

Prescribing Information (Ireland) JARDIANCE® (empagliflozin)

Film-coated tablets containing 10 mg or 25 mg empagliflozin. **Indication:** Type 2 diabetes mellitus: Jardiance is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: as monotherapy when metformin is considered inappropriate due to intolerance; in addition to other medicinal products for the treatment of diabetes. For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, refer to the Summary of Product Characteristics. Heart failure: Jardiance is indicated in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction. **Dose and Administration:** Type 2 diabetes mellitus: The recommended starting dose is 10 mg once daily. In patients tolerating empagliflozin 10 mg once daily who have eGFR ≥ 60 ml/min/1.73 m² and need tighter glycaemic control, the dose can be increased to 25 mg once daily. The maximum daily dose is 25 mg. **Renal impairment:** The glycaemic efficacy of empagliflozin is dependent on renal function. Empagliflozin should not be initiated in patients with an eGFR < 60 ml/min/1.73 m² or CrCl < 60 ml/min. In patients tolerating empagliflozin whose eGFR falls persistently below 60 ml/min/1.73 m² or CrCl below 60 ml/min, the dose of empagliflozin should be adjusted to or maintained at 10 mg once daily. Empagliflozin should be discontinued when eGFR is persistently below 45 ml/min/1.73 m² or CrCl persistently below 45 ml/min. No dose adjustment is required for patients with an eGFR ≥ 60 ml/min/1.73 m² or CrCl ≥ 60 ml/min. Heart failure: The recommended dose is 10 mg empagliflozin once daily. **Renal impairment:** For treatment of heart failure in patients with or without type 2 diabetes mellitus, empagliflozin 10 mg may be initiated or continued down to an eGFR of 20 ml/min/1.73 m² or CrCl of 20 ml/min. For patients with an eGFR < 20 ml/min/1.73 m² or CrCl < 20 ml/min empagliflozin is not recommended. All indications: When used with sulphonylurea or insulin a lower dose of these may be considered to reduce the risk of hypoglycaemia. If a dose is missed, it should be taken as soon as the patient remembers; however, a double dose should not be taken on the same day. **Renal impairment:** Empagliflozin should not be used in patients with end stage renal disease (ESRD) or on dialysis. **Hepatic impairment:** No dose adjustment is required for patients with hepatic impairment. Not recommended in severe hepatic impairment. **Elderly patients:** No dose adjustment is recommended based on age. In patients 75 years and older, an increased risk for volume depletion should be taken into account. In patients aged 85 years and older, initiation of empagliflozin therapy is not recommended due to the limited therapeutic experience. **Paediatric population:** No data are available. **Method of administration:** The tablets can be taken with or without food, swallowed whole with water. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and Precautions:** **Ketoacidosis:** Rare cases of ketoacidosis, including life-threatening and fatal cases, have been reported in patients with diabetes mellitus treated with SGLT2 inhibitors, including empagliflozin. The risk of ketoacidosis must be considered in the event of non-specific symptoms such as nausea, vomiting, anorexia, abdominal pain, excessive thirst, difficulty breathing, confusion, unusual fatigue or sleepiness. Assess patients for ketoacidosis immediately, regardless of blood glucose level. In patients where ketoacidosis is suspected or diagnosed, treatment with empagliflozin should be discontinued immediately. Treatment should be interrupted in patients who are hospitalised for major surgical procedures or acute serious medical illnesses. Monitoring of ketones is recommended in these patients. Measurement of blood ketone levels is preferred to urine. Treatment with empagliflozin may be restarted when the ketone values are normal and the patient's condition has stabilised. Before initiating empagliflozin, factors in the patient history that may predispose to ketoacidosis should be considered. Use with caution in patients who may be at higher risk of ketoacidosis. Restarting SGLT2 inhibitor treatment in patients with previous ketoacidosis while on SGLT-2 inhibitor treatment is not recommended, unless another clear precipitating factor is identified and resolved. Jardiance should not be used for treatment of patients with type 1 diabetes. **Renal impairment:** Empagliflozin should not be used in patients with ESRD or in patients on dialysis. For type 2 diabetes mellitus, as glycaemic control depends on renal function, Jardiance should not be initiated in patients with an eGFR below 60 ml/min/1.73 m² or CrCl < 60 ml/min. In patients tolerating empagliflozin whose eGFR is persistently below 60 ml/min/1.73 m² or CrCl < 60 ml/min, the dose of empagliflozin should be adjusted to or maintained at 10 mg once daily. Empagliflozin is not recommended when eGFR is persistently below 45 ml/min/1.73 m² or CrCl persistently below 45 ml/min. For heart failure, Jardiance is not recommended in patients with eGFR < 20 ml/min/1.73 m². **Monitoring of renal function:** Assessment is recommended prior to initiation and at least annually. **Risk for volume depletion:** Osmotic diuresis accompanying glucosuria may lead to a modest decrease in blood pressure. Therefore, caution should be exercised in patients with known cardiovascular disease, patients on anti-hypertensive therapy with a history of hypotension or patients aged 75 years and older.

