings co-pay support program is available online and in many doctors' offices for patients who qualify. For terms and conditions and any questions regarding eligibility or benefits, visit [JARDIANCEsavings.com](http://JARDIANCEsavings.com) or call 1-866-279-8990.

The FDA approval of JARDIANCE was based on results from a large clinical program comprised of more than 10 multinational clinical trials and more than 13,000 adults with T2D. Phase III studies showed JARDIANCE significantly reduced hemoglobin A1C (a measure of average blood glucose over the past two to three months) after 24 weeks as a stand-alone treatment or in combination with a range of background treatments, including metformin, sulfonylureas, insulin and pioglitazone. Although JARDIANCE is not approved for lowering weight or blood pressure, modest reductions in both weight and systolic blood pressure were observed in clinical trials.

The most common adverse reactions associated with JARDIANCE were urinary tract infections and vaginal yeast infections. Hypoglycemia was more commonly reported in patients treated with the combination of JARDIANCE and sulfonylurea or insulin.

To learn more about JARDIANCE and for full prescribing information visit: [www.JARDIANCE.com](http://www.JARDIANCE.com) 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.

#### **About Diabetes**

Approximately 29 million Americans and an estimated 382 million people worldwide have type 1 or type 2 diabetes. T2D is the most common type, accounting for an estimated 85 to 95 percent of all diabetes cases. Diabetes is a chronic condition that occurs when the body either does not properly produce, or use, the hormone insulin.

#### **What is JARDIANCE?**

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

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

## **IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know about JARDIANCE?**

**JARDIANCE can cause serious side effects, including:**

- **Dehydration.** JARDIANCE can cause some people to have dehydration (the loss of body water and salt). Dehydration may cause you to feel dizzy, faint, light-headed, or weak, especially when you stand up.

**You may be at a higher risk of dehydration if you:**

- have low blood pressure
- take medicines to lower your blood pressure, including water pills (diuretics)
- are on a low salt diet
- have kidney problems
- are 65 years of age or older.
  
- **Vaginal yeast infection.** Women who take JARDIANCE may get vaginal yeast infections. Talk to your doctor if you experience vaginal odor, white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese), and/or vaginal itching.
  
- **Yeast infection of the penis.** Men who take JARDIANCE may get a yeast infection of the skin around the penis, especially uncircumcised males and those with chronic infections. Talk to your doctor if you experience redness, itching or swelling of the penis, rash of the penis, foul smelling discharge from the penis, and/or pain in the skin around penis.

**Who should not take JARDIANCE?**

- Do not take JARDIANCE if you are allergic to empagliflozin or any of the ingredients in JARDIANCE.

**Symptoms of serious allergic reactions to JARDIANCE may include:**

- skin rash
- raised red patches on your skin (hives)
- swelling of the face, lips, tongue, and throat that may cause difficulty breathing or swallowing.

**If you have any of these symptoms, stop taking JARDIANCE and contact your doctor or go to the nearest emergency room right away.**

- Do not take JARDIANCE if you have severe kidney problems or are on dialysis.

**What should I tell my doctor before using JARDIANCE?**

**Tell your doctor if you:**

- have kidney problems. Your doctor may do blood tests to check your kidneys before and during your treatment with JARDIANCE
- have liver problems
- have a history of urinary tract infections or problems with urination
- have any other medical conditions
- are pregnant or planning to become pregnant. It is unknown if JARDIANCE will harm your unborn baby
- are breastfeeding, or plan to breastfeed. It is unknown if JARDIANCE passes into your breast milk.

**Tell your doctor about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you take water pills (diuretics) or medicines that can lower your blood sugar such as insulin.**

**What are other possible side effects of JARDIANCE?**

- **Low blood sugar (hypoglycemia):** if you take JARDIANCE with another medicine that can cause low blood sugar, such as sulfonylurea or insulin, your risk of low blood sugar is higher. The dose of your sulfonylurea or insulin may need to be lowered. Symptoms of low blood sugar may include:
  - Headache
  - Drowsiness
  - Weakness
  - Dizziness
  - Confusion
  - Irritability
  - Hunger
  - Fast heart beat
  - Sweating
  - Shaking or feeling jittery
- **Kidney Problems,** especially in people 75 years of age or older and people who already have kidney problems
- **Urinary Tract Infection:** symptoms may include burning feeling when passing urine, pain in the pelvis or back, or urine that looks cloudy
- **Increased fats in your blood (cholesterol).**

The most common side effects of JARDIANCE include urinary tract infections, and yeast infections in females.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

For more information, please see full Prescribing Information, including Patient Information.

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For more information, please see full [Prescribing Information, including Patient Information](#).

**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. The alliance leverages the strengths of two of the world's leading pharmaceutical companies. By joining forces, the companies demonstrate commitment in the care of people with diabetes and stand together to focus on patient needs. Find out more about the alliance at [www.boehringer-ingelheim.com](http://www.boehringer-ingelheim.com) or [www.lilly.com](http://www.lilly.com).

**About the Boehringer Ingelheim Cares Foundation Patient Assistance Programs**

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 everyone who needs them, 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.

**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 142 affiliates and more than 47,400 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel medications of high therapeutic value for human and veterinary medicine.

Social responsibility is a central element of Boehringer Ingelheim's culture. 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 2013, Boehringer Ingelheim achieved net sales of about \$18.7 billion (14.1 billion euro). R&D expenditure in the

Prescription Medicines business corresponds to 19.5% of its net sales.

For more information please visit <http://www.us.boehringer-ingenelheim.com>.

#### 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](http://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](http://www.lilly.com) and <http://newsroom.lilly.com/social-channels>.

*This press release contains forward-looking statements about JARDIANCE 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 JARDIANCE will prove to 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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The image shows the word "Lilly" written in a red, cursive script font. The letters are thick and connected, with a classic, elegant feel. The 'L' is particularly large and loops around the 'i'. The 'y' has a long, thin tail that extends downwards.

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

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

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