

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

VINMET TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated contains: Vildagliptin 50mg Metformin HCl USP 1000mg Excipients q.s.
Colour: Approved colour used

Full list of excipients in section 6.1

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

The combination of vildagliptin and metformin hydrochloride (HCl) is indicated for the treatment of type 2 diabetes mellitus in adults. For patients who are inadequately controlled on metformin hydrochloride monotherapy. Adding vildagliptin can help improve blood sugar levels. As an initial therapy in patients with type 2 diabetes mellitus when diet and exercise alone have not provided adequate glycemic control and who are likely to benefit from combination therapy based on high initial HbA1c levels and other factors. In combination with other glucose-lowering medications, including insulin, when these therapies do not provide adequate glycemic control. Metformin reduces hepatic glucose production and improves insulin sensitivity. Vildagliptin enhances insulin secretion and suppresses glucagon release by inhibiting the DPP-4 enzyme. By combining these mechanisms, the vildagliptin and metformin combination provides a more comprehensive approach to managing blood sugar levels in patients with type 2 diabetes, improving overall glycemic control and reducing the risk of diabetes-related complications

4.2. Posology and method of administration Posology:

Adults only: Once or twice daily (as prescribed by the doctor).

Practical advice:

Take at the same time daily to maintain stable blood sugar levels. Metformin can cause dehydration; drink plenty of water.

Take With Food: Helps prevent stomach upset and improves absorption.

Method of administration

Oral.

4.3. Contradictions

Do not use in patients with a known hypersensitivity to any of the active ingredients.
Any

4.4. Special warnings and precautions for use Warnings

Hypoglycemia: More likely if taken with insulin or other diabetes drugs.

Can worsen kidney function and lead to serious side effects.

Increases the risk of lactic acidosis and blood sugar fluctuations if alcohol consumption is not avoided. Not for Type 1 Diabetes or Diabetic Ketoacidosis

Precaution for use

Monitor kidney function regularly (metformin can cause lactic acidosis in kidney disease). Not recommended during pregnancy unless prescribed by a doctor.

If you feel dizzy, shaky, or weak, check your blood sugar and take appropriate action. Avoid if you have severe liver disease (vildagliptin can affect liver enzymes)

Regularly check blood glucose levels to prevent hypoglycemia or hyperglycemia.

4.5. Interaction with other medicinal products and other forms of interaction

Effects of other medicinal products on Vildagliptin and Metformin HCl tablet:

type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis)

Diabetic pre-coma

Severe renal failure (GFR < 30 ml/min)

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.

Results from clinical trials conducted with the oral antidiabetics pioglitazone, metformin and glyburide in combination with vildagliptin have shown no clinically relevant pharmacokinetic interactions in the target population.

Drug-drug interaction studies with digoxin (P-glycoprotein substrate) and warfarin (CYP2C9 substrate) in healthy subjects have shown no clinically relevant pharmacokinetic interactions after co-administration with vildagliptin.

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. However, this has not been established in the target population.

There may be an increased risk of angioedema in patients concomitantly taking ACE inhibitors

It's crucial for healthcare professionals to review the patient's complete medication list, including prescription, over-the-counter, and herbal products, to identify potential interactions.

Adjustments to the treatment plan or monitoring may be necessary based on the patient's specific circumstances. Always consult with a healthcare professional for personalized advice and to ensure the safe use of Vildagliptin and Metformin HCl in

combination with other medicinal products.

4.6. Pregnancy and lactation

Pregnancy

Lactation

There are no adequate data from the use of Vinmet 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. Galdis should not be used during pregnancy.

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 both

the potential risk of neonate hypoglycaemia related to metformin and the lack of human data with vildagliptin,

Vinmet should not be used during breast-feeding

4.7. Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. Patients who may

experience dizziness as an adverse reaction should avoid driving vehicles or using machines.

4.8. Undesirable effects

Safety data were obtained from a total of 6 197 patients exposed to vildagliptin/metformin in randomised placebo-controlled trials. Of these patients, 3 698 patients received vildagliptin/metformin and 2 499 patients received placebo/metformin.

There have been no therapeutic clinical trials conducted with VinmetM. However, bioequivalence of VinmetM with co-administered vildagliptin and metformin has been demonstrated (see section 5.2).

The majority of adverse reactions were mild and transient, not requiring treatment discontinuations. No association was found between adverse reactions and age, ethnicity, duration of exposure or daily dose. Vildagliptin use is associated with the risk of development of pancreatitis. Lactic acidosis has been reported following the use of metformin, especially in patients with underlying renal impairment.

