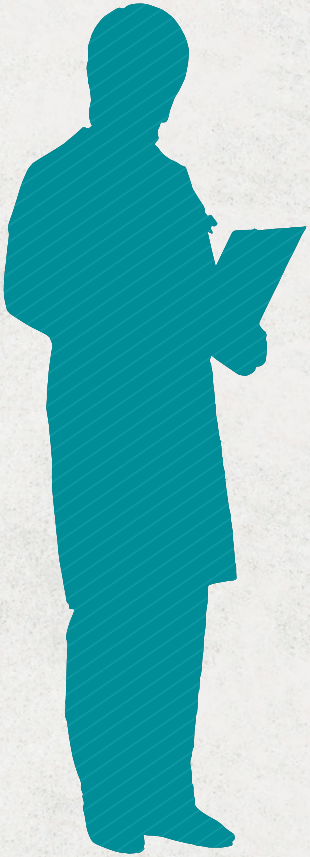


FOR ADULTS WITH ESTABLISHED CV DISEASE AND TYPE 2 DIABETES

# As a cardiologist, patients count on you to reduce their risk of CV death

## INDICATION AND LIMITATIONS OF USE

JARDIANCE is indicated to reduce the risk of cardiovascular (CV) death in adults with type 2 diabetes mellitus and established CV disease.

JARDIANCE is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

## IMPORTANT SAFETY INFORMATION

**CONTRAINDICATIONS:** History of serious hypersensitivity to empagliflozin or any of the excipients in JARDIANCE, severe renal impairment, end-stage renal disease, or dialysis.

**Please see additional Important Safety Information on the following pages.**

**Please see Prescribing Information, including Medication Guide.**

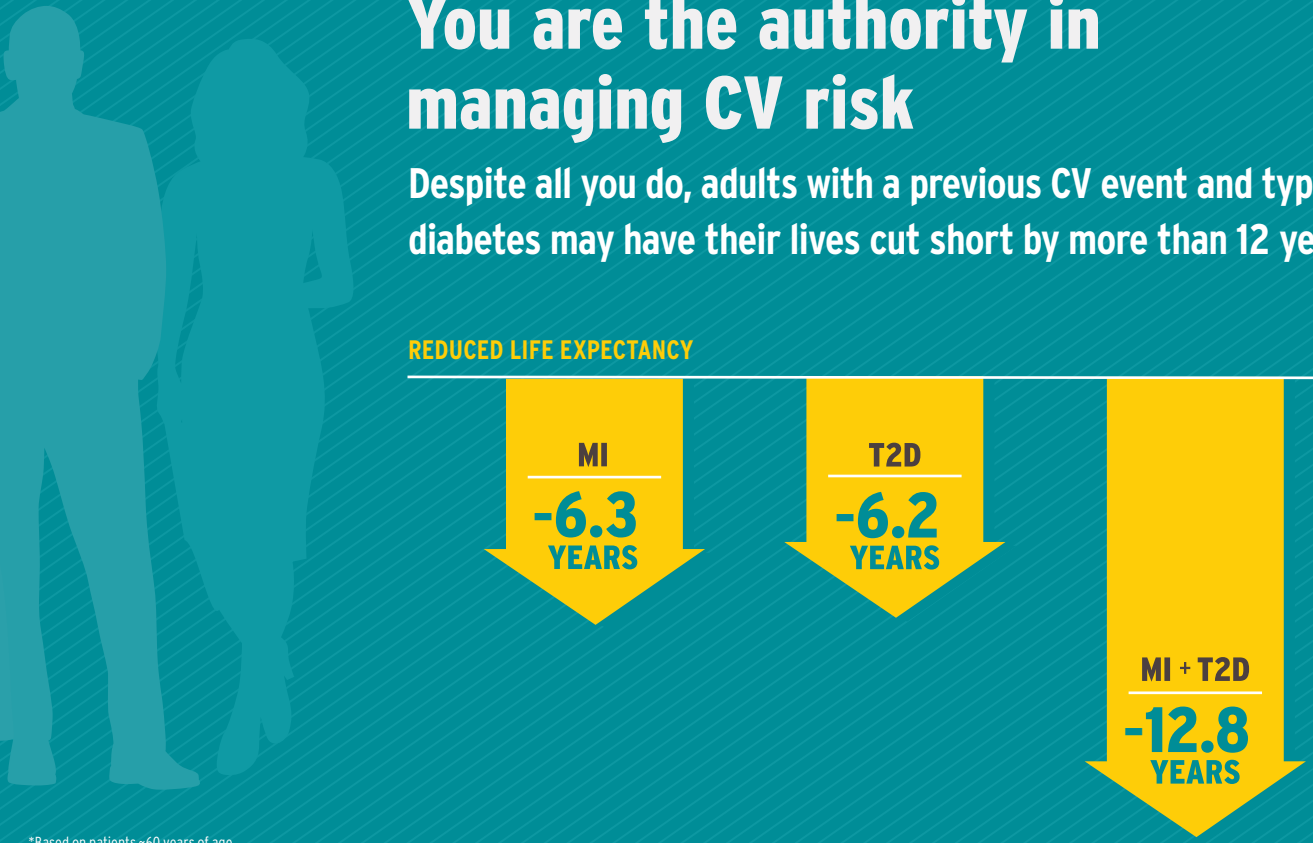
Jardiance®
(empagliflozin) tablets
10 mg/25 mg

CV=cardiovascular.

