Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Vildagliptin and Metformin Hydrochloride Tablets
(Brand Name: BLUGLIP-M and BLUGLIP-M Forte Tablets)

2. Qualitative and Quantitative Composition

BLUGLIP-M Tablets
Each Film-Coated Tablet Contains:
Vildagliptin……..…… 50 mg.
Metformin hydrochloride IP ……. 500 mg.
Excipients ……. q.s.
Colours: Titanium Dioxide IP, Ferric Oxide USP-NF (Yellow) and Ferric Oxide USP-NF (Red).

BLUGLIP-M Forte Tablets
Each Film-Coated Tablet Contains:
Vildagliptin……...…… 50 mg.
Metformin hydrochloride IP ……. 1000 mg.
Excipients ……. q.s.
Colours: Titanium Dioxide IP and Ferric Oxide USP-NF (Yellow).

3. Dosage Form and Strength

Dosage Form: Tablets.
Dosage Strength: Vildagliptin 50 mg with Metformin Hydrochloride 500 mg per tablet and Vildagliptin 50 mg with Metformin Hydrochloride 1000 mg per tablet.

4. Clinical Particulars

4.1 Therapeutic Indication

BLUGLIM-M and BLUGLIP-M Forte Tablets are indicated for the treatment of type 2 diabetes mellitus when single drug therapy along with diet and exercise do not result in adequate glycemic control.
BLUGLIM-M and BLUGLIP-M Forte Tablets controls hyperglycemia and thus, prevents or delays microvascular and macrovascular complications associated with it.
BLUGLIM-M and BLUGLIP-M Forte Tablets can be administered in combination with a sulphonylurea or with insulin.

4.2Posology and Method of Administration

Oral: Adults: Usual recommended dose is 1 tablet of BLUGLIP-M twice daily.

After a 2 to 4 week interval, dosage requirement should be assessed based on glycemic control. If good glycemic control is achieved, continue the same dose as a maintenance therapy. If adequate glycemic control is not achieved with BLUGLIP-M Tablets, switch to higher dosage strength i.e., 1 tablet of BLUGLIP-M Forte to be administered twice daily. If glycemic control is optimum, continue the dose as maintenance therapy. If effect is not satisfactory, consider a change to more appropriate treatment.

Dosage should be individualized on the basis of both efficacy and tolerance. If higher doses are required, dosage of individual components should not exceed the maximum recommended daily dose of 100 mg vildagliptin and 2000 mg metformin.

BLUGLIP-M / BLUGLIP-M Forte Tablets can be administered with or without a meal. However, taking tablets with or just after food may reduce gastrointestinal symptoms associated with metformin.

Or, as prescribed by the physician.

4.3Contraindications

BLUGLIP-M / BLUGLIP-M Forte Tablets are contraindicated in the following:

- Patients with known hypersensitivity to vildagliptin or to metformin hydrochloride or to any excipient of the formulation.
- Acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis).
- Diabetic pre-coma.
- Severe renal failure (glomerular filtration rate - GFR < 30 ml/min).
- Acute conditions with the potential to alter renal function, such as dehydration, severe infection, shock, intravascular administration of iodinated contrast agents.
- Acute or chronic disease which may cause tissue hypoxia, such as cardiac or respiratory failure, recent myocardial infarction, shock.
- Hepatic impairment.
- Acute alcohol intoxication, alcoholism.
- Breast-feeding.

4.4Special Warnings and Precautions for Use

General: BLUGLIP-M / BLUGLIP-M Forte Tablets are not a substitute for insulin in insulin-requiring patients and should not be used in patients with type 1 diabetes.

Lactic acidosis: Lactic acidosis, a very rare but serious metabolic complication, most often occurs at acute worsening of renal function, or cardiorespiratory illness or sepsis. Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis. In case of dehydration (severe diarrhoea or vomiting, fever or reduced fluid intake), metformin-containing preparations should be temporarily discontinued.

Medicinal products that can acutely impair renal function (such as antihypertensives, diuretics and non-steroidal anti-inflammatory drugs - NSAIDs) should be initiated with caution in metformin-treated patients. Other risk factors for lactic acidosis are excessive alcohol intake, hepatic insufficiency, inadequately controlled diabetes, ketosis, prolonged fasting and any conditions associated with hypoxia, as well as concomitant use of medicinal products that may cause lactic acidosis.

