

JARDIANCE®: A POWERFUL PARTNER

JARDIANCE® is indicated in adult patients with type 2 diabetes mellitus to improve glycemic control, when metformin used alone does not provide adequate glycemic control, in combination with: metformin, metformin and a sulfonylurea, pioglitazone (alone or with metformin), linagliptin and metformin, basal or prandial insulin (alone or with metformin), when the existing therapy, along with diet and exercise, does not provide adequate glycemic control.*

JARDIANCE® is indicated as an adjunct to diet, exercise and standard care therapy to reduce the incidence of cardiovascular death in patients with type 2 diabetes mellitus and established cardiovascular disease.



In patients with T2D and established CV disease

JARDIANCE[®], as an adjunct to SOC therapy^{4*}...

reduced the risk of CV death vs. placebo^{12††} (other adjudicated endpoint)

38% RRR in CV death
3.7% pooled JARDIANCE[®] (n=4,687)
vs. 5.9% placebo (n=2,333)[†]

HR=0.62; 95% CI:
0.49, 0.77;
p<0.0001

Demonstrated NNT with JARDIANCE[®]
for 3 years to prevent one CV death

NNT=46

reduced the risk of heart failure requiring hospitalization vs. placebo^{12††}
(other adjudicated endpoint)

35% RRR in hospitalization for HF

2.7% pooled JARDIANCE[®] (n=4,687)
vs. 4.1% placebo (n=2,333)[†]

HR=0.65; 95% CI:
0.50, 0.85;
p=0.0017

Demonstrated NNT with JARDIANCE[®]
for 3 years to prevent one hospitalization for HF

NNT=72

JARDIANCE[®] demonstrated 14% RRR in the MACE-3 primary analysis vs. placebo (10.5% pooled JARDIANCE[®] [n=490] vs. 12.1% placebo [n=282]).^{12†}

HR=0.86; 95% CI: 0.74, 0.99; p=0.0382

There was no significant change in non-fatal MI or non-fatal stroke.¹

T2D=type 2 diabetes; CV=cardiovascular; SOC=standard of care; RRR=relative risk reduction; HR=hazard ratio; CI=confidence interval; NNT=number needed to treat; MACE-3=Major Adverse Cardiovascular Events; MI=myocardial infarction.

* Baseline therapies included: renin angiotensin system inhibitors (81%), beta-blockers (65%), diuretics (43%), anti-thrombotic therapy (89%), lipid-lowering medication (81%), metformin (74%), insulin (48%), sulfonylurea (43%).

† EMPA-REG OUTCOME study: double-blind, placebo-controlled, event-driven study evaluating empagliflozin 10 mg and 25 mg as add-on to standard of care therapy in reducing CV events in T2D patients with ≥1 of: coronary artery disease, peripheral artery disease, history of MI, history of stroke. Primary endpoint was time to first event in composite endpoint of CV death, non-fatal MI, or non-fatal stroke (Major Adverse Cardiovascular Events [MACE-3]).

‡ Pre-specified pooled analysis of JARDIANCE[®] 10 and 25 mg vs. placebo in the treated set (patients receiving ≥1 dose of study drug).

A1C CONSIDERATIONS

In T2D patients with inadequate glycemic control

JARDIANCE[®], as an add-on to metformin, provided...

powerful **A1C reductions** vs. placebo^{13*}



Change from baseline A1C (7.9%) to Week 24:
-0.7% JARDIANCE[®] 10 mg, -0.8% JARDIANCE[®] 25 mg,
-0.1 placebo ($p < 0.0001$ for both)

WEIGHT CONSIDERATIONS

significant **reductions in body weight** vs. placebo^{13*} (2^o endpoint)



Change from baseline to Week 24:
-2.1 kg JARDIANCE[®] 10 mg, -2.5 kg JARDIANCE[®] 25 mg,
-0.5 kg placebo ($p < 0.0001$ for both)

JARDIANCE[®] is not indicated for weight loss.

A1C=glycated hemoglobin.

