







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 the practical management of type 2 diabetes during Ramadan and periods of fasting

-  Ramadan lasts from the pre-dawn meal (**sahur**) to the sunset meal (**iftar**) for 29–30 days
-  **Fasting:** abstinence from food, drink, smoking and consuming oral medications
-  **40–50 million** people with diabetes fast worldwide during Ramadan¹

Trajenta and Jardiance are not indicated for the treatment of type 1 diabetes

Risks during Ramadan for people with T2D²

-  **7.5-fold** increased incidence of **severe hypoglycaemic** complications in people with T2D compared with non-Ramadan periods
-  Increased risk of hyperglycaemia if **medications are over-reduced** or there is **overconsumption of calories** upon breaking the fast
-  Increased risk of **dehydration** and **thrombosis** compared to those who don't fast

Medication and insulin modifications during Ramadan^{3–5}

Dose adjustments generally required:

- Metformin
- SUs
- Insulin secretagogues
- Insulin

Dose adjustments usually NOT required:

- SGLT2 inhibitors (if established on a tolerable dose)
- DPP-4 inhibitors
- TZDs
- GLP-1 receptor agonists (if established on a tolerable dose)

When linagliptin or empagliflozin is used in combination with an SU or insulin, a lower dose of the SU or insulin may be considered to reduce the risk of hypoglycaemia^{6,7}

Case snapshots (fictional cases)

Mrs Bibi (66 years old)



History: Diagnosed with T2D. Multiple comorbidities: CKD (stage 3a), CVD, hypertension. HbA1c 86 mmol/mol. Her family express concerns about Mrs Bibi wishing to fast, given her recent decline in health

Risk assessment and next steps:

Risk: High risk, may choose not to fast. Stable, comorbid CVD and CKD³

Next steps: Assess uACR to further determine CKD status. Assess weight, cholesterol levels and blood pressure control. Check currently prescribed diabetes medications for risk of hypoglycaemia and adjust accordingly³

Mr Ahmed (56 years old)



History: No previous issues when fasting. Six months post-AIS, CVD and hypertension. HbA1c 58 mmol/mol, BP 120/75 mmHg, LDL-C 1.4 mmol/L, BMI 28 kg/m², eGFR 55 mL/min/1.73 m²

Medications: Atorvastatin 80 mg OD, metformin 500 mg BD, ezetimibe 10 mg OD, ramipril 10 mg OD, aspirin 75 mg OD, bisoprolol 2.5 mg OD

Risk assessment and medication changes:

Risk: High risk, may choose not to fast. Stable, comorbid CVD and increased risk of CKD³

Medication changes: No change to total daily metformin dose. Majority of medication to be taken in the evening (at *iftar*)³

Mrs Khan (72 years old)



History: T2D and reports feeling shaky occasionally, hypertension. HbA1c 68 mmol/mol, BP 155/85 mmHg, LDL-C 2.0 mmol/L, BMI 28 kg/m², eGFR >60 mL/min/1.73 m², uACR 2.5 mg/mmol

Medications: Atorvastatin 20 mg OD, metformin 500 mg TDS, gliclazide 80 mg BD

Risk assessment and medication changes:

Risk: High risk, may choose not to fast. Moderate hypoglycaemia; shakiness could be hypoglycaemia, advise accordingly (if recurrent, very high risk – do not fast)³

Medication changes: Consider stopping/reducing gliclazide. No change to total daily metformin dose; lunchtime metformin dose to be combined and taken with the evening dose (at *iftar*)^{3,4}

For more information on risk assessment and medication and insulin modifications during Ramadan and periods of fasting, please access:

Recommendations for management of diabetes during Ramadan: update 2020, applying the principles of the ADA/EASD consensus³ - available at:

<https://drc.bmj.com/content/bmjdr/8/1/e001248.full.pdf>

Recommendations for the management of diabetes during Ramadan applying the principles of the ADA/EASD consensus: Update 2025⁴ - available at:

<https://onlinelibrary.wiley.com/doi/10.1002/dmrr.70057>

ADA: American Diabetes Association; AIS: acute ischaemic stroke; BD: twice daily; BMI: body mass index; BP: blood pressure; CKD: chronic kidney disease; CVD: cardiovascular disease; DPP-4i: dipeptidyl peptidase-4 inhibitor; EASD: European Association for the Study of Diabetes; eGFR: estimated glomerular filtration rate; GLP-1: glucagon-like peptide-1; HbA1c: glycated haemoglobin; LDL-C: low-density lipoprotein cholesterol; OD: once daily; SGLT2: sodium-glucose cotransporter-2; SMBG: self-monitoring of blood glucose; SU: sulphonylurea; TDS: three times a day; TZD: thiazolidinedione; T2D: type 2 diabetes; uACR: urine albumin-to-creatinine ratio.

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 www.medicines.ie (ROI).

1. Ahmed MH, Abdu TA. *Ann Saudi Med*. 2011;31(4):402–406; 2. International Diabetes Federation. Diabetes and Ramadan Practical Guidelines. 2021. Available at: https://idf.org/media/uploads/2024/07/IDF_DaR_Practical_Guidelines_Ramadan.pdf (accessed November 2025); 3. Ibrahim M, et al. *BMJ Open Diabetes Res Care*. 2020;8(1):e001248; 4. Ibrahim M, et al. *Diabetes Metab Res Rev*. 2025;41(5):e70057; 5. International Diabetes Federation. Diabetes and Ramadan Practical Guidelines. 2021. Available at: https://idf.org/media/uploads/2024/07/IDF_DaR_Practical_Guidelines_Ramadan.pdf (accessed November 2025); 6. Trajenta® (linagliptin) Summary of Product Characteristics. Available at: www.medicines.org.uk/emc/ (UK), and www.medicines.ie/medicines (IRE) (accessed November 2025); 7. Jardiance® (empagliflozin) Summary of Product Characteristics. Available at: www.medicines.org.uk/emc/ (UK), and www.medicines.ie/medicines (IRE) (accessed November 2025).

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 m² 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 m². In patients with an eGFR < 60 ml/min/1.73 m² 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 m² and likely absent in patients with an eGFR < 30 ml/min/1.73 m². Therefore, if eGFR falls below 45 ml/min/1.73 m², 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 ($\geq 1/10$), 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 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 inducer of P-glycoprotein and CYP3A4, decreased linagliptin steady state AUC and C_{max}. 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 C_{max} 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 ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1\,000$ to $< 1/100$), rare ($\geq 1/10\,000$ to $< 1/1\,000$) 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