Patients and/or care-givers should be informed of the risk of lactic acidosis. Lactic acidosis is characterized by acidotic dyspnoea, abdominal pain, muscle cramps, asthenia and hypothermia followed by coma. In case of suspected symptoms, the patient should stop taking metformin-containing preparation and seek immediate medical attention. Diagnostic laboratory findings are decreased blood pH (< 7.35), increased plasma lactate levels (> 5 mmol/l) and an increased anion gap and lactate/pyruvate ratio.

Administration of iodinated contrast agents: Intravascular administration of iodinated contrast agents may lead to contrast-induced nephropathy, resulting in metformin accumulation and increased risk of lactic acidosis. Metformin-containing preparations should be discontinued prior to or at the time of the imaging procedure and not restarted until at least 48 hours after, provided that renal function has been re-evaluated and found to be stable.

Renal function: GFR should be assessed before treatment initiation and regularly thereafter. Metformin-containing preparations are contraindicated in patients with GFR < 30 ml/min and should be temporarily discontinued in the presence of conditions that alter renal function.

Hepatic impairment: Patients with hepatic impairment, including those with pre-treatment alanine aminotransferase (ALT) or aspartate aminotransferase (AST) levels more than 3 times (3x) of upper limit of normal (ULN), should not be treated with BLUGLIP-M / BLUGLIP-M Forte Tablets.

Liver enzyme monitoring: Rare cases of hepatic dysfunction (including hepatitis) have been reported with vildagliptin. 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 in order to know the patient's baseline value. Liver function should be monitored during 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 LFTs until the abnormality(ies) return(s) to normal. Should an increase in AST or in ALT of 3x ULN or greater persist, withdrawal of drug therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue drug therapy immediately.

Following withdrawal of treatment and LFT normalization, treatment with BLUGLIP-M / BLUGLIP-M Forte Tablets should not be re-initiated.

Skin disorders: Skin lesions, including blistering and ulceration have been reported with vildagliptin in non-clinical toxicology studies. Further, there have been post-marketing reports of

bullous and exfoliative skin lesions with vildagliptin therapy. Therefore, in diabetic patient, monitoring for skin disorders such as blistering or ulceration is recommended.

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.

If pancreatitis is suspected, vildagliptin-containing preparation should be discontinued; if acute pancreatitis is confirmed, vildagliptin or vildagliptin-containing preparation should not be restarted. Caution should be exercised in patients with a history of acute pancreatitis.

Hypoglycaemia: Sulphonylureas are known to cause hypoglycaemia. Patients receiving vildagliptin in combination with a sulphonylurea may be at risk for hypoglycaemia. Therefore, a lower dose of sulphonylurea may be considered to reduce the risk of hypoglycaemia.

Surgery: Metformin-containing preparation must be discontinued at the time of surgery under general, spinal or epidural anaesthesia. Therapy may be restarted no earlier than 48 hours following surgery or resumption of oral nutrition and provided that renal function has been re-evaluated and found to be stable.

4.5Drug Interactions

There have been no formal drug interactions studies done for vildagliptin with metformin combination therapy. The following drug interactions information is available for individual active substances.

Vildagliptin

Vildagliptin has a low potential for interactions with co-administered medicinal products. Since vildagliptin is not a cytochrome P 450 (CYP) 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 angiotensin converting enzyme (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.

Metformin

Combinations not recommended with the following:

Alcohol: Alcohol intoxication is associated with an increased risk of lactic acidosis, particularly in cases of fasting, malnutrition or hepatic impairment.

Iodinated contrast agents: Metformin must be discontinued prior to or at the time of the imaging procedure and not restarted until at least 48 hours after, provided that renal function has been re-evaluated and found to be stable.

Cationic active substances: Cationic active substances that are eliminated by renal tubular secretion (e.g., cimetidine) may interact with metformin by competing for common renal tubular transport systems and hence delay the elimination of metformin, which may increase the risk of

lactic acidosis. A study in healthy volunteers showed that cimetidine, administered as 400 mg twice daily, increased metformin systemic exposure (AUC) by 50%. Therefore, close monitoring of glycaemic control, dose adjustment, and changes in diabetic treatment should be considered when cationic medicinal products that are eliminated by renal tubular secretion are co-administered.