# Don't count on someone else to treat them

# You are the authority in managing CV risk

## Despite all you do, adults with a previous CV event and type 2 diabetes may have their lives cut short by more than 12 years[1]*



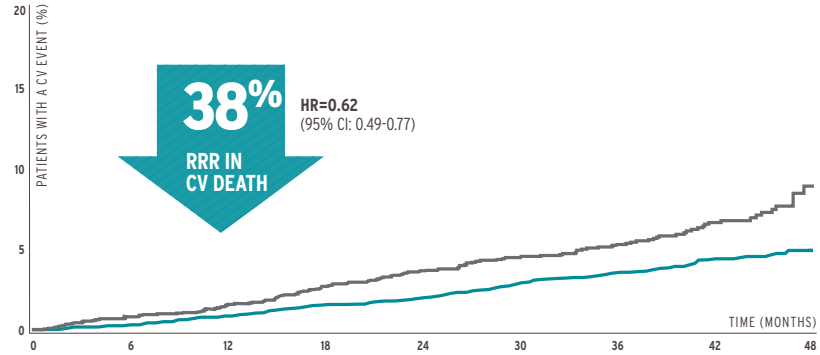

*Based on patients ~60 years of age.
MI=myocardial infarction; T2D=type 2 diabetes.

FOR ADULTS WITH ESTABLISHED CV DISEASE AND TYPE 2 DIABETES

# Prescribe JARDIANCE now to give your patients a lifesaving CV benefit*

**Results were achieved on top of standard of care† and were consistent for the two JARDIANCE dosing strengths**

Jardiance® (empagliflozin) tablets 10 mg/25 mg




EARLY AND SUSTAINED REDUCTIONS IN CV DEATH[2]

**REDUCED RISK OF CV DEATH**

Placebo
+ standard of care (N=2333)

JARDIANCE‡
+ standard of care (N=4687)

**Absolute rates for CV death**
5.9% placebo VS 3.7% JARDIANCE

**2.2% ABSOLUTE RISK REDUCTION**

**Please see Study Design on next page.**

**JARDIANCE DEMONSTRATED A 14% RRR FOR THE PRIMARY COMPOSITE ENDPOINT**
(HR=0.86 [95% CI: 0.74-0.99]; p=0.04)

- The absolute risk reduction for the composite endpoint was 1.6%
- There was no change in risk of nonfatal MI (HR=0.87 [95% CI: 0.70-1.09]) or nonfatal stroke (HR=1.24 [95% CI: 0.92-1.67]); the 14% RRR in CV events was due to a reduction in the risk of CV death (HR=0.62 [95% CI: 0.49-0.77])

## IMPORTANT SAFETY INFORMATION (continued)

## WARNINGS AND PRECAUTIONS

**Hypotension:** Empagliflozin causes intravascular volume contraction and symptomatic hypotension may occur. Before initiating JARDIANCE, assess and correct volume status in the elderly, and in patients with renal impairment, low systolic blood pressure, or on diuretics. Monitor for hypotension.

**Ketoacidosis:** Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been identified in patients with type 1 and type 2 diabetes mellitus receiving SGLT2 inhibitors, including empagliflozin. Fatal cases of ketoacidosis have been reported in patients taking empagliflozin. Patients who present with signs and symptoms of metabolic acidosis should be assessed for ketoacidosis, even if blood glucose levels are less than 250 mg/dL. If suspected, discontinue JARDIANCE, evaluate, and treat promptly. Before initiating JARDIANCE, consider risk factors for ketoacidosis. Patients may require monitoring and temporary discontinuation in situations known to predispose to ketoacidosis. For patients who undergo scheduled surgery, consider temporarily discontinuing JARDIANCE for at least 3 days prior to surgery.

**Please see Prescribing Information, including Medication Guide.**

*JARDIANCE is indicated to reduce the risk of cardiovascular (CV) death in adults with type 2 diabetes mellitus and established CV disease.
†CV and glucose-lowering medications.
‡Pooled data from JARDIANCE 10 mg and JARDIANCE 25 mg; similar magnitude of reduction was shown with both doses.CI=confidence interval; HR=hazard ratio; MI=myocardial infarction; RRR=relative risk reduction.

**46**

**NUMBER NEEDED TO TREAT TO PREVENT ONE CV DEATH**

Median 3.1 years

**Study Design:** A randomized, double-blind, parallel-group trial comparing the risk of experiencing a major adverse cardiovascular event between JARDIANCE and placebo when these were added to and used concomitantly with standard of care treatments for type 2 diabetes and cardiovascular disease. A total of 7020 patients were treated (JARDIANCE 10 mg [N=2345]; JARDIANCE 25 mg [N=2342]; placebo [N=2333]) and followed for a median of 3.1 years. All patients had established atherosclerotic cardiovascular disease at baseline, including one or more of the following: a documented history of coronary artery disease, peripheral artery disease, myocardial infarction, or stroke. The primary outcome was reduction in risk of cardiovascular events, defined by the composite of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke.

