BIOS LAB PVT. LTD.

B-8, MILAN COMPLEX, SARKHEJ, AHMEDABAD.

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

The Drugs & Cosmetic Act 1945 and The Rules thereunder

Report No. :	**FP/211874**	**Mfg. No.: 68/UA/2009**
Sample Name :	**BIOVILDA®100 SR TABLETS**	
Generic Name :	**Vildagliptin Sustained Release 100 mg Tablets**	

Product Name	**BIOVILDA® 100 SR**	**A.R.No.**	QC/FP/211874
Batch No.	MT212416C	**Batch Size**	0.50 Lac Tablets
Mfg. Date	JUNE. 2021	**Sample Qty.**	40 Tablets
Exp. Date	MAY. 2023	**Test as per**	Manufacturer Specification
Date of Receipt	11-06-2021	**Date of Release**	12-06-2021

S NO.	TEST	SPECIFICATION	RESULT	
1.	Description	White colored round shaped, biconvex uncoated sustained release tablets	White colored round shaped, biconvex uncoated sustained release tablets	
2.	Identification	Positive test for Vildagliptin	Complies	
3.	Average weight	295 mg ± 7.5%	296.89 mg	
4.	Uniformity of weight	± 7.5% of average weight	Complies (Within limit)	
5.	Dissolution time	3rd Hour	37.74% to 39.48%	[25% to 55%]
		8th Hour	65.39% to 66.47%	[50% to 80%]
		16th Hour	84.73% to 86.00%	[NLT -75%]
6.	ASSAY	Each uncoated bilayered tablet contains:		
	Contents	**Claim**	**Limit**	**Obtained**
			Lower / **Upper**	
	Vildagliptin	100.0 mg	90.0 mg / 110.0 mg	103.01 mg

Conclusion: The product complies with the prescribed standard of quality as per in house specification.

*** Manufactured by:** MASCOT HEALTH SERIES PVT. LTD. (HARIDWAR)

BIOVILDA® 100 SR

PRODUCT DESCRIPTION

Each uncoated sustained release tablet contains

Vildagliptin – 100 mg
Excipients – q.s.

PHARMACEUTICAL DESCRIPTION

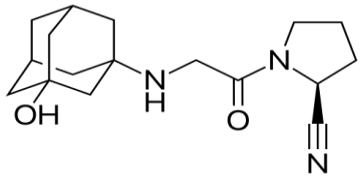
VILDAGLIPTIN:

Generic name: Vildagliptin

Chemical name: (2*S*)-1-{2-[(3-hydroxy-1-adamantyl) amino] acetyl} pyrrolidine-2-carbonitrile

Molecular mass: 303.399 g/mol

Structural formula:



Empirical formula: $C_{17}H_{25}N_3O_2$

PHARMACODYNAMIC PROPERTIES & MECHANISM OF ACTION

Vildagliptin

Vildagliptin, a member of the islet enhancer class, is a potent and selective dipeptidyl-peptidase-4 (DPP-4) inhibitor that improves glycemic control. Vildagliptin inhibition of DPP-4 results in increased fasting and postprandial endogenous levels of the incretion hormones GLP-1 (glucagon-like peptide 1) and GIP (glucose- dependent insulinotropic polypeptide).

The administration of vildagliptin results in rapid and complete inhibition of DPP-4 activity. In patients with type 2 diabetes, administration of vildagliptin led to inhibition of DPP-4 enzyme activity for a 24-hour period. By increasing the endogenous levels of these incretin hormones; vildagliptin enhances the sensitivity of beta cells to glucose resulting in improved glucose-dependent insulin secretion. Treatment with 100 mg daily in patients with type 2 diabetes significantly improved markers of beta cell function. The degree of improvement in beta-cell function is dependent on the initial degree of impairment; in non-diabetic (normal glycemic) individuals, vildagliptin does not stimulate insulin secretion or reduce glucose levels.

By increasing endogenous GLP-1 levels, vildagliptin enhances the sensitivity of alpha cells to glucose, resulting in more glucose-appropriate glucagon secretion. The reduction in inappropriate glucagon during meals in turn attenuates insulin resistance.