Combinations with following drugs require precautions for use:
Some medicinal products can adversely affect renal function which may increase the risk of lactic acidosis, e.g., NSAIDs, including selective cyclo-oxygenase 2 (COX-2) inhibitors, ACE inhibitors, angiotensin II receptor antagonists and diuretics, especially loop diuretics. When starting or using such products in combination with metformin, close monitoring of renal function is necessary.
Glucocorticoids, beta-2-agonists, and diuretics have intrinsic hyperglycaemic activity. The patient should be informed and more frequent blood glucose monitoring performed, especially at the beginning of treatment. If necessary, the dosage of vildagliptin with metformin therapy may need to be adjusted during concomitant therapy and on its discontinuation.
ACE inhibitors may decrease the blood glucose levels. If necessary, the dosage of the antihyperglycaemic medicinal product should be adjusted during therapy with the other medicinal product and on its discontinuation.

4.6Use in Special Populations

Pregnant Women
There are no adequate data from the use of vildagliptin and metformin combination therapy in pregnant women. For vildagliptin, studies in animals have shown reproductive toxicity at high doses. For metformin, studies in animals have not shown reproductive toxicity. Studies in animals performed with vildagliptin and metformin have not shown evidence of teratogenicity, but foetotoxic effects at maternotoxic doses. The potential risk for humans is unknown. BLUGLIP-M / BLUGLIP-M Forte Tablets should not be used during pregnancy.

Lactating Women
Studies in animals have shown excretion of both metformin and vildagliptin in milk. It is unknown whether vildagliptin is excreted in human milk, but metformin is excreted in human milk in low amounts. Due to the potential risk of neonate hypoglycaemia related to metformin and the lack of human data with vildagliptin, BLUGLIP-M / BLUGLIP-M Forte Tablets should not be used during breast-feeding.

Paediatric Patients
As safety and efficacy of vildagliptin with metformin combination therapy have not been established in children and adolescents, it is not recommended for use in paediatric patients.

Geriatric Patients
As metformin is excreted via the kidney, and elderly patients have a tendency to decreased renal function, elderly patients taking vildagliptin with metformin combination therapy should have their renal function monitored regularly.

Renal Impairment Patients
In patients with impaired renal function, usually lower dosage should be administered. A GFR should be assessed before initiation of treatment with metformin-containing products and at least annually thereafter. If GFR is >60 ml/min, usually dosage adjustment is not required. If GFR is between 45 to 59 ml/min, maximum recommended dose of vildagliptin is 50 mg daily whereas metformin can be given up to 2000 mg daily. If GFR is between 30 to 44 ml/min, maximum recommended dose of vildagliptin is 50 mg daily while metformin should not be exceeded 1000 mg daily. Metformin-containing preparations are contraindicated in patients with GFR < 30 ml/min.

Hepatic Impairment Patients
BLUGLIP-M / BLUGLIP-M Forte Tablets should not be used in patients with hepatic impairment, including patients with pre-treatment ALT or AST >3x of ULN.

4.7Effect on Ability to Drive and Use Machines
Data is not available on the effects of vildagliptin with metformin combination therapy on ability to drive and use machines. Patients who experience dizziness as an adverse reaction should avoid driving vehicles or using machines.

4.8Undesirable Effects
Vildagliptin
Frequencies of adverse reactions are defined as 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), not known (cannot be estimated from the available data).
Clinical Trials Experience
Adverse reactions reported in patients who received vildagliptin in double-blind clinical studies are listed below:
Infections and infestations: Very rare - Upper respiratory tract infection, nasopharyngitis.
Metabolism and nutrition disorders: Uncommon – Hypoglycaemia.
Nervous system disorders: Common – Dizziness; Uncommon – Headache.
Vascular disorders: Uncommon - Peripheral edema; Rare - Angioedema.
Gastrointestinal disorders: Uncommon – Constipation.
Musculoskeletal and connective tissue disorders: Uncommon – Arthralgia.
Post-Marketing Experience
Adverse reactions reported with vildagliptin in post-marketing surveillance studies include:

Gastrointestinal disorders: Not known – Pancreatitis.
Hepatobiliary disorders: Not known - Hepatitis (reversible upon discontinuation of the drug), abnormal liver function tests i.e., increased ALT and AST (reversible upon discontinuation of the drug).
Musculoskeletal and connective tissue disorders: Not known – Myalgia.
Skin and subcutaneous tissue disorders: Not known – Urticaria, exfoliative and bullous skin lesions, including bullous pemphigoid.

