

ENCELIN 50

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for ENCELIN 50 [Vildagliptin Tablets 50mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Encelin contains vildagliptin. Vildagliptin acts primarily by inhibiting DPP-4, the enzyme responsible for the degradation of the incretin hormones GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic polypeptide).

INDICATION: As an adjunct to diet and exercise to improve glycemic control in patients with type-II diabetes mellitus.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients

WARNINGS & PRECAUTIONS: General vildagliptin is not a substitute for insulin in insulin-requiring patients. Vildagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. *Renal impairment:* There is limited experience in patients with ESRD on haemodialysis. Therefore Vildagliptin should be used with caution in these patients. *Hepatic impairment:* Vildagliptin should not be used in patients with hepatic impairment, including patients with pretreatment ALT or AST > 3x ULN. *Liver enzyme monitoring:* rare cases of hepatic dysfunction (including hepatitis) have been reported. In these cases, the patients were generally asymptomatic without clinical sequelae and liver function test results returned to normal after discontinuation of treatment. *Cardiac failure:* A clinical trial of vildagliptin in patients with New York Heart Association (NYHA) functional class I-III showed that treatment with vildagliptin was not associated with a change in left-ventricular function or worsening of pre-existing congestive heart failure (CHF) versus placebo. *Skin disorders:* Skin lesions, including blistering and ulceration have been reported in extremities of monkeys in non-clinical toxicology studies. *Acute pancreatitis:* Use of vildagliptin has been associated with a risk of developing acute pancreatitis. Patients should be informed of the characteristic symptom of acute pancreatitis. *Hypoglycaemia:* Sulphonylureas are known to cause hypoglycaemia. Patients receiving vildagliptin in combination with a sulphonylurea may be at risk for hypoglycaemia. *Excipients:* The tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

DRUG INTERACTIONS: *Combinations not recommended:* Vildagliptin has a low potential for interactions with co-administered medicinal products. Since vildagliptin is not a cytochrome P (CYP) 450 enzyme substrate and does not inhibit or induce CYP 450 enzymes, it is not likely to interact with active substances that are substrates, inhibitors or inducers of these enzymes. *Combination with pioglitazone, metformin and glyburide:* Results from studies conducted with these oral antidiabetics have shown no clinically relevant pharmacokinetic interactions. *Digoxin (Pgp substrate), warfarin (CYP2C9 substrate):* Clinical studies performed with healthy subjects have shown no clinically relevant pharmacokinetic interactions. However, this has not been established in the target population. *Combination with amlodipine, ramipril, valsartan or simvastatin:* Drug-drug interaction studies in healthy subjects were conducted with amlodipine, ramipril, valsartan and simvastatin. In these studies, no clinically relevant pharmacokinetic interactions were

observed after co-administration with vildagliptin. *Combination with ACE-inhibitors:* There may be an increased risk of angioedema in patients concomitantly taking ACE-inhibitors. As with other oral antidiabetic medicinal products the hypoglycaemic effect of vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics.

ADVERSE REACTIONS: Hypoglycaemia, tremor, headache, chills, dizziness, fatigue, asthenia, nausea, diarrhoea, constipation, flatulence, gastro-oesophageal reflux disease, pancreatitis, weight increase, oedema peripheral, upper respiratory tract infection, nasopharyngitis, hyperhidrosis, Hepatitis (reversible upon discontinuation of the medicinal product), abnormal liver function tests (reversible upon discontinuation of the medicinal product), myalgia, arthralgia, urticarial, exfoliative and bullous skin lesions, including bullous pemphigoid.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)