The enhanced increase in the insulin/glucagon ratio during hyperglycemia due to increased incretin hormone levels, it results in a decrease in fasting and postprandial hepatic glucose production, leading to reduced glycemia.

The known effect of increased GLP-1 levels to delay gastric emptying is not observed with vildagliptin treatment. In addition, a reduction in postprandial lipemia that is not associated with vildagliptin's incretin- mediated effect to improve islet function has been observed.

PHARMACOKINETIC PROPERTIES

Absorption

Following oral administration in the fasting state, vildagliptin is rapidly absorbed with an absolute bioavailability of 85%. Peak plasma concentrations for vildagliptin and the area under the plasma concentration versus time curve (AUC) increased in an approximately dose-proportional manner over the therapeutic dose range. A peak plasma concentration for vildagliptin was observed at 1.75 hours. Co- administration with food slightly decreases the rate of absorption of vildagliptin, as characterized by a 19% decrease in peak concentrations, and a delay in the time to peak plasma concentration to 2.5 hours. There is no change in the extent of absorption, and food does not alter the overall exposure (AUC).

Distribution

The plasma protein binding of vildagliptin is low (9.3%), and vildagliptin is distributed equally between plasma and red blood cells. The mean volume of distribution of vildagliptin at steady state after intravenous administration (V_{SS}) is 71 liters, suggesting extravascular distribution.

Metabolism

Metabolism is the major elimination pathway for vildagliptin in humans, accounting for 69% of the dose. The major metabolite, LAY151, is pharmacologically inactive and is the hydrolysis product of the cyano moiety, accounting for 57% of the dose, followed by the amide hydrolysis of product (4% of the dose). DPP-4 contributes partially to the hydrolysis of vildagliptin. Vildagliptin is not metabolized by cytochrome P450 enzymes to any quantifiable extent. *In vitro* studies demonstrated that vildagliptin does not inhibit or induce cytochrome P450 enzymes.

Excretion

Following oral administration of vildagliptin, approximately 85% of the dose is excreted into the urine and 15% of the dose is recovered in the feces. Renal excretion of unchanged vildagliptin accounts for 23% of the dose after oral administration. After intravenous administration to healthy subjects, the total plasma and renal clearances of vildagliptin are 41 liters/hour and 13 liters/hour, respectively. The mean elimination half- life after intravenous administration is approximately 2 hours. The elimination half-life after oral administration is approximately 3 hours and is independent of the dose.

INDICATION

Type 2 diabetes mellitus

BIOVILDA® 100 SR is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus (T2DM).

As Monotherapy

In Dual combination

With metformin, when diet and exercise and metformin alone do not result in adequate glycemic control with a sulfonylurea (SU), when diet, exercise and a SU alone do not result in adequate glycemic control with a thiazolidinedione (TZD) when diet and exercise and a TZD do not provide adequate glycemic control.

In Triple combination

With a sulfonylurea and metformin when diet and exercise plus dual therapy with these agents do not provide adequate glycemic control.

BIOVILDA® 100 SR is also indicated in combination with insulin (with or without metformin) when diet, exercise and a stable dose of insulin do not result in adequate glycemic control.

BIOVILDA® 100 SR is also indicated as initial combination therapy with metformin in patients with T2DM whose diabetes is not adequately controlled by diet and exercise alone.

CONTRAINDICATIONS

BIOVILDA® 100 SR is contraindicated in patients with known hypersensitivity to vildagliptin or to any of the excipients.

DOSAGE AND ADMINISTRATION

Vildagliptin

The management of antidiabetic therapy should be individualized. The recommended dose of BIOVILDA® 100 SR is once or twice daily. The maximum daily dose of BIOVILDA® is 100 mg. For monotherapy, and for combination with metformin, with a TZD or with insulin (with or without metformin), the recommended dose of BIOVILDA® 100 SR is 100 mg daily. When used in dual combination with a sulfonylurea, the recommended dose of BIOVILDA® 100 SR is 100 mg once daily. In this patient population, vildagliptin 100 mg daily was no more effective than vildagliptin 100 mg once daily. For triple combination with metformin and a SU, the recommended dose of BIOVILDA® 100 SR is 100 mg daily. If tighter glycemic control is required on the top of the maximum recommended daily dose of vildagliptin, the addition of other antidiabetic drugs such as metformin, an SU, a TZD or insulin may be considered.