* 24-week, double-blind, placebo-controlled study of T2D patients evaluating the efficacy and safety of empagliflozin 10 mg (n=217) and 25 mg (n=213) as add-on to metformin vs. placebo (n=207) plus metformin ≥ 1500 mg (maximum tolerated dose, or maximum dose from local label). Primary endpoint was A1C reduction at 24 weeks.

Indications and clinical use not discussed elsewhere in the piece

Monotherapy: JARDIANCE® (empagliflozin) is indicated for use as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus for whom metformin is inappropriate due to contraindications or intolerance.

Important limitation of use: Use of JARDIANCE® with insulin mix (regular or analogue mix) has not been studied. Therefore, JARDIANCE® should not be used with insulin mix.

Contraindications

- Patients with severe renal impairment (eGFR <30 mL/min/1.73 m²), end-stage renal disease and patients on dialysis

Most serious warnings and precautions

Diabetic ketoacidosis (DKA): Cases of DKA, a serious, life-threatening condition requiring urgent hospitalization, have been reported for JARDIANCE® or other SGLT2i, including fatal cases for patients taking JARDIANCE® and atypical cases with blood glucose <13.9 mmol/L (250 mg/dL). Consider the risk of DKA if non-specific symptoms occur, regardless of blood glucose level, and **immediately discontinue JARDIANCE® and assess for DKA.** JARDIANCE® should not be used for the treatment of DKA or in patients with a history of DKA. JARDIANCE® is not indicated, and should not be used, in patients with type 1 diabetes.

Other relevant warnings and precautions

- Not recommended in volume-depleted patients; drops in blood pressure; monitor volume status and electrolytes
- Caution in patients at high risk for cerebrovascular accidents

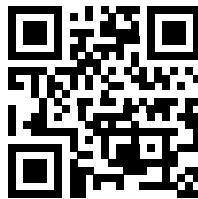
SGLT2i=sodium-glucose co-transporter 2 inhibitor;
eGFR=estimated glomerular filtration rate;
LDL-C=low-density lipoprotein cholesterol.
* Comparative clinical significance not established.

References: **1.** JARDIANCE® Product Monograph, Boehringer Ingelheim (Canada) Ltd., April 15, 2020. **2.** Zinman B, et al. Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. *N Engl J Med* 2015;373(22):2117-28. **3.** Häring HU, et al. Empagliflozin as Add-On to Metformin in Patients with Type 2 Diabetes: A 24-Week, Randomized, Double-Blind, Placebo-Controlled Trial. *Diabetes Care* 2014;37(6):1650-9. **4.** IQVIA TRx Data, June 1, 2020.

- Temporarily discontinue in situations predisposing to ketoacidosis
- Caution when reducing concomitant insulin dose
- Hypoglycemia when used in combination with insulin secretagogues or insulin
- Risk and monitoring of LDL-C increases
- Genital mycotic infections
- Urinary tract infections
- Necrotizing fasciitis of the perineum (Fournier's gangrene)
- Caution in patients with elevated hematocrit
- Not recommended in patients with severe hepatic impairment
- Serious hypersensitivity reactions
- Intravascular volume contraction, increases in serum creatinine, decreases eGFR; assess renal function prior to initiation and regularly thereafter; monitor renal function with concomitant drug use; more intensive monitoring if eGFR <60 mL/min/1.73 m² (especially if eGFR <45 mL/min/1.73 m²); discontinue if eGFR <30 mL/min/1.73 m²
- Acute kidney injury
- Use in settings of reduced oral intake or fluid loss
- Do not use during pregnancy or breastfeeding
- Do not use in patients <18 years; caution in patients ≥65 years and ≥75 years; not recommended in patients ≥85 years
- Patients will test positive for glucose in urine

For more information

Please refer to the Product Monograph at www.JardiancePM.ca for important information relating to adverse events, drug interactions, dosing, and conditions of clinical use. The Product Monograph is also available by calling 1-800-263-5103 ext. 84633.



Scan the QR code with your cell phone camera for more information about JARDIANCE®


Jardiance[®]
(empagliflozin)

**The #1 dispensed
SGLT2i in Canada**^{4*}

JARDIANCE® is a registered trademark of Boehringer Ingelheim International GmbH, used under license.

EMP-CA-101408
EMP-LI-101408

