Prescribing information and Adverse events reporting details are available on page 6

Trajenta®

(linagliptin) 5mg tablets

When a DPP-4 inhibitor is needed

Choose Simplicity.

for a BROAD RANGE of adult patients with type 2 diabetes (T2D)

5mg once daily

UNIQUE CONVENIENCE

through always one dose, once daily [1]

Demonstrated

CV AND KIDNEY SAFETY PROFILE [2,3]

HbA1c

PROVEN EFFICACY VS PLACEBO

for your adult T2D patients [1,4]

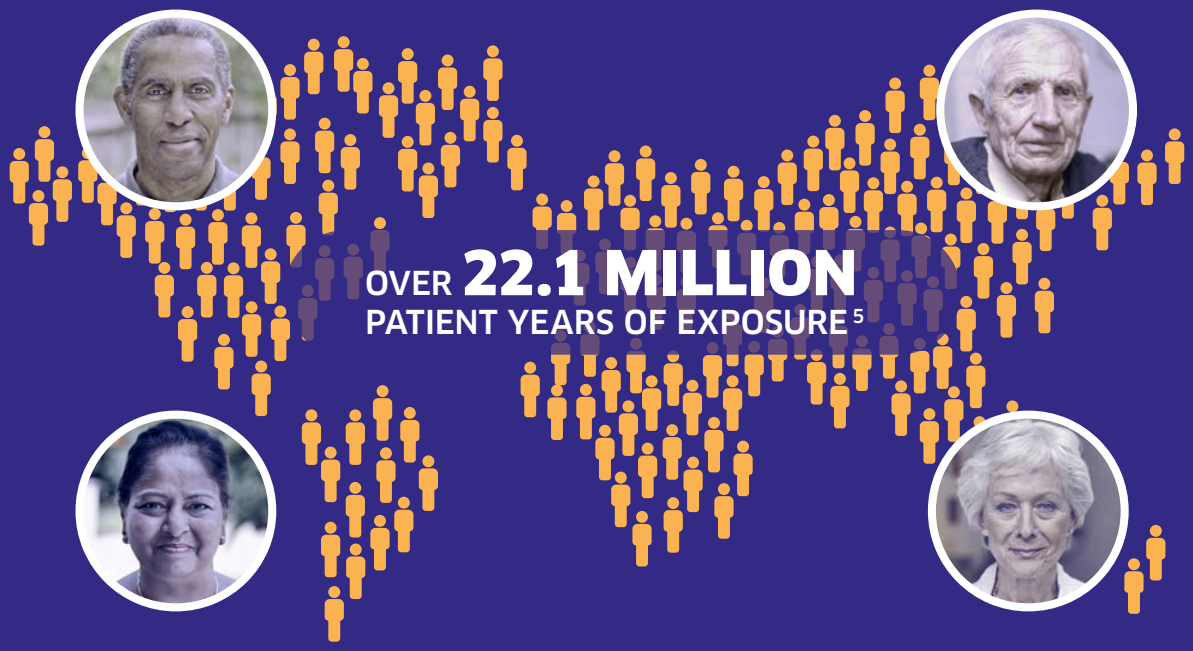
TRAJENTA® (linagliptin) is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control as:

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 (see sections 4.4, 4.5 and 5.1 of the SmPC for available data on different combinations).

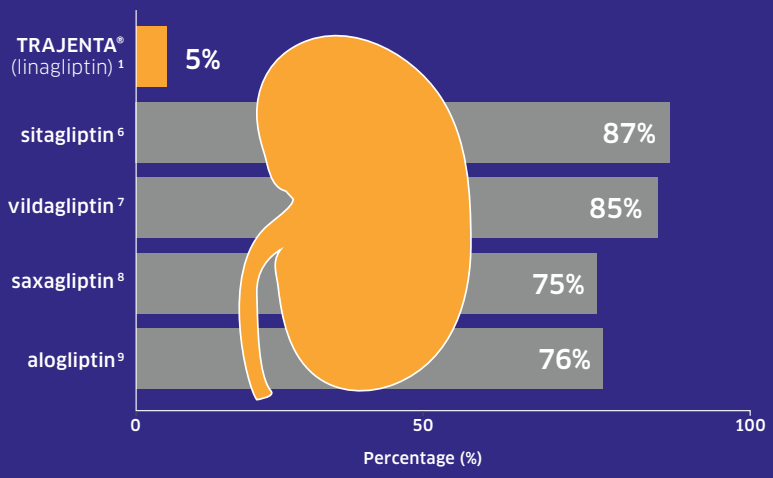
Boehringer Ingelheim

Physicians and T2D patients worldwide rely on **more than 10 years of Simplicity** experience with TRAJENTA®.[5]