Renal Impairment

No dosage adjustment of BIOVILDA® 100 SR is required in patients with mild renal impairment. In patients with moderate or severe renal impairment or End Stage Renal Disease (ESRD), the recommended dose of BIOVILDA® 100 SR ™ is 100 mg once daily.

Hepatic Impairment

BIOVILDA® 100 SR is not recommended in patients with hepatic impairment including patients with a pre-treatment ALT or AST >2.5x the upper limit of normal (ULN).

Pediatric

BIOVILDA® 100 SR has not been studied in patients under 18 years of age; therefore, the use of BIOVILDA® 100 SR in pediatric patients is not recommended.

Geriatric

In patients treated with BIOVILDA® 100 SR ≥65 years of age and ≥75 years of age, no differences were observed in the overall safety, tolerability, or efficacy between this elderly population and younger patients. No dosage adjustments are therefore necessary in the elderly patients.

METHOD OF ADMINISTRATION

For oral use, BIOVILDA® 100 SR can be administered with or without meals.

The 100 mg dose should be administered once daily in the morning. The 100 mg dose should be administered as two divided doses of 50 mg given in the morning and evening.

If a dose of BIOVILDA® 100 SR is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day.

UNDESIRABLE EFFECTS

Vildagliptin

The majority of adverse reactions in these trials were mild and transient, not requiring treatment discontinuations. No association was found between adverse reactions and age, ethnicity, duration of exposure or daily dose.

Rare cases of angioedema have been reported on vildagliptin at a similar rate to controls. A greater proportion of cases were reported when vildagliptin was administered in combination with an angiotensin converting enzyme inhibitor (ACE-Inhibitor). The majorities of events were mild in severity and resolved with ongoing vildagliptin treatment.

Rare cases of hepatic dysfunction (including hepatitis) have been reported. In these cases, the patients were generally asymptomatic without clinical sequelae and liver function tests (LFTs) returned to normal after discontinuation of treatment. In data from controlled monotherapy and add-on therapy trials up to 24 weeks in duration, the incidence of ALT or AST elevations >= 3x ULN (classified as present on at least 2 consecutive measurements or at the final on-treatment visit) was 0.2%, 0.3% and 0.2% for vildagliptin 100 mg daily, vildagliptin 50 mg twice daily and all comparators, respectively. These elevations in transaminases were generally asymptomatic, non-progressive in nature and not associated with cholestasis or jaundice.

Summary of Adverse Drug Reactions from Clinical Trials

Adverse reactions reported in patients who received BIOVILDA® 100 SR as monotherapy and add-on therapies, are listed below, for each indication, by MedDRA system organ class and absolute frequency. Within each system organ class, the adverse drug reactions are ranked by frequency, with the most frequent reactions first. Within each frequency grouping, adverse drug reactions are presented in order of decreasing seriousness. In addition, the corresponding frequency category for each adverse drug reaction is based on the following convention (CIOMS III): very common

(≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

Monotherapy

The overall incidence of withdrawal from monotherapy trials due to adverse reactions was no greater for patients treated with vildagliptin at a dose of 100 mg once daily (0.2%) or vildagliptin at a dose of 50 mg twice daily (0.1%) than for placebo (0.6%) or comparators (0.5%).

BIOVILDA® 100 SR is weight neutral when administered as monotherapy.

Table 1: Adverse reactions reported in patients who received BIOVILDA® 100 SR once daily or 50 mg twice daily as monotherapy

Nervous system disorders		
	Common	Dizziness
	Uncommon	Headache
Gastrointestinal disorders		
	Uncommon	Constipation
General disorders and administration site conditions		
	Uncommon	Edema peripheral

Long term clinical trials of up to 2 years did not show any additional safety signals or unforeseen risks with vildagliptin monotherapy.

Combination with a Sulfonylurea

In clinical trials with the combination of vildagliptin + glimepiride, the overall incidence of withdrawals due to adverse reactions was 0.6% in the vildagliptin + glimepiride treatment group versus 0% in the placebo + glimepiride treatment group.

