Vipidia® (alogliptin) and Vipdomet® (alogliptin plus metformin) PRESCRIBING INFORMATION

Refer to summary of Product Characteristics (SmPC) before prescribing. Presentation: VIPIDIA: Alogliptin 6.25 mg, 12.5 mg and 25 mg film-coated tablets. VIPDOMET: Alogliptin plus metformin 12.5 mg/1000 mg film-coated tablets. **Indication:** VIPIDIA: Adults (over 18 years) with Type 2 diabetes to improve glycaemic control in combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. VIPDOMET: Adults (over 18 years) with Type 2 diabetes as an adjunct to diet and exercise to improve glycaemic control in inadequately controlled patients on (1) their maximal tolerated dose of metformin alone, or already being treated with the combination of metformin and alogliptin (2) their maximal tolerated dose of metformin in combination with pioglitazone or (3) metformin in combination with insulin at a stable dose. **Dosage & Administration:** VIPIDIA: The usual recommended dose is one 25mg tablet mg once daily (o.d.) with or without food. VIPDOMET: The dose is one 12.5mg/1,000mg tablet twice daily. The current metformin dose should be considered and should be at a similar dose to that of Vipdomet. A lower dose of metformin, thiazolidinedione or insulin may be considered to reduce the risk of hypoglycaemia. For patients switching from separate tablets of alogliptin and metformin, the current treatment regimen of alogliptin and metformin should be 25mg and 2,000mg per day respectively. Elderly: VIPIDIA/VIPDOMET: No dose adjustment is necessary. Renal impairment: VIPIDIA: Mild renal impairment, no dose adjustment is necessary. Moderate renal impairment 12.5 mg o.d. Severe renal impairment or end-stage renal disease requiring dialysis 6.25 mg o.d. Experience in patients on dialysis is limited. Vipidia has not been studied in patients undergoing peritoneal dialysis. VIPDOMET: GFR 60-89mL/min, no dose adjustment is necessary. GFR 45-59 mL/min, maximum daily dose 12.5mg alogliptin and 2000mg metformin, GFR 30-44mL/min, maximum daily dose 12.5mg alogliptin and 1000mg metformin. If adequate strength of Vipdomet not available, use individual monocomponents instead. Contraindicated in severe renal failure (GFR<30 mL/min). Hepatic impairment: VIPIDIA: No dose adjustment is necessary in mild to moderate hepatic impairment. Not recommended for use in severe hepatic impairment. VIPDOMET: Should not be used in patients with hepatic impairment. Paediatric population: VIPIDIA/VIPDOMET: No data available. **Contraindications:** VIPIDIA/VIPDOMET: Hypersensitivity to the active substance or to its excipients or history of a serious hypersensitivity reaction to any dipeptidyl-peptidase-4 (DPP-4) inhibitor. VIPDOMET: Acute metabolic acidosis, severe renal failure (eGFR<30 mL/min), acute conditions with the potential to alter renal function, acute or chronic disease which may cause tissue hypoxia (e.g. cardiac failure), hepatic impairment, acute alcohol intoxication, alcoholism. **Warnings & Precautions:** General: VIPIDIA/VIPDOMET: Do not use in Type 1 diabetes or for treatment of diabetic ketoacidosis. Use with other antihyperglycaemic medicinal products and hypoglycaemia: VIPIDIA: When used in combination with a sulphonylurea, insulin or combination therapy with thiazolidinedione plus metformin, a lower dose of these medications may be considered to reduce the risk of hypoglycaemia. VIPDOMET: Should not be used in combination with a sulphonylurea. When used in combination with insulin or pioglitazone, a lower dose of these medications may be considered to reduce the risk of hypoglycaemia. Combinations not studied: VIPIDIA: Has not been studied in combination with sodium glucose cotransporter 2 (SGLT-2) inhibitors or glucagon like peptide 1 (GLP-1) analogues nor formally as triple therapy with metformin and sulphonylurea. Renal impairment: VIPIDIA/VIPDOMET: GFR should be assessed before treatment initiation and regularly thereafter. VIPDOMET: Metformin should be temporarily discontinued in the presence of conditions that alter renal function. Cardiac failure: VIPIDIA: Caution for use in patients with congestive heart failure of New York Heart Association functional class III – IV due to limited experience. Hypersensitivity reactions: VIPIDIA/VIPDOMET: Anaphylactic reactions, angioedema and exfoliative skin conditions including Stevens-Johnson syndrome and erythema multiforme have been observed for DPP-4 inhibitors and have been spontaneously reported for alogliptin in the post-marketing setting. Acute pancreatitis: VIPIDIA/VIPDOMET: Use of DPP-4 inhibitors have been associated with a risk of developing acute pancreatitis and so patients should be informed of the characteristic symptoms. If pancreatitis is suspected, Vipidia/Vipdomet should be discontinued; and if