TRAJENTA® is different:
excreted primarily via the bile [1,6-9]

Proportions of medication excreted via the kidney



Unique convenience
through always one dose, once daily [1]

Independent of:

Adapted from: 1. TRAJENTA® SmPC. 6. Sitagliptin SmPC.
7. Vildagliptin SmPC. 8. Saxagliptin SmPC. 9. Alogliptin SmPC.

* Pharmacokinetic studies suggest that no dose adjustment is required for patients with hepatic impairment but clinical experience in such patients is lacking (TRAJENTA® SmPC).

† Sulphonylureas and insulin are known to cause hypoglycaemia. Therefore, 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 (TRAJENTA® SmPC).

NB Please note, Alogliptin is not marketed in the Republic of Ireland.

BMI: Body mass index; **T2D:** Type 2 diabetes

Trajenta®
(linagliptin) 5mg tablets

TRAJENTA® demonstrated its **long-term safety profile** across a broad range of T2D patients.[2,3]

CARMELINA®
A CV and kidney outcome study with linagliptin

T2D patients with established CV and/or kidney disease [2,11*]

n=6,979
TRAJENTA® vs. placebo

2.2 years median follow-up

CAROLINA®
A CV outcome study of linagliptin versus glimepiride

Relatively early T2D patients at increased CV risk [3,12]

n=6,033
TRAJENTA® vs. glimepiride

6.3 years median follow-up

BROAD RANGE OF T2D PATIENTS

CV safety profile [2†‡] (vs. placebo)

HR: 1.02 (95% CI, 0.89, 1.17); p=0.74 for superiority
p<0.001 for non-inferiority

Not associated with increased risk of HHF (vs. placebo)

HR: 0.90 (95% CI, 0.74, 1.08); p=0.26 for superiority

Kidney safety profile [2#**]

HR: 1.04 (95% CI, 0.89, 1.22); p=0.62

A sequentially rejective multiple test procedure was applied, first testing the primary hypothesis of non-inferiority for linagliptin, and, only if this first test was significant, followed by 2 parallel confirmatory superiority tests: 3-point MACE and the secondary kidney outcome. Primary outcome met the non-inferiority criterion. Both the tests for superiority outcomes were not met so all analyses subsequent to the primary analysis are considered exploratory.

Long-term CV safety profile [3††] (vs. glimepiride)

HR: 0.98 (95% CI, 0.84, 1.14); p=0.76 for superiority
p<0.0001 for non-inferiority

Lower risk of hypoglycaemia [3‡‡] (vs. glimepiride)

Incidence of ≥1 episode of hypoglycaemic event was lower with linagliptin (n=320 (10.6%)) vs. glimepiride (n=1132 (37.7%)) across all predefined hypoglycaemia-severity categories
HR: 0.23 (95% CI, 0.21, 0.26)

Hierarchical testing strategy was used starting with testing for non-inferiority of linagliptin vs. glimepiride for the time to 3P-MACE. This primary outcome was achieved. The subsequent significance testing was not met including superiority for the primary outcome and secondary outcomes which should be interpreted as exploratory.

CARMELINA® - CArdiovascular safety and Renal Microvascular outcomE study with LINAgliptin
CAROLINA® - CARdiovascular Outcome study of LINAgliptin versus glimepiride in patients with type 2 diabetes

* CARMELINA® included patients with albuminuria & previous macrovascular disease, and/or impaired kidney function with or without CV comorbidities.

† When added to standard of care.

‡ The CARMELINA® primary endpoint was time to first occurrence of any of the following components: CV death, non-fatal MI, non-fatal stroke. The primary endpoint occurred in 434/3,494 (12.4%) and 420/3,485 (12.1%) patients in the linagliptin and placebo groups, respectively (HR: 1.02 (95% CI, 0.89, 1.17) non-inferiority p<0.001).