At the recommended dose of 100 mg, BIOVILDA® 100 SR is weight neutral when administered in combination with glimepiride.

Table 2: Adverse reactions reported in patients who received BIOVILDA® 100 SR once daily in combination with a sulfonylurea

Nervous system disorders		
	Common	Tremor, headache, dizziness
General disorders and administration site conditions		
	Common	Asthenia

Combination with Metformin

In clinical trials with the combination of vildagliptin + metformin, 0.4% of patients withdrew due to adverse reactions in the vildagliptin 100 mg once daily + metformin treatment group, and no withdrawal due to adverse reactions was reported in either the vildagliptin 50 mg twice daily + metformin or the placebo + metformin treatment groups.

In clinical trials, the incidence of hypoglycemia was uncommon in patients receiving vildagliptin 100 mg once daily in combination with metformin (0.9%), patients receiving vildagliptin 50 mg twice daily in combination with metformin (0.5%) and in patients receiving placebo + metformin (0.4%). No severe hypoglycemic events were reported in the vildagliptin arms.

BIOVILDA® 100 SR is weight neutral when administered in combination with metformin.

Table 3: Adverse reactions reported in patients who received BIOVILDA® 100 SR once daily or 50 mg twice daily in combination with metformin

BIOVILDA® 100 SR in dual oral therapy with metformin		
Nervous system disorders		
	Common	Tremor, dizziness, headache

Long-term clinical trials of up to more than 2 years did not show any additional safety signal or unforeseen risks when vildagliptin was added on to metformin.

When vildagliptin was studied as an initial combination therapy with metformin, no additional safety signal or unforeseen risk was observed.

Combination with a Thiazolidinedione

In clinical trials with the combination of vildagliptin and a thiazolidinedione, 0.7% of patients withdrew for adverse reactions in the vildagliptin 100 mg once daily + pioglitazone group, and there were no withdrawals due to adverse reactions reported in either the vildagliptin 50 mg twice daily + pioglitazone or the placebo + pioglitazone treatment groups.

In the pioglitazone add-on study, the change in body weight compared to placebo was +0.1 kg and +1.3 kg for BIOVILDA® 100 SR 100 mg daily and 100 mg of BIOVILDA® 100 SR twice daily, respectively.

The incidence of peripheral edema when vildagliptin was added to a maximum dose of background pioglitazone (45 mg once daily) was 8.2% as 100 mg once daily and 7.0%, as 50 mg twice daily compared to 2.5% for background pioglitazone alone. The incidence of edema when vildagliptin was added to pioglitazone as dual initial therapy in drug naïve patients was, however, less than for pioglitazone alone (100 mg once daily 3.5%, 50 mg twice daily 6.1% vs. pioglitazone 30 mg 9.3%).

Table 4: Adverse reactions reported in patients who received BIOVILDA® 100 SR once daily or 50 mg twice daily in combination with a thiazolidinedione

Investigations		
	Common	Weight increase
General disorders and administration site conditions		
	Common	Edema peripheral

Combination with Insulin

In controlled clinical trials using vildagliptin 50 mg twice daily in combination with insulin, with or without concomitant metformin, the overall incidence of withdrawal due to adverse reactions was 0.3% in the vildagliptin treatment group and there were no cases of withdrawal in the placebo group.

The incidence of hypoglycemia was similar in both treatment groups (14.0% in the vildagliptin group versus 16.4 % in the placebo group). Two patients reported severe hypoglycemic events in the vildagliptin group, and 6 patients - in the placebo group.

At the end of the study, the effect on mean body weight was neutral (+0.6 kg change from baseline in the vildagliptin group and no weight change in the placebo group).

Table 5: Adverse reactions reported in patients who received BIOVILDA® 100 SR twice daily in combination with insulin {with or without metformin}

Nervous system disorders		
	Common	Headache
Gastrointestinal disorders		
	Common	Nausea, gastroesophageal reflux disease
	Uncommon	Diarrhea, flatulence
General disorders and administration site conditions		
	Common	Chills
Investigations		
	Common	Blood glucose decreased

Combination with Metformin and SU

There were no cases of withdrawal reported due to adverse reactions in the vildagliptin + metformin + glimepiride treatment group versus 0.6% in the placebo + metformin + glimepiride treatment group.

