Jardiance® (empagliflozin)

Click for Jardiance® (empagliflozin) UK prescribing information

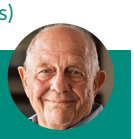
Trajenta® (linagliptin) 5mg tablets

Click for Trajenta® (linagliptin) UK prescribing information

This promotional document has been developed and funded by Boehringer Ingelheim for healthcare professionals in the UK and Ireland only. Republic of Ireland prescribing information for Trajenta® (linagliptin) and Jardiance® (empagliflozin), and adverse event reporting information for the UK and the Republic of Ireland is available on page 2.

All onboard? A case-based approach to managing T2D in adults with complex comorbidities

Case snapshots (fictional cases)



Fabian (61 y.o.)

History: T2D, hypertension, smoker, raised NT-proBNP (650 pg/mL)

Medications: metformin 1 g BD, CCB, statin

Diagnosis: HF with mildly reduced EF (LVEF 44%)

Action: Consider SGLT2i Jardiance® for HF and glycaemic control

Learning: NT-proBNP can guide early HF detection in T2D[1]

Moira (58 y.o.)

History: T2D, hypertension, ACR 28 mg/mmol, eGFR 85 mL/min/1.73 m^2

Medications: metformin 1 g BD, ARB, statin

Diagnosis: Early CKD (A2 albuminuria)

Action: Optimise BP, consider SGLT2i Jardiance® for renal protection

Learning: Albuminuria may precede eGFR decline – screen regularly[2]

Martha (79 y.o.)

History: T2D, CKD stage 3b, recent collapse

Medications: metformin 1 g BD, sulphonylurea, empagliflozin 10 mg/day, ACEi, statin

Diagnosis: Recurrent hypoglycaemia

Action: Discontinue sulphonylurea, and initiate Trajenta®

Learning: Trajenta® is generally well-tolerated in the elderly¶ and those with CKD and T2D[§3,8,9]

Medication insights

Jardiance® (empagliflozin) – Composite primary endpoints:

CKD – EMPA-KIDNEY

(3.6% ARR)*

28%

Relative risk reduction in kidney disease progression or CV death versus placebo[4]

HFrEF – EMPEROR-REDUCED

(5.3% ARR)†

25%

Relative risk reduction in CV death or HHF in LVEF ≤40% versus placebo[5]

HFmrEF and HFpEF – EMPEROR-PRESERVED

(3.3% ARR)‡

21%

Relative risk reduction in CV death or HHF in LVEF >40% versus placebo[6]

It is not recommended to initiate treatment with Jardiance® in patients with an eGFR <20 ml/min/1.73 m^2.[7]

Trajenta® (linagliptin)

- Trajenta® has demonstrated efficacy in adults, including elderly patients over the age of 75 versus placebo when used as a monotherapy or an add-on therapy (post-hoc)[§8]
- Efficacy of Trajenta® remains consistent across all stages of kidney function in eligible patients with T2D[¶9,10]
- Trajenta® is always 5 mg once daily, with no need for dose adjustments in renal impairment[3]

Safety information

The most frequently reported adverse event for Trajenta® was hypoglycaemia when given in combination with metformin plus a sulphonylurea. When Trajenta® is used in combination with a sulphonylurea and/or insulin, caution is advised and a dose reduction of the sulphonylurea or insulin may be considered.

The most frequently reported adverse event for Jardiance® was hypoglycaemia when given with a sulphonylurea or insulin. When Jardiance® is used in combination with a sulphonylurea and/or insulin, a lower dose of the sulphonylurea or insulin may be considered.

Therapeutic indications

Trajenta® is indicated in adults with type 2 diabetes as an adjunct to diet and exercise to improve glycaemic control as monotherapy (when metformin is inappropriate due to intolerance, or contraindicated due to renal impairment) and in combination therapy.