\# The CARMELINA® key secondary endpoint was time to first occurrence of any of the following components: Death due to kidney disease, sustained ESRD or a sustained decrease of ≥40% in eGFR from baseline. The key secondary kidney endpoint occurred in 327/3,494 (9.4%) and 306/3,485 (8.8%) patients in the linagliptin and placebo groups, respectively (HR: 1.04 (95% CI, 0.89, 1.22) p=0.62).

** Test for superiority did not achieve statistical significance.

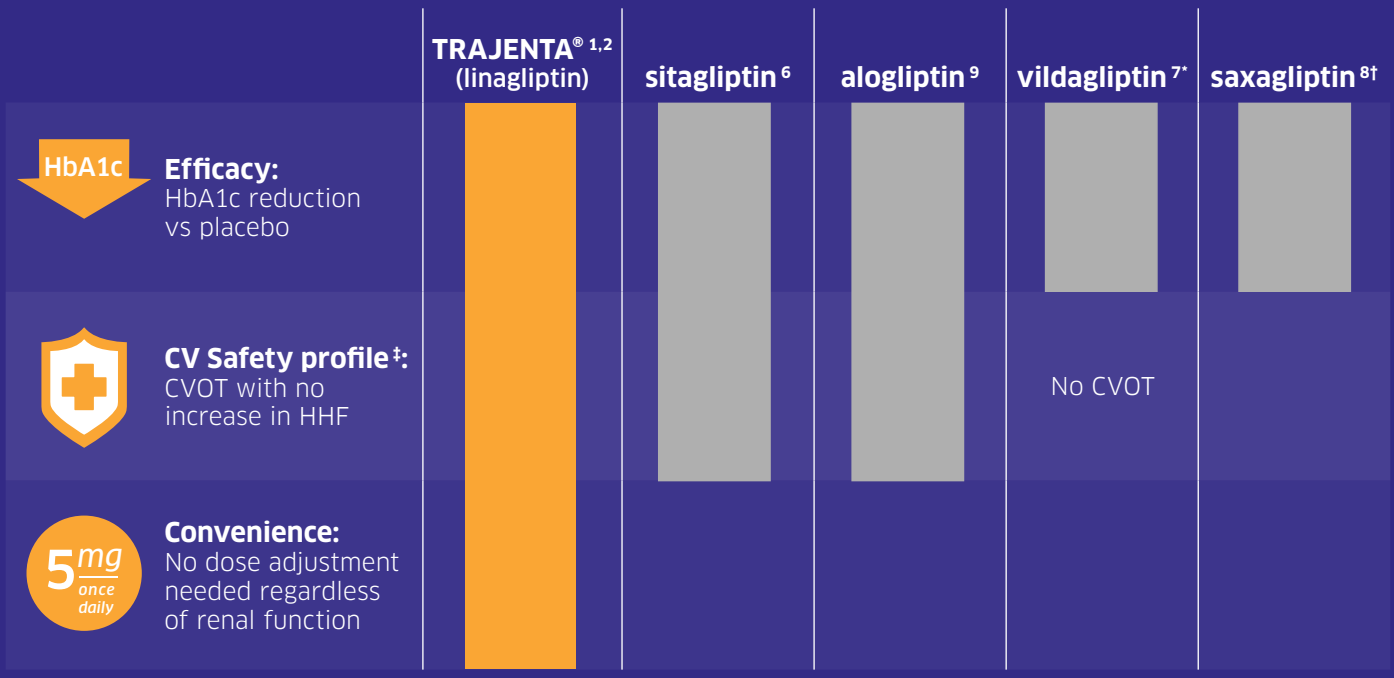
†† The CAROLINA® primary endpoint was time to first occurrence of any of the following components: CV death, non-fatal MI, non-fatal stroke. The primary endpoint occurred in 356/3,023 (11.8%) and 362/3,010 (12.0%) patients in the linagliptin and glimepiride groups, respectively (HR: 0.98 (95% CI, 0.84, 1.14) non-inferiority p<0.0001).

‡‡ Time to first occurrence of any hypoglycaemic adverse event within the treated set (events occurring between first study drug intake until 7 days after last permanent study drug stop). Percentage of patients experiencing a hypoglycaemic event was 10.6% for linagliptin and 37.7% for glimepiride (HR: 0.23 (95% CI, 0.21, 0.26) non-inferiority p<0.0001).