The incidence of hypoglycemia was common in both treatment groups (5.1% for the vildagliptin + metformin + glimepiride vs. 1.9% for the placebo + metformin + glimepiride). One severe hypoglycemic event was reported in the vildagliptin group.

At the end of the study, the effect on mean body weight was neutral (+0.6 kg in the vildagliptin group and - 0.1 kg in the placebo group).

Table 6: Adverse reactions reported in patients who received BIOVILDA® 100 SR, 50 mg twice daily in combination with metformin and SU

Nervous system disorders		
	Common	Dizziness, tremor
General disorders and administration site condition		
	Common	Asthenia
Metabolism and nutritional disorders		
	Common	Hypoglycemia
Skin and subcutaneous tissue disorders		
	Common	Hyperhidrosis

Adverse drug reactions from spontaneous reports and literature cases - Post-Marketing Experience (frequency not known)

The following adverse drug reactions have been derived from post-marketing experience with BIOVILDA® 100 SR via spontaneous case reports and literature cases. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency, which is therefore categorized as not known.

Hepatitis reversible upon drug discontinuation
Urticaria, bullous and exfoliative skin lesions, including bullous pemphigoid
Pancreatitis Arthralgia, sometimes severe

If you experience any side-effects, talk to your doctor or pharmacist or write to info@bioslab.co.in
By reporting side-effects, you can help provide more information on the safety of this product.

OVERDOSAGE

In healthy subjects (seven to fourteen subjects per treatment group), BIOVILDA® 100 SR was administered in once-daily doses of 25, 50, 100, 200, 400, and 600 mg for up to 10 consecutive days. Doses up to 200 mg were well tolerated. At 400 mg, there were three cases of muscle pain, and individual cases of mild and transient paresthesia, fever, edema and transient increase in lipase levels (2x ULN). At 600 mg, one subject experienced edema of the feet and hands, and an excessive increase in creatine phosphokinase (CPK) levels, accompanied by elevations of aspartate aminotransferase (AST), C-reactive protein, and myoglobin. Three additional subjects in this dose group presented with edema of both feet, accompanied by paresthesia in two cases. All symptoms and laboratory abnormalities resolved after study drug discontinuation.

BIOVILDA® 100 SR is not dialyzable; however the major hydrolysis metabolite (LAY151) can be removed by hemodialysis.

INCOMPATIBILITY: Not applicable.

WARNINGS AND PRECAUTIONS

Drug Interactions

Vildagliptin has low potential for drug interactions. Since vildagliptin is not a cytochrome P (CYP) 450 enzyme substrate nor does it inhibit or induce CYP 450 enzymes, it is not likely to interact with co-medications that are substrates, inhibitors or inducers of these enzymes.

Furthermore, vildagliptin does not affect metabolic clearance of co-medications metabolized by CYP 1A2, CYP 2C8, CYP 2C9, CYP 2C19, CYP 2D6, CYP 2E1, and CYP 3A4/5. Drug-drug interaction studies were conducted with commonly co-prescribed medications for patients with type 2 diabetes or medications with a narrow therapeutic window. As a result of these studies, no clinically relevant interactions with other oral antidiabetics (glibenclamide, pioglitazone, and metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with vildagliptin.

Hepatic Impairment

BIOVILDA® 100 SR is not recommended in patients with hepatic impairment, including patients with a pre-treatment ALT or AST >2.5x ULN.

Hepatic 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 tests (LFTs) returned to normal after discontinuation of treatment. LFTs should be performed prior to the initiation of treatment with BIOVILDA® 100 SR. LFTs should be monitored during BIOVILDA® 100 SR treatment at three-month intervals during the first year and periodically thereafter. Patients who develop increased transaminase levels should be monitored with a second liver function evaluation to confirm the finding and be followed thereafter with frequent liver function tests until the abnormality (ies) return to normal. Should an increase in AST or ALT of 3x ULN or greater persist, withdrawal of therapy with BIOVILDA® 100 SR is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue BIOVILDA® 100 SR and contact their physician immediately. Following withdrawal of treatment with BIOVILDA® 100 SR and LFT normalization, vildagliptin treatment should not be reinitiated.