Metformin

The most common adverse reactions reported with metformin are nausea, vomiting, diarrhoea, indigestion, abdominal pain, abdominal discomfort, constipation, dyspepsia, heartburn, flatulence, dizziness, taste disturbance, headache, upper respiratory infection, asthenia, and loss of appetite. These undesirable effects occur most frequently during initiation of therapy and resolve spontaneously in most cases. Very rarely, metformin may cause skin reactions such as erythema, pruritus, urticaria; abnormal liver function test or hepatitis; and lactic acidosis which generally resolve upon metformin discontinuation. Cholestatic, hepatocellular, and mixed hepatocellular liver injury have been reported with post-marketing use of metformin.

4.9 Overdose

No data are available with regard to overdose of vildagliptin with metformin combination therapy.
Symptoms related to vildagliptin: Overdose symptoms reported with vildagliptin 400 mg dosage are muscle pain, individual cases of mild and transient paraesthesia, fever, edema, transient increase in lipase levels. Symptoms reported with 600 mg dosage are edema of the feet and hand, increases in creatine phosphokinase (CPK), aspartate aminotransferase (AST), C-reactive protein (CRP) and myoglobin levels. All symptoms and laboratory abnormalities resolved without treatment after discontinuation of the drug.
Symptoms related to metformin: A large overdose of metformin (or co-existing risk of lactic acidosis) may lead to lactic acidosis, which is a medical emergency and must be treated in hospital.
Treatment: The most effective method of removing metformin is haemodialysis. However, vildagliptin cannot be removed by haemodialysis, although the major hydrolysis metabolite (LAY 151) of vildagliptin can be removed. Supportive management is usually recommended.

5. Pharmacological Properties

5.1 Mechanism of Action

Vildagliptin

Vildagliptin is a potent and selective dipeptidyl peptidase-4 (DPP-4) inhibitor. 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).

Metformin

Metformin exert its glucose-lowering effect via three mechanisms:

1. By reduction of hepatic glucose production through inhibition of gluconeogenesis and glycogenolysis.
2. In muscle, by modestly increasing sensitivity of peripheral tissues to insulin, improving peripheral glucose uptake and utilization.
3. By delaying intestinal glucose absorption.

Metformin stimulates intracellular glycogen synthesis by acting on glycogen synthase and increases the transport capacity of specific types of membrane glucose transporters (GLUT-1 and GLUT-4).

5.2Pharmacodynamic Properties

Vildagliptin

By increasing the endogenous levels of incretin hormones (GLP-1 and GIP), vildagliptin enhances the sensitivity of beta cells to glucose, resulting in improved glucose-dependent insulin secretion. Treatment with vildagliptin 50 to 100 mg daily in patients with type 2 diabetes significantly improved markers of beta cell function including HOMA-β (Homeostasis Model Assessment–β), proinsulin to insulin ratio, and measures of beta cell responsiveness.

In non-diabetic (normal glycaemic) individuals, vildagliptin does not stimulate insulin secretion or reduce glucose levels.

By increasing endogenous GLP-1 levels, vildagliptin also enhances the sensitivity of alpha cells to glucose, resulting in more glucose-appropriate glucagon secretion.

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

Metformin

Metformin is a biguanide with antihyperglycaemic effects, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycaemia or increased weight gain.

5.3Pharmacokinetic Properties

Vildagliptin

Absorption: Following oral administration in the fasting state, vildagliptin is rapidly absorbed with peak plasma concentrations observed at 1.7 hours. The C_{max} and the area under the plasma concentrations versus time curves (AUC) of vildagliptin increases in a dose proportional manner over the therapeutic dose range. The absolute bioavailability is 85%.

Food slightly delays the time to peak plasma concentration to 2.5 hours, but does not alter the overall exposure (AUC). Thus, vildagliptin can be given with or without food.

Distribution: The plasma protein binding of vildagliptin is low (9.3%) and vildagliptin distributes equally between plasma and red blood cells (RBCs). Vildagliptin is distributed mainly in the extravascular compartment.

Metabolism: About 69% of the orally administered dose of vildagliptin is metabolized. The major metabolite i.e., LAY 151 is pharmacologically inactive and is the hydrolysis product of the cyano moiety, accounting for 57% of the dose, followed by the glucuronide (BQS867) and the amide hydrolysis products (4% of dose). Kidney is one of the major organs contributing to the hydrolysis of vildagliptin to its major inactive metabolite, LAY151. DPP-4 enzymes contribute partially to the hydrolysis of vildagliptin.

Vildagliptin is not metabolized by CYP 450 enzymes to any quantifiable extent. Further, vildagliptin does not inhibit or induce CYP 450 enzymes. Therefore, vildagliptin is not likely to affect metabolic clearance of medicines commonly co-prescribed with it.

