Vildishal 50

(Vildagliptin Tablets 50 mg)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Vildishal 50 (Vildagliptin Tablets 50 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chemical Name	Approved Name (if any)	Quantity per Tablet in mg	Active / Non- active
Active Ingredients			
(S)-1-[2-(3-Hydroxyadamantan-1-ylamino) acetyl]pyrrolidine-2-carbonitrile	Vildagliptin	50	Active Ingredient
Excipients			
-------	Lactose Anhydrous BP	48.00	Binding agent
-------	Microcrystalline Cellulose PH 102 BP	92.500	Diluent
-------	Sodium Starch Glycolate BP (Priimogel)	7.500	Disintegrant
-------	Magnesium Stearate BP	2.000	Lubricant

Definitions:

BP: British Pharmacopoeia

3. PHARMACEUTICAL FORM

Uncoated Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Therapeutic Indications:

As monotherapy

- In patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

As dual oral therapy in combination with

- Metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin,
- A sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance,
- A thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.

As triple oral therapy in combination with

- A sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.
- Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.

4.2 Posology and method of administration

The management of antidiabetic therapy should be individualized

The recommended daily dose is 50 mg once or twice a day. The maximum recommended dose is 100 mg per day

- When used as monotherapy, in combination with metformin, in combination with thiazolidinedione, in combination with metformin or in combination with insulin: The recommended dose is 50 mg or 100 mg daily
- When used in dual combination with a sulphonylurea, the recommended dose of vildagliptin is 50 mg once daily administered in the morning. In this patient population, vildagliptin 100 mg daily was no more effective than vildagliptin 50 mg once daily.
- When used in triple combination with metformin and a sulphonylurea, the recommended dose is 100 mg daily administered as one dose of 50 mg in the morning and one dose of 50 mg in the evening.

If a dose is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day.

Special population:

Elderly (≥ 65 years)

No dose adjustments are necessary in elderly patients

Renal impairment:

No dose adjustment is required in patients with mild renal impairment (creatinine clearance ≥ 50 ml/min). In patients with moderate or severe renal impairment or with end-stage renal disease (ESRD), the recommended dose of vildagliptin is 50 mg once daily

Hepatic impairment:

Vildagliptin should not be used in patients with hepatic impairment, including patients with pre-treatment alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 3x the upper limit of normal (ULN)

Paediatric population:

Not recommended

4.3 Contraindications

In patient with hypersensitivity to the vildagliptin or to any component of the formulation

4.4 Special warnings and precautions for use

- 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.
- Should be used with caution in patients with ESRD on haemodialysis
- Should not be used in patients with hepatic impairment, including patients with pre-treatment ALT or AST > 3x ULN
- Liver function should be monitored during treatment with vildagliptin at three-month intervals during the first year and periodically thereafter.
- Should an increase in AST or ALT of 3x ULN or greater persist, withdrawal of vildagliptin therapy is recommended.
- In patients with NYHA functional class IV and use of vildagliptin is not recommended
- In keeping with routine care of the diabetic patient, monitoring for skin disorders, such as blistering or ulceration, is recommended.
- Use of vildagliptin has been associated with a risk of developing acute pancreatitis. Patients should be informed of the characteristic symptom of acute pancreatitis. If pancreatitis is suspected, vildagliptin should be discontinued; if acute pancreatitis is confirmed, vildagliptin should not be restarted. Caution should be exercised in patients with a history of acute pancreatitis.
- Patients receiving vildagliptin in combination with a sulphonylurea, a lower dose of sulphonylurea may be considered to reduce the risk of hypoglycaemia.
- This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

- 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.
- 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.

4.6 Pregnancy and lactation

Vildagliptin should not be used in pregnancy and nursing mother.

4.7 Adverse Reactions

The commonly reported adverse reactions when combined with metformin are hypoglycaemia, tremor, headache, dizziness, nausea; when combined with sulphonyl urea are hypoglycaemia, tremor, headache, dizziness, asthenia; when combined with thiazolidinedione are weight gain, edema peripheral; when used in combination with insulin are decreased blood glucose, headache, chills, nausea, gastro-oesophageal reflux disease; when used in combination with metformin and sulphonylurea are Hypoglycaemia, dizziness, tremor, hyperhidrosis and asthenia. When used as monotherapy the common adverse reaction is dizziness and the other adverse reactions of uncommon frequency, reported with monotherapy are hypoglycaemia, headache, peripheral edema, constipation and arthralgia.

4.8 Symptoms of Overdosage & Treatment

At 400mg, there were three cases of muscle pain, and individual cases of mild and transient paraesthesia, fever, oedema and a transient increase in lipase levels. At 600 mg, one subject experienced oedema of the feet and hands, and increases in creatine phosphokinase (CPK), aspartate aminotransferase (AST), C-reactive protein (CRP) and myoglobin levels. Three other subjects experienced oedema of the feet, with paraesthesia in two cases. All symptoms and laboratory abnormalities resolved without treatment after discontinuation of the study medicinal product.

Management: In the event of an overdose, supportive management is recommended. Vildagliptin cannot be removed by haemodialysis. However, the major hydrolysis metabolite (LAY 151) can be removed by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological category: Oral hypoglycemic agent.

ATC Code: A10BH02

Pharmacological Properties: Vildagliptin, a member of the islet enhancer class, is a potent and selective dipeptidyl peptidase 4 (DPP-4) inhibitor.

Pharmacological Action: The administration of Vildagliptin results in a rapid and complete inhibition of DPP-4 activity, resulting in increased fasting and postprandial endogenous levels of the incretin hormones GLP-1 (glucagon-like peptide 1) and GIP (glucose-dependent insulinotropic polypeptide) resulting in enhancement of sensitivity of beta cells to glucose, resulting in improved glucose-dependent insulin secretion.

5.2 Pharmacokinetic properties

Pharmacokinetics: Following oral administration in the fasting state, vildagliptin is rapidly absorbed, with peak plasma concentrations observed at 1.7 hours. The absolute bioavailability is 85%.The plasma protein binding of vildagliptin is low (9.3%) and vildagliptin distributes equally between plasma and red blood cells. Metabolism is the major elimination pathway for vildagliptin in humans, accounting for 69% of the dose. Vildagliptin is not likely to affect metabolic clearance of co-medications metabolised by CYP 1A2, CYP 2C8, CYP 2C9, CYP 2C19, CYP 2D6, CYP 2E1 or CYP 3A4/5. Following oral administration, approximately 85% of the dose was excreted into the urine and 15% of the dose is recovered in the faeces. The elimination half-life is approximately 3 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Anhydrous BP, Microcrystalline Cellulose PH 102 BP, Sodium Starch Glycolate BP (Priimogel) and Magnesium Stearate BP.

6.2 Incompatibilities

None.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Protect from light and moisture. Keep out of reach of children.

6.5 Nature and contents of container

Vildishal 50 is available as 3 blisters of 10 tablets each packed in a carton along with pack insert.

7. MARKETING AUTHORISATION HOLDER

M/s SHALINA HEALTHCARE DMCC

Physical and Postal Address: 30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

Country: Dubai

8. MARKETING AUTHORISATION IN OTHER COUNTRIES

Application for granting new registration certificate

9. DATE OF FIRST AUTHORISATION

Application for granting new registration certificate

10. DATE OF UPDATE OF TEXT

November 2021