In case of conditions that may lead to fluid loss (e.g. gastrointestinal illness), careful monitoring of volume status and electrolytes is recommended. Temporary interruption of treatment with empagliflozin should be considered until the fluid loss is corrected. **Elderly:** See under Dose and Administration; special attention should be given to volume intake of elderly patients in case of co-administered medicinal products which may lead to volume depletion (e.g. diuretics, ACE-inhibitors). **Complicated urinary tract infections:** Temporary interruption of empagliflozin should be considered in patients with complicated urinary tract infections. **Necrotising fasciitis:** Cases of necrotising fasciitis of the perineum (Fournier's gangrene), have been reported in patients with diabetes mellitus taking SGLT2 inhibitors. This is a rare but serious and potentially life-threatening event that requires urgent surgical intervention and antibiotic treatment. Patients should be advised to seek medical attention if they experience a combination of symptoms of pain, tenderness, erythema, or swelling in the genital or perineal area, with fever or malaise. Be aware that either uro-genital infection or perineal abscess may precede necrotising fasciitis. If Fournier's gangrene is suspected, Jardiance should be discontinued and prompt treatment should be instituted. **Lower limb amputation:** An increase in cases of lower limb amputation (primarily of the toe) has been observed in long-term clinical studies with another SGLT2 inhibitor, counsel patients on routine preventative footcare. **Hepatic injury:** Cases of hepatic injury have been reported with empagliflozin in clinical trials. A causal relationship between empagliflozin and hepatic injury has not been established. **Elevated haematocrit:** Haematocrit increase was observed with empagliflozin treatment. **Urine laboratory assessments:** Due to its mechanism of action, patients taking Jardiance will test positive for glucose in their urine. **Lactose:** The tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take this medicinal product. **Interactions:** Use with diuretics may increase the risk of dehydration and hypotension. Insulin and insulin secretagogues may increase the risk of hypoglycaemia therefore, a lower dose of insulin or an insulin secretagogue may be required. The effect of UGT induction (e.g. induction by rifampicin or phenytoin) on empagliflozin has not been studied. Co-treatment with known inducers of UGT enzymes is not recommended due to a potential risk of decreased efficacy. If an inducer of these UGT enzymes must be co-administered, monitoring of glycaemic control to assess response to Jardiance is appropriate. Interaction studies suggest that the pharmacokinetics of empagliflozin were not influenced by coadministration with metformin, glimepiride, pioglitazone, sitagliptin, linagliptin, warfarin, verapamil, ramipril, simvastatin, torasemide and hydrochlorothiazide. Interaction studies conducted in healthy volunteers suggest that empagliflozin had no clinically relevant effect on the pharmacokinetics of metformin, glimepiride, pioglitazone, sitagliptin, linagliptin, simvastatin, warfarin, ramipril, digoxin, diuretics and oral contraceptives. **Fertility, pregnancy and lactation:** There are no data from the use of empagliflozin in pregnant women. As a precautionary measure, it is preferable to avoid the use of Jardiance during pregnancy. No data in humans are available on excretion of empagliflozin into milk. Jardiance should not be used during breast-feeding. No studies on the effect on human fertility have been conducted for Jardiance. **Undesirable effects:** Frequencies are defined as very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$). Very common: hypoglycaemia (when used with sulphonylurea or insulin), volume depletion. Common: vaginal moniliasis, vulvovaginitis, balanitis and other genital infections, urinary tract infection (including pyelonephritis and urosepsis), thirst, constipation, pruritus (generalised), rash, increased urination, serum lipids increased. Uncommon: urticaria, angioedema, dysuria, blood creatinine increased/glomerular filtration rate decreased, haematocrit increased. Rare: necrotising fasciitis of the perineum (Fournier's gangrene), diabetic ketoacidosis. Prescribers should consult the Summary of Product Characteristics for further information on side effects. **Pack sizes:** 10 mg; 28 tablets, 25 mg: 28 tablets. **Legal category:** POM. **MA numbers:** 10 mg/28 tablets EU/1/14/930/013; 25 mg/28 tablets EU/1/14/930/004. **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, 55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. Additional information is available on request from Boehringer Ingelheim Ireland Ltd, The Crescent Building, Northwood, Santry, Dublin 9. **Prepared in July 2021.**

Adverse events should be reported. Reporting forms and information can be found at <https://www.hpra.ie/homepage/about-us/report-an-issue>. Adverse events should also be reported to Boehringer-Ingelheim Drug Safety on 01 2913960, Fax: +44 1344 742661, or by e-mail: PV_local_UK_Ireland@boehringer-ingelheim.com

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