Excretion: Following oral administration of vildagliptin, approximately 85% of the dose is excreted into the urine and 15% of the dose is excreted via biliary route. About 23% of the oral dose of vildagliptin excretes unchanged via renal route. The elimination half-life after oral administration is approximately 3 hours.

Metformin

Absorption: After oral administration, metformin absorption is non-linear and incomplete. At the usual metformin doses and dosing schedules, steady state plasma concentrations are reached within 24 to 48 hours and are generally less than 1 µg/ml. Maximum plasma concentration (Cmax) of metformin is achieves in about 2.5 hours. Absolute bioavailability of a 500 mg metformin tablet is approximately 50 to 60% in healthy subjects.

Food slightly delays and decreases the extent of the absorption of metformin.

Distribution: Plasma protein binding is negligible. Metformin partitions into erythrocytes. The mean volume of distribution (Vd) ranged between 63-276 litres.

Metabolism and Excretion: Metformin is excreted unchanged in the urine. No metabolites have been identified in humans. Following an oral dose, the apparent terminal elimination half-life is approximately 6.5 hours. When renal function is impaired, renal clearance is decreased in proportion to that of creatinine and thus the elimination half-life is prolonged, leading to increased levels of metformin in plasma.

6. Nonclinical Properties

6.1 Animal Toxicology

Animal studies of up to 13-week duration have been conducted with the vildagliptin with metformin combination therapy. No new toxicities associated with the combination were identified. The following data are available when vildagliptin or metformin studied individually.

Vildagliptin

In a 13-week toxicology study in cynomolgus monkeys, skin lesions have been recorded at doses ≥ 5 mg/kg/day. These were consistently located on the extremities (hands, feet, ears and tail). At 5 mg/kg/day (approximately equivalent to human AUC exposure at the 100 mg dose), only blisters were observed. They were reversible despite continued treatment and were not associated with histopathological abnormalities. Flaking skin, peeling skin, scabs and tail sores with correlating histopathological changes were noted at doses ≥ 20 mg/kg/day (approximately 3 times human AUC exposure at the 100 mg dose). Necrotic lesions of the tail were observed at ≥ 80 mg/kg/day. Skin lesions were not reversible in the monkeys treated at 160 mg/kg/day during a 4-week recovery period.

Vildagliptin was not mutagenic in conventional *in vitro* and *in vivo* tests for genotoxicity.

A fertility and early embryonic development study in rats revealed no evidence of impaired fertility, reproductive performance or early embryonic development due to vildagliptin. Embryo-foetal toxicity was evaluated in rats and rabbits. An increased incidence of wavy ribs was observed in rats in association with reduced maternal body weight parameters, with a no-effect dose of 75 mg/kg (10-fold human exposure). In rabbits, decreased foetal weight and skeletal variations indicative of developmental delays were noted only in the presence of severe maternal toxicity, with a no-effect dose of 50 mg/kg (9-fold human exposure). A pre- and postnatal development study was performed in rats. Findings were only observed in association with maternal toxicity at ≥ 150 mg/kg and included a transient decrease in body weight and reduced motor activity in the F1 generation.

A two-year carcinogenicity study was conducted in rats at oral doses up to 900 mg/kg (approximately 200 times human exposure at the maximum recommended dose). No increases in tumour incidence attributable to vildagliptin were observed. Another two-year carcinogenicity study was conducted in mice at oral doses up to 1,000 mg/kg. An increased incidence of mammary adenocarcinomas and haemangiosarcomas was observed with a no-effect dose of 500 mg/kg (59-fold human exposure) and 100 mg/kg (16-fold human exposure), respectively. The increased incidence of these tumours in mice is considered not to represent a significant risk to humans based on the lack of genotoxicity of vildagliptin and its principal metabolite, the occurrence of tumours only in one species and the high systemic exposure ratios at which tumours were observed.

Metformin

Non-clinical data on metformin reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

7. Description

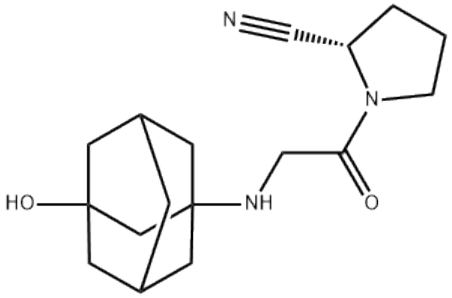
BLUGLIP-M Tablets are yellow coloured film coated, elongated, biconvex tablet having plain surface on both sides.