Heart Failure

Vildagliptin showed that treatment with vildagliptin was not associated with a change in left-ventricular function or worsening of pre-existing congestive heart failure (CHF). Clinical experience in patients were treated with vildagliptin is still limited and results are inconclusive. There is no experience of vildagliptin use in clinical studies in patients and therefore use is not recommended in these patients.

General

BIOVILDA® 100 SR is not a substitute for insulin in patients requiring insulin. BIOVILDA® 100 SR should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

Females and Males of Reproductive Potential

No studies on the effect on human fertility have been conducted for BIOVILDA® 100 SR. Fertility studies have been performed in rats at doses up to 200 times the human dose and have revealed no evidence of impaired fertility or early embryonic development due to vildagliptin.

Pregnancy

There is insufficient experience with BIOVILDA® 100 SR in pregnant women. Vildagliptin was not teratogenic in either rats or rabbits. BIOVILDA® 100 SR should not be used during pregnancy unless the benefit to the mother outweighs the potential risk to the fetus.

Lactation

As it is not known whether vildagliptin is excreted in human milk, BIOVILDA® 100 SR should not be administered to breast-feeding women.

SPECIAL POPULATIONS:

Gender

No differences in the pharmacokinetics of vildagliptin were observed between male and female subjects with a diverse range of age and body mass index (BMI). DPP-4 inhibition by vildagliptin was unaffected by gender.

Obesity

BMI does not show any impact on the pharmacokinetic parameters of vildagliptin. DPP-4 inhibition by vildagliptin was unaffected by BMI.

Hepatic Impairment

The effect of impaired hepatic function on the pharmacokinetics of vildagliptin was studied in subjects with mild, moderate, and severe hepatic impairment based on the Child-Pugh scores (ranging from 6 for mild to 12 for severe) in comparison to subjects with normal hepatic function. The exposure to vildagliptin (100 mg) after a single dose in subjects with mild and moderate hepatic impairment was decreased (20% and 8%, respectively), while the exposure to vildagliptin for subjects with severe impairment was increased by 22%. The maximum change (increase or decrease) in the exposure to vildagliptin is ~30%, which is not considered to be clinically relevant. There was no correlation between the severity of hepatic function impairment and changes in exposure to vildagliptin.

The use of vildagliptin is not recommended in patients with hepatic impairment including patients with a pre- treatment ALT or AST >2.5x the ULN.

Renal Impairment

The AUC of vildagliptin increased on average 1.4, 1.7 and 2-fold in patients with mild, moderate and severe renal impairment, respectively, compared to normal healthy subjects. The AUC of the metabolites LAY151 increased 1.6, 3.2 and 7.3-fold and that of BQS867 increased 1.4, 2.7 and 7.3-fold in patients with mild, moderate and severe renal impairment, respectively, compared to healthy volunteers. Limited data from patients with end stage renal disease (ESRD) indicate that vildagliptin exposure is similar to that in patients with severe renal impairment. LAY151 concentrations in ESRD patients were approximately 2 to 3-fold higher than in patients with severe renal impairment. Dosage adjustment may be required in patients with renal impairment. Vildagliptin was removed by hemodialysis to a limited extent (3% over a 3 to 4 hour hemodialysis session starting 4 hours post dose).

Geriatric

In otherwise healthy elderly subjects (≥70 years), the overall exposure to vildagliptin (100 mg once daily) was increased by 32% with an 18% increase in peak plasma concentration compared to younger healthy subjects (18 to 40 years). These changes are not considered to be clinically relevant. DPP-4 inhibition by vildagliptin is not affected by age in the age groups studied.

Pediatric

No pharmacokinetic data available.

Ethnicity

There was no evidence that ethnicity affects the pharmacokinetics of vildagliptin.

STORAGE CONDITION

- Store protected from direct light & moisture at a temperature not exceeding 30°C.
- Keep the medicine out of reach of children.

PRECAUTION

Tablets should be swallowed whole and not to be chewed or crushed.

PRESENTATION- Vildagliptin Sustained Release 100mg Tablets

PACKING- 1*10 TAB

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