Brand: Villa-M

Generic Name: Vildagliptin + Metformin (Fixed-dose combination)

Dosage Forms: Oral Tablet

Composition of Villa-M:

- **Vildagliptin**: 50 mg
- **Metformin Hydrochloride**: 500 mg

The combination of vildagliptin and metformin Villa-M is used to manage type 2 diabetes mellitus by improving glycemic control. Here's a breakdown of their mechanisms of action (MOA):

1. Vildagliptin:

- **Class: DPP-4 inhibitor (Dipeptidyl Peptidase-4 inhibitor)**
- **MOA: Vildagliptin works by inhibiting the enzyme DPP-4 (Dipeptidyl Peptidase-4). DPP-4 is responsible for breaking down incretin hormones, specifically GLP-1 (glucagon-like peptide-1) and GIP (gastric inhibitory peptide). These incretin hormones help regulate glucose homeostasis by:**
    - **Stimulating insulin release from the pancreas when blood glucose levels are high.**
    - **Inhibiting glucagon release from the pancreas (glucagon typically increases blood glucose).**

By inhibiting DPP-4, vildagliptin prolongs the action of GLP-1 and GIP, which leads to:

- **Enhanced insulin secretion (especially after meals, when blood glucose levels are elevated).**
- **Decreased glucagon secretion, leading to reduced liver glucose production.**
- **This results in improved postprandial (after meal) and overall glucose control.**

2. Metformin:

- **Class: Biguanide**
- **MOA: Metformin primarily works by reducing hepatic glucose production (gluconeogenesis) in the liver. It also improves insulin sensitivity in peripheral tissues, such as muscle and fat, leading to:**
    - **Increased glucose uptake and utilization by the muscles.**
    - **Decreased hepatic glucose output, which lowers blood glucose levels.**
    - **Metformin also slightly reduces intestinal glucose absorption.**

Metformin activates AMP-activated protein kinase (AMPK), which is an enzyme that plays a central role in regulating energy balance, leading to the beneficial effects on glucose metabolism.

Combined Effect:

- **Vildagliptin increases insulin secretion and reduces glucagon secretion in response to meals, improving glucose control.**
- **Metformin decreases liver glucose production and improves insulin sensitivity in peripheral tissues.**

Together, these drugs provide complementary effects on multiple aspects of glucose regulation:

- **Vildagliptin enhances insulin release when glucose levels are high and reduces excess glucose production from the liver.**
- **Metformin works to improve insulin sensitivity and reduce glucose production from the liver, further controlling blood sugar levels.**

This combination is effective in improving both fasting and postprandial blood glucose levels in patients with type 2 diabetes.

Indications of Villa-M:

- **Vildagliptin 50 mg + Metformin 500 mg** is indicated for the treatment of **type 2 diabetes mellitus**:
    - As an adjunct to diet and exercise to improve glycemic control.
    - In patients who are inadequately controlled on **Metformin** alone or **Vildagliptin** alone.
    - In combination with other oral antidiabetic agents if needed.

Dosage and Administration of Villa-M:

- **Starting dose**: Typically, one tablet of Vildagliptin 50 mg + Metformin 500 mg once daily.
- **Dosage adjustment**: Depending on the patient's blood sugar levels, the dose may be adjusted. If glycemic control is not adequate, the dose may be increased to **one tablet twice daily**.
- **Administration**: Should be taken with food to reduce gastrointestinal side effects associated with metformin (e.g., nausea, upset stomach).

Contraindications:

- **Hypersensitivity** to **Vildagliptin**, **Metformin**, or any other component of the formulation.
- **Severe renal impairment** (e.g., **eGFR** < 30 mL/min/1.73 m²).
- **Acute or chronic metabolic acidosis**, including **diabetic ketoacidosis**.
- **Pregnancy** and **breastfeeding**.
- **Severe hepatic impairment**.

Warnings and Precautions:

- **Lactic acidosis**: Metformin is associated with a rare but serious condition called **lactic acidosis**, which requires immediate medical attention. Risk factors include impaired renal function, liver disease, alcohol abuse, and severe dehydration.
- **Renal function monitoring**: Renal function should be assessed before starting therapy and monitored regularly during treatment. Vildagliptin should not be used in patients with **severe renal impairment**.
- **Hepatic function**: Caution is advised in patients with liver disease. It is contraindicated in severe liver impairment.
- **Pancreatitis**: Caution is advised in patients with a history of pancreatitis.
- **Hypoglycemia**: Vildagliptin alone does not cause significant hypoglycemia, but it may occur when combined with other antidiabetic agents (e.g., sulfonylureas or insulin).

Drug Interactions:

- **Vildagliptin**: The potential for drug-drug interactions is low, but caution should be taken when co-administered with certain medications like **CYP3A4 inducers or inhibitors**, as well as **antihypertensives**.
- **Metformin**: Can interact with **iodinated contrast media**, **corticosteroids**, **diuretics**, and other agents that may affect renal function or increase the risk of **lactic acidosis**.

Side Effects:

Common side effects may include:

- **Gastrointestinal**: Nausea, diarrhoea, abdominal discomfort, flatulence, and loss of appetite (related to Metformin).
- **Hypoglycemia**: This may occur when used in combination with other antidiabetic agents.
- **Skin reactions**: Rash, pruritus, or allergic reactions.
- **Headache** or **dizziness** may also occur.

Serious but rare side effects include:

- **Lactic acidosis** (due to Metformin).
- **Pancreatitis** (due to Vildagliptin).
- **Severe allergic reactions** (e.g., anaphylaxis).

Use in Specific Populations:

- **Pregnancy**: Not recommended during pregnancy. If pregnancy is planned or occurs, treatment should be stopped, and insulin therapy may be needed.
- **Breastfeeding**: Not recommended due to lack of data on excretion in breast milk.
- **Pediatrics**: Safety and effectiveness in children have not been established.
- **Geriatrics**: Elderly patients may be more sensitive to the effects of Metformin, especially with declining renal function, so close monitoring is required.

Overdose:

- **Vildagliptin**: There is no specific treatment for an overdose. In case of overdose, symptomatic treatment should be initiated.
- **Metformin**: Overdose can lead to **lactic acidosis**. In the event of an overdose, immediate medical attention is needed. **Hemodialysis** may be required to remove Metformin from the system.

Storage:

- Store at room temperature, away from moisture and heat.
- Keep out of reach of children.

Packaging:

- Each Alu-Alu strip of Villa-M contains 10 tablets.
- Each box of Villa-M contains 10 strips.

Note: This summary provides general prescribing information.