BLUGLIP-M Forte Tablets are yellow coloured film coated, elongated, biconvex tablet having plain surface on both sides.

Each tablet of BLUGLIP-M contains 50 mg of vildagliptin and 500 mg of metformin hydrochloride for oral administration.
Each tablet of BLUGLIP-M Forte contains 50 mg of vildagliptin and 1000 mg of metformin hydrochloride for oral administration.

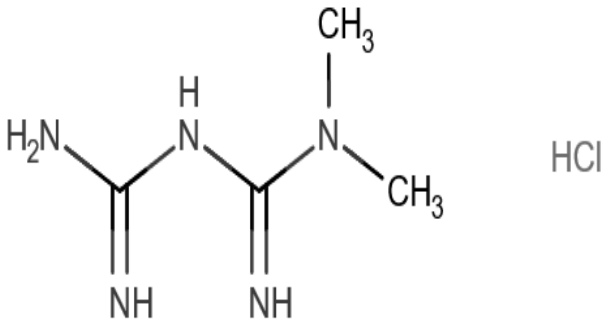
Vildagliptin

Vildagliptin is a cyanopyrrolidine-based oral anti-hyperglycemic agent. Vildagliptin is a potent and selective inhibitor of dipeptidyl peptidase 4 (DPP-4) enzymes.
Vildagliptin is a white solid compound.
Molecular Weight: 303.4 g/mol.
Molecular Formula: C17H25N3O2.
Chemical Name: (2S)-1-[2-[(3-hydroxy-1-adamantyl)amino]acetyl]pyrrolidine-2-carbonitrile.
Structural Formula:



Metformin

Metformin hydrochloride is the hydrochloride salt of the biguanide metformin with antihyperglycemic effect.
Metformin hydrochloride is white powder which is freely soluble in water and slightly soluble in alcohol.
Molecular Weight: 165.62 g/mol.
Molecular Formula: C4H12ClN5.
Chemical Name: 3-(diaminomethylidene)-1,1-dimethylguanidine;hydrochloride.
Structural Formula:



Inactive ingredients (excipients) of BLUGLIP-M Tablet contain Microcrystalline Cellulose, Croscarmellose Sodium, Povidone, Propylene Glycol, Magnesium Stearate, Opadry II White (Polyvinyl Alcohol, Macrogol 3350, Titanium Dioxide, Talc), Ferric Oxide USP-NF (Yellow), and Ferric Oxide USP-NF (Red).

Inactive ingredients (excipients) of BLUGLIP-M Forte Tablet contain Microcrystalline Cellulose, Croscarmellose Sodium, Povidone, Propylene Glycol, Magnesium Stearate, Opadry II White (Polyvinyl Alcohol, Macrogol 3350, Titanium Dioxide, Talc), and Ferric Oxide USP-NF (Yellow).

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2Shelf-life

18 months.

8.3Packaging Information

15 Tablets packed in Alu – Alu Blister.

8.4Storage and Handling Instructions

Store protected from light and moisture at a temperature not exceeding 25°C.
Keep out of reach of children.

9. Patient Counseling Information

- Instruct patients to take this medicine exactly as prescribed by your doctor. Do not change the dose or stop therapy without consulting your doctor.
- Instruct patients not to take this medicine during pregnancy and lactation.
- Instruct patients not to take this medicine if they have liver and/or kidney dysfunction.
- Advise patients not to take this medicine if they have a severe infection or if they are seriously dehydrated.

- Patients are advised not to take this medicine for type 1 diabetes or for the treatment of diabetic ketoacidosis.
- Instruct patients not to take this medicine if they are going to have a contrast x-ray.
- Advise patients not to drink alcohol excessively while on this drug therapy.

10.Details of Manufacturer

Pure & Cure Healthcare Pvt. Ltd.
(A subsidiary of Akums Drugs & Pharmaceutical Ltd.)
Plot No. 26A, 27-30, Sector -8A, I.I.E., SIDCUL, Ranipur,
Haridwar – 249 403, Uttarakhand, India.

11.Details of Permission or License Number with Date

DCG(I) approval date: 21/07/2008.
Manufacturing License No: 31/UA/2013.
Date of Product Permission: 13/12/2019.

12. Date of Revision

February 2021.

Marketed by:
EXCEL BLUE CROSS || EXCEL
Division of
BLUE CROSS LABORATORIES PVT LTD.
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Regd. Off.: Peninsula Chambers, G. K. Marg, Mumbai-400 013.