Jardiance® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes as an adjunct to diet and exercise as monotherapy (when metformin is inappropriate due to intolerance) and in combination therapy. Jardiance® is indicated in adults for the treatment of chronic kidney disease. Jardiance® is indicated in adults for the treatment of symptomatic chronic heart failure.

* HR=0.72; 95% CI: 0.64, 0.82; p<0.001. † HR=0.75; 95% CI: 0.65, 0.86; p<0.001. ‡ HR=0.79; 95% CI: 0.69, 0.90; p<0.001; §Data based on post-hoc subgroup analysis from pooled data; ¶Data based on pooled analysis and randomised control trials where Trajenta® was given as either monotherapy or an add-on therapy.

ACEi: angiotensin-converting enzyme inhibitor; **ACR:** albumin-to-creatinine ratio; **ARB:** angiotensin II receptor blocker; **ARR:** absolute risk reduction; **BD:** twice daily; **BP:** blood pressure; **CCB:** calcium channel blockers; **CKD:** chronic kidney disease; **CV:** cardiovascular; **EF:** ejection fraction; **eGFR:** estimated glomerular filtration rate; **HF:** heart failure; **HFpEF:** heart failure with preserved ejection fraction; **HFrEF:** heart failure with reduced ejection fraction; **HHF:** hospitalisation for heart failure; **LVEF:** left ventricular ejection fraction; **NT-proBNP:** N-terminal pro-B-type natriuretic peptide; **SGLT2i:** sodium-glucose cotransporter-2 inhibitor; **T2D:** type 2 diabetes.

Please review the Summary of Product Characteristics for TRAJENTA (linagliptin) and JARDIANCE (empagliflozin) for the full information on dosing, adverse events, contraindications, special warnings and precautions for use before prescribing. Available at: www.medicines.org.uk (UK) and https://www.medicines.ie (ROI).

1. NICE guideline. NG106. Available at: https://www.nice.org.uk/guidance/ng106 (accessed August 2025); 2. Kidney Disease: Improving Global Outcomes CKD Work Group. Kidney Int. 2024;105:S117–S314; 3 TRAJENTA (linagliptin) Summary of product characteristics. Available at: www.medicines.org.uk (UK) and https://www.medicines.ie (ROI) (accessed August 2025); 4. Herrington WG et al. N Engl J Med. 2023;388(2):117–127; 5. Packer M et al. N Engl J Med. 2020;383(15):1413–1424; 6. Anker SD et al. N Engl J Med. 2021;385(16):1451–1461; 7. JARDIANCE (empagliflozin) Summary of Product Characteristics. Available at: www.medicines.org.uk (UK) and https://www.medicines.ie (ROI) (accessed August 2025); 8. Del Prato S et al. Nutr Metab Cardiovasc Dis. 2016;26:886–892; 9. Groop PH et al. Diabetes Obes Metab. 2014;16:560–568; 10. McGill JB et al. Diabetes Care. 2013;36:237–244.

