







 Krass I et al (2015) Diabet Med 32: 725-37
 García-Pérez LE et al (2013) Diabetes Ther 4: 175-94 Cuevas H, Stuifbergen A (2017) J Diabetes Metab Disord **16:** 7 Linetzky B et al (2017) J Diabetes 9: 596-605 Munshi MN et al (2013) Diabetes Care 36: 543-9 Harrison G (2014) J Diabetes Nursing 18: 362-8 Britt E et al (2004) Patient Educ Couns 53: 147-55 Holmen H et al (2016) BMJ Open Diabetes 4: e000193 Inzucchi SE et al (2015) Diabetes Care 38: 140-9 10. NHS Digital (2017) National Diabetes Audit. Report 1: Care Processes and Treatment Targets. Available at: http://bit.ly/2kZOW7T (accessed 24.07.2017)

11. American Diabetes Association (2017) Diabetes Care 40: (suppl): S1-135

12. Linagliptin Summary of Product Characteristics (SPC). Available at: http://bit.ly/1lzKcKy (accessed 24.07.2017) 13. Epstein et al (2008) Fam Pract Manag 15: 35-40

TRAJENTA® 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:

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

monotherapy when metformin is inappropriate due to intolerance, or

Seek confirmation and commitment from the patient

OmniaMed

Prescribing Information (UK)

This infographic was sponsored by the Boehringer Ingelheim and Boehringer Ingelheim Lilly Diabetes Alliance. OmniaMed SB has provided editorial support. The content has been developed in conjunction with a Programme Steering Committee. Prescribing information and adverse event reporting information can be found at the end of this infographic. **Job code:** UK/TRJ/00635h **Date of preparation:** August 2017

reactions reported in patients who received linagliptin 5 mg daily as

monotherapy or as add-on therapies (frequencies identified from pooled analysis of placebo-controlled studies) in clinical trial and from

post-marketing experience. The adverse reactions are listed by absolute

frequency. 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) or not known (cannot

be estimated from the available data). Very common: hypoglycaemia

(combination with/add-on to metformin and sulphonylurea). Common:

lipase increased (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea: combination

with/add-on to insulin; combination with/add-on to metformin and

empagliflozin). Uncommon: nasopharyngitis (monotherapy; combination with/add-on to metformin; combination with/add-on to insulin);

hypersensitivity e.g. bronchial hyperreactivity (monotherapy;

combination with/add-on to metformin; combination with/add-on to

Abbreviations

DPP-4, dipeptidyl peptidase-4

Make change manageable

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 however, clinical experience in patients > 80 years of age is limited and caution should be exercised when treating this population. 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: In post-marketing experience of linagliptin there have been spontaneously reported adverse reactions of acute pancreatitis. 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: 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-gp 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

metformin and sulphonylurea; combination with/add-on to insulin); cough (monotherapy; combination with/add-on to metformin; combination with/add-on to insulin); pancreatitis (combination with/add-on to insulin); constipation (combination with/add-on to insulin); rash (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination

with/add-on to insulin); amylase increased (combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to metformin and empagliflozin). Rare: angioedema (monotherapy: combination with/add-on to metformin: combination with/add-on to metformin and sulphonylurea; combination with/add-on to insulin); urticaria (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to insulin); amylase increased (monotherapy). Not known: nasopharyngitis (combination with/add-on to metformin and sulphonylurea; combination with/add-on to metformin and empagliflozin); hypersensitivity e.g. bronchial hyperreactivity (combination with/add-on to metformin and empagliflozin); cough (combination with/add-on to metformin and sulphonylurea; combination with/add-on to metformin and empagliflozin); pancreatitis (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to metformin and empagliflozin); bullous pemphigoid (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to insulin); amylase increased (combination with/add-on to insulin). 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** April 2017.

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).