When it comes to DPP-4 inhibition

TRAJENTA® (linagliptin): The only approved DPP-4i that does not require dose reduction based on renal function [1*]

Dosing adjustment based on renal function as defined by SmPC †

	Normal function	Mild impairment	Moderate impairment		Severe impairment/ESRD
TRAJENTA® (linagliptin) [1]	5 mg OD				
sitagliptin [2‡]	100 mg OD	100 mg OD GFR ≥60 to <90 ml/min	100 mg OD GFR ≥45 to <60 ml/min	50 mg OD GFR ≥30 to <45 ml/min	25 mg OD GFR ≥15 to <30 ml/min; ESRD (GFR <15 ml/min) including on haemodialysis or peritoneal dialysis
vildagliptin [3]	50 mg BD 50 mg OD with an SU	50 mg BD 50 mg OD with an SU CrCl 50 to <80 ml/min	50 mg OD CrCl 30 to <50 ml/min		50 mg OD CrCl <30 ml/min ESRD on haemodialysis: use with caution
saxagliptin [4‡]	5 mg OD	5 mg OD GFR ≥60 to <90 ml/min	5 mg OD GFR ≥45 to <60 ml/min	2.5 mg OD GFR ≥30 to <45 ml/min	2.5 mg OD GFR <30 ml/min ESRD on haemodialysis: not recommended
alogliptin [5#‡]	25 mg OD	25 mg OD CrCl >50 to ≤80 ml/min	12.5 mg OD CrCl ≥30 to ≤50 ml/min		6.25 mg OD CrCl <30 ml/min Limited experience in renal dialysis. Not studied in peritoneal dialysis

For individual guidance on DPP-4 inhibitor dosing in renal impairment please refer to the individual product SmPC

Adapted from:
1. TRAJENTA® SmPC 2. Sitagliptin SmPC 3. Vildagliptin SmPC 4. Saxagliptin SmPC
5. Alogliptin SmPC

* Summary of Product Characteristics for sitagliptin, alogliptin, vildagliptin and saxagliptin are available at: www.medicines.org.uk

† As defined by respective Summaries of Product Characteristics.

‡ Assessment of renal function is recommended prior to initiation and periodically thereafter.

Not indicated as monotherapy.

GFR: Glomerular filtration rate **CrCl**: Creatinine Clearance (based on Cockcroft-Gault formula)
OD: Once daily **BD**: Twice daily **SU**: Sulphonylurea **ESRD**: End-stage renal disease

Trajenta®
(linagliptin) 5mg tablets

Prescribing information can be found on the next page

PC-GB-103814 V1 March 2021

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References:

1. TRAJENTA® (linagliptin) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/4762/smpc.
2. Sitagliptin Summary of Product Characteristics May 2020. Available at: https://www.medicines.org.uk/emc/product/7888/smpc.
3. Vildagliptin Summary of Product Characteristics October 2020. Available at: https://www.medicines.org.uk/emc/product/6225/smpc.
4. Saxagliptin Summary of Product Characteristics March 2020. Available at: https://www.medicines.org.uk/emc/product/6675/smpc.
5. Alogliptin Summary of Product Characteristics May 2018. Available at: https://www.medicines.org.uk/emc/product/7572/smpc.

Prescribing Information (UK) 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: the safety and efficacy of linagliptin in children and adolescents has not yet been established. No data are available. Take the tablets 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. 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 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 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. The risk for clinically meaningful interactions by other medicinal products on linagliptin is low and 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 information on clinical data). **Fertility, pregnancy and lactation:** 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 breast-feeding 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 and NHS price:** 28 tablets £33.26. **Legal category:** POM. **MA number:** EU/1/11/707/003. **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. **Prepared in** December 2019.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone).

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