## JARDIANCE provides convenient once-daily oral dosing

Jardiance® (empagliflozin) tablets 10 mg/25 mg

**10 mg**

The recommended dose for JARDIANCE is **10 mg once daily**

JARDIANCE can be taken **with or without food** in the morning

- In patients who tolerate JARDIANCE 10 mg, the dose can be increased to 25 mg once daily
- In patients with volume depletion, correcting this condition prior to initiation of JARDIANCE is recommended
- Dosing in patients with renal impairment:
  - Assessment of renal function is recommended prior to initiation of JARDIANCE and periodically thereafter
  - Should not be initiated if eGFR is <45 mL/min/1.73 $m^2$
  - No dose adjustment required in patients with eGFR ≥45 mL/min/1.73 $m^2$
  - Should be discontinued if eGFR drops to <45 mL/min/1.73 $m^2$
- A lower dose of insulin or insulin secretagogues (eg, sulfonylureas) may be required to reduce the risk of hypoglycemia when JARDIANCE is used in combination with these agents
- JARDIANCE is contraindicated in patients with severe renal impairment, end-stage renal disease, or dialysis. It should not be used in patients with a history of serious hypersensitivity to JARDIANCE

## IMPORTANT SAFETY INFORMATION (continued)

### WARNINGS AND PRECAUTIONS

**Acute Kidney Injury and Impairment in Renal Function:** Empagliflozin causes intravascular volume contraction and can cause renal impairment. Acute kidney injury requiring hospitalization and dialysis has been identified in patients taking SGLT2 inhibitors, including empagliflozin; some reports involved patients younger than 65 years of age. Before initiating JARDIANCE, consider factors that may predispose patients to acute kidney injury. Consider temporary discontinuation in settings of reduced oral intake or fluid losses. Monitor patients for signs and symptoms of acute kidney injury. If it occurs, discontinue JARDIANCE and treat promptly.

Empagliflozin increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Before initiating JARDIANCE, evaluate renal function and monitor thereafter. More frequent monitoring is recommended in patients with eGFR <60 mL/min/1.73 $m^2$. Discontinue JARDIANCE in patients with a persistent eGFR <45 mL/min/1.73 $m^2$.

**Please see Prescribing Information, including Medication Guide.**

Jardiance®
(empagliflozin) tablets
10 mg/25 mg

FOR ADULTS WITH ESTABLISHED CV DISEASE AND TYPE 2 DIABETES

# Reducing the risk of CV death. It's why you became a cardiologist; it's why you prescribe JARDIANCE

## IMPORTANT SAFETY INFORMATION (continued)

## WARNINGS AND PRECAUTIONS (continued)

**Urosepsis and Pyelonephritis:** Serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization have been identified in patients receiving SGLT2 inhibitors, including empagliflozin. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate for signs and symptoms of urinary tract infections and treat promptly.

**Hypoglycemia: The use of JARDIANCE in combination with insulin or insulin secretagogues** can increase the risk of hypoglycemia. A lower dose of insulin or the insulin secretagogue may be required.

**Necrotizing Fasciitis of the Perineum (Fournier's Gangrene):** Serious, life-threatening cases requiring urgent surgical intervention have occurred in both females and males. Serious outcomes have included hospitalization, multiple surgeries, and death. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment and discontinue JARDIANCE.

**Genital Mycotic Infections:** Empagliflozin increases the risk for genital mycotic infections, especially in patients with prior infections. Monitor and treat as appropriate.

**Hypersensitivity Reactions:** Serious hypersensitivity reactions have occurred with JARDIANCE (angioedema). If hypersensitivity reactions occur, discontinue JARDIANCE, treat promptly, and monitor until signs and symptoms resolve..

**Increased Low-Density Lipoprotein Cholesterol (LDL-C):** Monitor and treat as appropriate.

## MOST COMMON ADVERSE REACTIONS (≥5%):

Urinary tract infections and female genital mycotic infections.

## DRUG INTERACTIONS:

Coadministration with diuretics may enhance the potential for volume depletion.

## USE IN SPECIAL POPULATIONS

**Pregnancy:** JARDIANCE is not recommended, especially during the second and third trimesters.

**Lactation:** JARDIANCE is not recommended while breastfeeding.

**Geriatric Use:** JARDIANCE is expected to have diminished efficacy in elderly patients with renal impairment. Renal function should be assessed more frequently in elderly patients. The incidence of volume depletion-related adverse reactions and urinary tract infections increased in patients ≥75 years treated with empagliflozin.

CL-JAR-100056 01.27.2020

**Please see Prescribing Information, including Medication Guide.**

**References: 1.** Angelantonio DE, Kaptoge S, Wormser D, et al; Emerging Risk Factors Collaboration. *JAMA*. 2015;314(1):52-60.
**2.** Zinman B, Wanner C, Lachin JM, et al; EMPA-REG OUTCOME Investigators. *N Engl J Med*. 2015;373(22):2117-2128.

Boehringer Ingelheim



Lilly