Vipidia®▼(alogliptin) Prescribing information

Refer to summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Alogliptin 6.25 mg, 12.5 mg and 25 mg film-coated tablets. **Indication:** Adults aged 18 years and older with Type 2 diabetes mellitus 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. **Dosage & Administration**: In adults the usual recommended dose of Vipidia is one tablet of 25 mg once daily (o.d.) with or without food. Elderly: No dose adjustment is necessary. Renal impairment: 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. Hepatic impairment: No dose adjustment is necessary for patients with mild to moderate hepatic impairment. Has not been studied in patients with severe hepatic impairment, therefore not recommended for use in these patients. Paediatric population: No data are available. **Contraindications:** Hypersensitivity to the active substance or to its excipients or history of a serious hypersensitivity reaction to any dipeptidyl-peptidase-4 (DPP-4) inhibitor. **Warnings & Precautions:** General: Do not use in patients with Type 1 diabetes mellitus or for treatment of diabetic ketoacidosis. Use with other antihyperglycaemic medicinal products and hypoglycaemia: 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. Combinations not studied: 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: Renal function assessment is recommended prior to initiation of Vipidia therapy and periodically thereafter. Cardiac failure: Caution for use in patients with congestive heart failure of New York Heart Association (NYHA) functional class III – IV due to limited experience. Hypersensitivity reactions: 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: Use of DPP-4 inhibitors has been associated with a risk of developing acute pancreatitis. Spontaneous reports of adverse reactions of acute pancreatitis in the post-marketing setting. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, Vipidia should be discontinued; if acute pancreatitis is confirmed, Vipidia should not be restarted. Caution should be exercised in patients with a history of pancreatitis. Hepatic effects: Postmarketing reports of hepatic dysfunction, including failure, have been received. Patients should be observed for possible liver abnormalities and liver function should be obtained promptly in patients with any symptoms. Discontinue Vipidia treatment if an abnormality is found and an alternative aetiology is not established. **Interactions:** Primarily excreted unchanged in the urine and metabolism by the cytochrome (CYP) P450 system is negligible. Studies show no clinically relevant pharmacokinetic interactions. **Fertility, Pregnancy & Lactation:** No data from use in pregnant women. Avoid use during pregnancy. Unknown whether Vipidia is excreted in human milk, a risk to the suckling child cannot be excluded. Consider the risk-benefit balance of use in breast-feeding mothers. The effect of Vipidia on fertility in humans has not been studied. **Undesirable Effects:** Common (≥1/100 to <1/10): Upper respiratory tract infections; nasopharyngitis; headache; abdominal pain; gastro-oesophageal reflux disease; pruritis; rash. Other serious undesirable effects (frequency unknown): Acute pancreatitis; hepatic dysfunction including hepatic failure; angioedema; hypersensitivity; exfoliative skin conditions. **Refer to the SmPC for details on full side effect profile and interactions.** **Basic NHS Price:** £26.60 for 28 tablets **Legal Classification:** POM. **Marketing Authorisation**: EU/1/13/844/009 6.25 mg; EU/1/13/844/018 12.5 mg; EU/1/13/844/027 25 mg. Takeda UK Ltd. is responsible for the sale and supply of Vipidia 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/1604/0044 **Date of revision:** April 2016

Please refer to the summary of product characteristics for details on the full side-effect profile and drug interactions of Vipidia. 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

Reference:

1. National Institute for Health and Care Excellence, 2015. Type 2 diabetes in adults: management, NG28. Available from https://www.nice.org.uk/guidance/ng28 (last accessed November 2016).

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