Trajenta® (linagliptin) is indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as:

monotherapy
• in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment

combination therapy
• in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control
• in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control

Prescribing Information (UK). TRAJENTA® 5 mg film-coated tablets

Film-coated tablets containing 5 mg linagliptin. Indication: Trajenta is indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as monotherapy - in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment; as combination therapy: - in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control; - in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products 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, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia. Patients with renal impairment: - in combination with a sulphonylurea and metformin or contraindicated due to renal impairment; - as combination therapy in patients inadequately controlled by diet and exercise alone and for whom metformin and a sulphonylurea cannot be tolerated plus metformin alone do not provide adequate glycaemic control.

Elderly: no dose adjustment is necessary based on age however, clinical experience in patients > 75 years of age is limited. The safety and efficacy of linagliptin in children and adolescents has not yet been established. No data are available. Trajenta 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: Trajenta 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; a dose reduction of the sulphonylurea may be considered.

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, glyburide, 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 Trajenta 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 Trajenta. Undesirable effects: Adverse reactions reported in patients who received linagliptin 5 mg daily as monotherapy or as add-on therapies (pooled analysis of placebo-controlled studies). 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 <1/1000), or very rare (<1/10,000), not known (cannot be estimated from the available data). Very common: hypoglycaemia (combination with/add on to metformin and sulphonylurea). Uncommon: nasopharyngitis (monotherapy; combination with/add on to metformin); hypersensitivity (combination with/add on to metformin); cough (monotherapy; combination with/add on to metformin). Not known: nasopharyngitis (combination with/add on to metformin and sulphonylurea); hypersensitivity (monotherapy; combination with/add on to metformin and sulphonylurea); cough (combination with/add on to metformin and sulphonylurea); pancreatitis (monotherapy; combination with/add on to metformin; combination with/add on to metformin and sulphonylurea). 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/1/1/707/003. 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 September 2011.

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).