CI: Confidence intervals; **CV:** Cardiovascular; **CVOT:** Cardiovascular outcomes trial; **HHF:** Hospitalisation for heart failure; **HR:** Hazard ratio **T2D:** Type 2 diabetes

Trajenta®
(linagliptin) 5mg tablets

TRAJENTA®: Meeting the needs of your adult patients with T2D.[1,2]



‡ These are not head-to-head comparisons. For illustration only, due to differences in study design, inclusion criteria and population direct comparisons cannot and should not be made. The primary endpoint in each CVOT of 3P MACE met the endpoint for non-inferiority.




Could more of your adult T2D patients benefit from the Simplicity of TRAJENTA®?

TRAJENTA®: The only approved DPP-4i that does not require dose reduction based on renal function [1,6-9#]

* Vildagliptin does not have a CVOT.

† Saxagliptin has a CVOT that showed non-inferiority for the primary composite endpoint (time to first occurrence of 3 point MACE [CV death, non-fatal myocardial infarction or non-fatal ischaemic stroke]). Hospitalisation for heart failure occurred at a greater rate in the saxagliptin group (3.5%) compared with the placebo group (2.8%); (HR=1.27 [95% CI, 1.07, 1.51; p=0.007]).

\# Summary of Product Characteristics for sitagliptin, alogliptin, vildagliptin and saxagliptin are available at www.medicines.org.uk (GB) and www.emcmedicines.com/en-GB/northernireland/(NI) and www.medicines.ie (IE).

NB Please note, Alogliptin is not marketed in the Republic of Ireland.

BMI: Body mass index; **T2D:** Type 2 diabetes

Trajenta® (linagliptin) 5mg tablets

References:

1. TRAJENTA® (linagliptin) Summary of Product Characteristics. SmPCs available at EMC: www.medicines.org.uk (GB) and www.emcmedicines.com/en-GB/northernireland/ (NI) and www.medicines.ie (IE).
2. Rosenstock J, *et al.* JAMA. 2019;321(1):69–79.
3. Rosenstock J, *et al.* JAMA. 2019;322(12):1155–1166.
4. McGill JB, *et al.* Diabetes Care. 2013;36:237–44.
5. TRAJENTA® global patient data. Data on File, Boehringer Ingelheim, 16 September 2020.
6. Sitagliptin Summary of Product Characteristics. SmPCs available at EMC: www.medicines.org.uk (GB) and www.emcmedicines.com/en-GB/northernireland/ (NI) and www.medicines.ie (IE).
7. Vildagliptin Summary of Product Characteristics. SmPCs available at EMC: www.medicines.org.uk (GB) and www.emcmedicines.com/en-GB/northernireland/ (NI) and www.medicines.ie (IE).
8. Saxagliptin Summary of Product Characteristics. SmPCs available at EMC: www.medicines.org.uk (GB) and www.emcmedicines.com/en-GB/northernireland/ (NI) and www.medicines.ie (IE).
9. Alogliptin Summary of Product Characteristics. SmPCs available at EMC: www.medicines.org.uk (GB) and www.emcmedicines.com/en-GB/northernireland/ (NI).
10. Lajara R, *et al.* Clin Ther. 2014;36(11):1595–605.
11. Rosenstock J, *et al.* Cardiovasc Diabetol. 2018;17:39.
12. Marx N, *et al.* Diab Vasc Res. 2015;12:164–74.

Prescribing Information (Great Britain) 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. 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:* The risk for clinically meaningful interactions by other medicinal products on linagliptin 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. Co-administration with other potent inducers of P-glycoprotein and CYP3A4, such as carbamazepine, phenobarbital and phenytoin has not been studied. *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 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:** PLGB 14598/0225. **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** September 2021.

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).

Prescribing Information (Northern 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:* The risk for clinically meaningful interactions by other medicinal products on linagliptin 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. Co-administration with other potent inducers of P-glycoprotein and CYP3A4, such as carbamazepine, phenobarbital and phenytoin has not been studied. *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 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, 55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. **Prepared in** May 2023.

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).

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. 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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** May 2023

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