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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 combination of therapies, effects on glycaemic control, cardiovascular and renal 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. Chronic kidney disease: Jardiance is indicated in adults for the treatment of chronic kidney disease. 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 m^2 and need tighter glycaemic control, the dose can be increased to 25 mg once daily. The maximum daily dose is 25 mg. Heart failure: The recommended dose is 10 mg empagliflozin once daily. Chronic kidney disease: The recommended dose is 10 mg empagliflozin once daily. 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. Special populations: *Renal impairment:* Due to limited experience, it is not recommended to initiate treatment with empagliflozin in patients with an eGFR <20 ml/min/1.73 m^2. In patients with an eGFR <60 ml/min/1.73 m^2 the daily dose of empagliflozin is 10 mg. In patients with type 2 diabetes mellitus, the glucose lowering efficacy of empagliflozin is reduced in patients with an eGFR <45 ml/min/1.73 m^2 and likely absent in patients with an eGFR <30 ml/min/1.73 m^2. Therefore, if eGFR falls below 45 ml/min/1.73 m^2, additional glucose lowering treatment should be considered if needed. *Monitoring of renal function:* Assessment of renal function is recommended prior to initiation and at least annually; prior to initiation of any concomitant medicinal product that may have a negative impact on renal function. *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. *Paediatric population:* Refer to Summary of Product Characteristics. 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:** Empagliflozin should not be used in patients with Type 1 diabetes mellitus. *Ketoacidosis:* Cases of ketoacidosis, including life-threatening and fatal cases, have been reported in patients with diabetes mellitus treated with SGLT2 inhibitors, including empagliflozin. Although ketoacidosis is less likely to occur in patients without diabetes mellitus, cases have also been reported in these patients. 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. Prolonged ketoacidosis and prolonged glucosuria have been observed with empagliflozin. Ketoacidosis may last longer after discontinuation of empagliflozin than expected from the plasma half-life. Use with caution in patients who may be at higher risk of ketoacidosis. Restarting SGLT2 inhibitor treatment in patients with previous ketoacidosis while on SGLT2 inhibitor treatment is not recommended, unless another clear precipitating factor is identified and resolved. Jardiance should not be used in patients with Type 1 diabetes. *Renal impairment:* See under 'renal impairment' of Dose and administration section. *Monitoring of renal function:* See under 'monitoring of renal function' of Dose and administration section. *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 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. Patients with pronounced elevations in haematocrit should be monitored and investigated for underlying haematological disease. *Chronic kidney disease:* Patients with albuminuria may benefit more from treatment with empagliflozin. Infiltrative disease or Takotsubo cardiomyopathy: Patients with infiltrative disease or Takotsubo cardiomyopathy have not been specifically studied. Therefore, efficacy in these patients has not been established. *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. *Sodium:* Each tablet contains less than 1 mmol sodium (23 mg), essentially 'sodium free'. **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. Empagliflozin may increase renal lithium excretion and the blood lithium levels may be decreased. Serum concentration of lithium should be monitored more frequently after empagliflozin initiation and dose changes. 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 (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1 000 to <1/100), rare (≥1/10 000 to <1/1 000), very rare (<1/10 000). 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: ketoacidosis, urticaria, angioedema, dysuria, blood creatinine increased/glomerular filtration rate decreased, haematocrit increased. Rare: necrotising fasciitis of the perineum (Fournier's gangrene). Very rare: tubulointerstitial nephritis. Cases of phimosis/acquired phimosis have been reported concurrent with genital infections and in some cases, circumcision was required. 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, 4045 Kingswood Road, Citywest Business Campus, D24 V06K. **Prepared in February 2025**.

Prescribing Information (Ireland) TRAJENTA® (Linagliptin)