confirmed, not be restarted. Caution in patients with a history of pancreatitis. Hepatic effects: VIPIDIA/VIPDOMET: Postmarketing reports of hepatic dysfunction, including failure, have been received. Patients should be observed for possible liver abnormalities and liver function should be tested promptly in patients with any symptoms. Discontinue Vipidia/Vipdomet treatment if an abnormality is found and an alternative aetiology is not established. Hepatic impairment: VIPIDIA: not recommended in severe hepatic impairment. VIPDOMET: see contraindications. Lactic acidosis: VIPDOMET: Greatest risk at acute worsening of renal function or cardiorespiratory illness or sepsis. Can occur with metformin accumulation. In case of dehydration, temporarily discontinue Vipdomet and contact a healthcare professional. Medicines that can impair renal function should be initiated with caution. Other risk factors include excessive alcohol intake, hepatic insufficiency, inadequately controlled diabetes, ketosis, prolonged fasting and any condition associated with hypoxia. Inform patients/care-givers on risks and symptoms and if suspected, discontinue Vipdomet and seek immediate medical attention. Surgery: VIPDOMET: Discontinue at the time of surgery and restart 48 or more hours following surgery or resumption of oral nutrition, provided renal function is stable. Administration of iodinated contrast agents: VIPDOMET: Due to potential risk of nephropathy and lactic acidosis, Vipdomet should be discontinued prior to, or at the time of, the test and not restarted until 48 hours afterwards, and only after renal function is stable. Change in clinical status of patients with previously controlled Type 2 diabetes: VIPDOMET: Patients who develop laboratory abnormalities or clinical illness should be evaluated promptly for evidence of ketoacidosis or lactic acidosis. If acidosis of either form occurs, stop Vipdomet immediately. **Interactions:** VIPIDIA: Primarily excreted unchanged in the urine and metabolism by the cytochrome (P450 system is negligible. Studies show no clinically relevant pharmacokinetic interactions. VIPDOMET: Interactions with metformin: Not recommended with alcohol due to increased risk of lactic acidosis. Cationic medicinal products may interact with metformin - close monitoring recommended. Iodinated contrast agents – refer to warnings & precautions section above. Combinations requiring precautions for use: Closely monitor renal function when using with medicines that can affect renal function and increase risk of lactic acidosis. Medicinal products with intrinsic hyperglycaemic activity - glucocorticoids, beta 2 agonists, diuretics; or ACE inhibitors, which may lower blood glucose: dose of Vipdomet may need review during therapy with, and on stopping, the other medicinal product. **Fertility, Pregnancy & Lactation:** VIPIDIA/VIPDOMET: Avoid use during pregnancy. A risk to the breast-fed infant cannot be excluded. Consider the risk-benefit balance of use in breast-feeding mothers. The effect of Vipidia/Vipdomet on fertility in humans has not been studied. **Undesirable Effects:** VIPIDIA/ VIPDOMET: Common (≥1/100 to <1/10): Upper respiratory tract infections; nasopharyngitis; headache; abdominal pain; gastro-oesophageal reflux disease; pruritus; diarrhoea, rash. Other serious undesirable effects (frequency unknown): Acute pancreatitis; hepatic dysfunction including hepatic failure; angioedema; hypersensitivity; exfoliative skin conditions including Stevens-Johnson Syndrome, urticaria. In addition, VIPDOMET: Common (≥1/100 to <1/10): Gastroenteritis, diarrhoea, vomiting, gastritis. In addition, metformin only: Very common (≥1/10): Abdominal pain, diarrhoea, loss of appetite, nausea, vomiting. Common (≥1/100 to <1/10) Metallic taste. Other serious undesirable effects (frequency very rare (<1/10,000)): Hepatitis, lactic acidosis. **Refer to the SmPCs for details on full side effect profile and interactions. Basic NHS Price:** VIPIDIA £26.60 for 28 tablets, VIPDOMET £26.60 for 56 tablets. **Legal Classification:** POM. **Marketing Authorisations:** VIPIDIA: EU/1/13/844/009 6.25 mg; EU/1/13/844/018 12.5 mg; EU/1/13/844/027 25 mg. VIPDOMET: EU/1/13/843/017. Takeda UK Ltd. is responsible for the sale and supply of Vipidia and Vipdomet in the UK. Further information is available from Takeda UK Ltd, Building 3, Glory Park, Glory Park Avenue, Wooburn Green, Bucks, HP10 0DF. Tel 01628 537900. Fax 01628 526617. **PI Approval Code:** UK/VIP/1805/0060 **Date of revision:** June 2018

Please refer to the summary of product characteristics for details on the full side-effect profile and drug interactions of Vipidia and Vipdomet. Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/. Adverse events should also be reported to Takeda UK Ltd 01628-537900