Film-coated tablets containing 5 mg linagliptin. **Indication:** Trajenta is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control as: monotherapy when metformin is inappropriate due to intolerance, or contraindicated due to renal impairment; combination therapy in combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycaemic control. **Dose and Administration:** 5 mg once daily. If added to metformin, the dose of metformin should be maintained and linagliptin administered concomitantly. When used in combination with a sulphonylurea or with insulin, a lower dose of the sulphonylurea or insulin, may be considered to reduce the risk of hypoglycaemia. *Renal impairment:* no dose adjustment required. *Hepatic impairment:* pharmacokinetic studies suggest that no dose adjustment is required for patients with hepatic impairment but clinical experience in such patients is lacking. *Elderly:* no dose adjustment is necessary based on age. *Paediatric population:* a clinical trial did not establish efficacy in paediatric patients 10 to 17 years of age. Therefore, treatment of children and adolescents with linagliptin is not recommended. Linagliptin has not been studied in paediatric patients under 10 years of age. The tablets can be taken with or without a meal at any time of the day. If a dose is missed, it should be taken as soon as possible but a double dose should not be taken on the same day. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and Precautions:** Linagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. *Hypoglycaemia:* Caution is advised when linagliptin is used in combination with a sulphonylurea and/or insulin; a dose reduction of the sulphonylurea or insulin may be considered. *Acute pancreatitis:* Acute pancreatitis has been observed in patients taking linagliptin. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, Trajenta should be discontinued. If acute pancreatitis is confirmed, Trajenta should not be restarted. Caution should be exercised in patients with a history of pancreatitis. *Bullous pemphigoid:* Bullous pemphigoid has been observed in patients taking Linagliptin. If bullous pemphigoid is suspected, Trajenta should be discontinued. **Interactions:** Linagliptin is a weak competitive and a weak to moderate mechanism-based inhibitor of CYP isozyme CYP3A4, but does not inhibit other CYP isozymes. It is not an inducer of CYP isozymes. Linagliptin is a P-glycoprotein substrate and inhibits P-glycoprotein mediated transport of digoxin with low potency. Based on these results and in vivo interaction studies, linagliptin is considered unlikely to cause interactions with other P-glycoprotein substrates. *Effects of other medicinal products on linagliptin:* Based on in vivo assessment of selected interactions, clinical data suggest that the risk for clinically meaningful interactions by co-administered medicinal products is low. *Rifampicin:* Multiple co-administration of 5 mg linagliptin with rifampicin, a potent inductor of P-glycoprotein and CYP3A4, decreased linagliptin steady state AUC and Cmax. Thus, full efficacy of linagliptin in combination with strong P-glycoprotein inducers might not be achieved, particularly if administered long term. Coadministration with other potent inducers of P-glycoprotein and CYP3A4, such as carbamazepine, phenobarbital and phenytoin has not been studied. *Ritonavir:* Co-administration with single dose 5 mg linagliptin with ritonavir, a potent inhibitor of P-glycoprotein and CYP3A4, increased the AUC and Cmax of linagliptin. These changes in linagliptin pharmacokinetics were not considered to be clinically relevant. Therefore, clinically relevant interactions would not be expected with other P-glycoprotein/CYP3A4 inhibitors. *Effects of linagliptin on other medicinal products:* In clinical studies linagliptin had no clinically relevant effect on the pharmacokinetics of metformin, glibenclamide, simvastatin, warfarin, digoxin or oral contraceptives (please refer to Summary of Product Characteristics for a full list of interactions and clinical data). **Fertility, pregnancy and lactation:** The use of linagliptin has not been studied in pregnant women. As a precautionary measure, avoid use during pregnancy. A risk to the breast-fed child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from linagliptin therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman. No studies on the effect on human fertility have been conducted for linagliptin. **Undesirable effects:** Adverse reactions reported in patients who received linagliptin 5 mg daily as monotherapy or as add-on therapies in clinical trials and from post-marketing experience. Frequencies are defined as very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000) or very rare (<1/10,000). Adverse reactions with linagliptin 5 mg daily as monotherapy: *Common:* lipase increased. *Uncommon:* nasopharyngitis; hypersensitivity; cough; rash; amylase increased. *Rare:* pancreatitis; angioedema; urticaria; bullous pemphigoid. Adverse reaction with linagliptin in combination with metformin plus sulphonylurea: *Very common:* hypoglycaemia. Adverse reaction with linagliptin in combination with insulin: *Uncommon:* constipation. Prescribers should consult the Summary of Product Characteristics for further information on side effects. **Pack sizes:** 28 tablets. **Legal category:** POM. **MA number:** EU/1/11/707/003. **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, 4045 Kingswood Road, Citywest Business Campus, D24 V06K. **Prepared in** August 2024.

Adverse events should be reported. Reporting forms and information can be found at https://www.mhra.gov.uk/yellowcard (UK) or https://www.hpra.ie/homepage/about-us/report-an-issue (IRE). Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone) (UK) or 01 2913960 (IRE), Fax: +44 1344 742661, or by e-mail: PV_local_UK_Ireland@boehringer-ingelheim.com

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