Adverse reactions reported in patients who received vildagliptin in double-blind clinical trials as monotherapy and add-on therapies are listed below by system organ class and absolute frequency. Frequencies are defined as very common ($\geq 1/10$); common ($\geq 1/100$ to $<1/10$); uncommon ($\geq 1/1\ 000$ to $<1/100$); rare ($\geq 1/10\ 000$ to $<1/1\ 000$); very rare ($<1/10$

000), not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

4.9. Overdose:

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

symptoms of overdose with vildagliptin was taken from a

rising dose tolerability study in healthy subjects given vildagliptin for 10 days. At 400 mg, there were three

cases of muscle pain, and individual cases of mild and transient paraesthesia, fever, oedema and a transient

creatine phosphokinase (CPK), 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.

increase in lipase levels. At 600 mg, one subject experienced oedema of the feet and hands, and increases in

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Anti diabetic

ATC Code: A10BD08

The product is an oral Vildagliptin and Metformin HCl use to treat diabetes. Mechanism of action:

Vildagliptin

Vildagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor. Its mechanism of action involves the following steps:

1. **Inhibition of DPP-4 Enzyme:** Vildagliptin inhibits the DPP-4 enzyme, which is responsible for the breakdown of incretin hormones (glucagon-like peptide-1 [GLP-1] and glucose-dependent insulinotropic polypeptide [GIP]).
2. **Increased Incretin Levels:** By inhibiting DPP-4, vildagliptin increases the levels of active incretin hormones.
3. **Enhanced Insulin Secretion:** The incretin hormones stimulate the pancreas to release insulin in a glucose-dependent manner, meaning insulin is released more effectively when blood glucose levels are high.
4. **Reduced Glucagon Secretion:** Incretins also reduce the secretion of glucagon from the alpha cells of the pancreas, which in turn decreases glucose production in the liver.

Metformin
Metformin is a biguanide, and its primary mechanism of action involves:

1. **Inhibition of Hepatic Gluconeogenesis:** Metformin primarily reduces glucose production in the liver. It inhibits the mitochondrial respiratory-chain complex 1, which leads to a decrease in hepatic gluconeogenesis.
2. **Increased Insulin Sensitivity:** Metformin increases the sensitivity of peripheral tissues (such as muscle) to insulin, promoting glucose uptake and utilization.
3. **Improved Glucose Utilization:** Metformin enhances the insulin-stimulated uptake and utilization of glucose in the skeletal muscles.
4. **Reduced Intestinal Absorption of Glucose:** Metformin may also reduce the absorption of glucose from the gastrointestinal tract.

5.2. Pharmacokinetic properties:

The pharmacokinetic (PK) and pharmacodynamic (PD) relationship describes how a drug's concentrations (PK) relate to its effects (PD) on the body. For the combination of vildagliptin and metformin, this relationship is crucial to understanding their efficacy and safety in managing type 2 diabetes

Vildagliptin:

Pharmacokinetics (PK):

Absorption: Rapidly absorbed with a peak plasma concentration (C_{max}) reached in approximately 1.7 hours.

Distribution: Vildagliptin has a moderate volume of distribution and is not extensively bound to plasma

protein.

5.3.

6. 6.1.

Metabolism: Primarily metabolized by hydrolysis to an inactive metabolite. CYP450 enzymes are minimally involved.

Elimination: Excreted mostly via the kidneys, with a half-life of about 3 hours.

Pharmacodynamics (PD):

Inhibits the DPP-4 enzyme, increasing levels of incretin hormones (GLP-1 and GIP), which enhance insulin secretion and suppress glucagon release. Leads to improved postprandial insulin and glucagon responses, lowering blood glucose levels.

Metformin:

Absorption: Absorbed slowly with a peak plasma concentration (C_{max}) reached in about 2.5 hours. Distribution: Metformin is distributed to various tissues, including the intestines, liver, and kidneys, and is minimally bound to plasma proteins.

Metabolism: Metformin is not metabolized and is excreted unchanged in the urine

Elimination: Excreted via the kidneys with a half-life of approximately 6.5 hours.

Pharmacodynamics (PD):

Reduces hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity. Lowers basal and postprandial blood glucose levels..

Preclinical safety data: In general, preclinical safety studies for Iron-III polymaltose complex may include: Toxicology studies: Animal studies (rodents, non-rodents) to assess the effects of the drug on various organs

and systems.

Evaluation of dose-dependent toxic effects.

Assessment of the drug's impact on reproductive and developmental outcomes.

Pharmacokinetic Studies: Studies investigating how the drug is absorbed, distributed, metabolized, and eliminated in animals.

Identification of metabolites and understanding their potential toxicity.

Genotoxic studies: Evaluation of the drug's potential to cause genetic damage.

PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch, Lactose Monohydrate, Sodium Starch Glycolate, PVPK-30, Sodium Benzoate, Aerosil 200, Talcum, Crosscarmellose Sodium

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Store at a temperature not exceeding 30°C, protect from light and moisture.

6.5. Nature and contents of container

6X10 ALU-ALU

6.6. Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing site address:-

Starr Life Sciences -

House No 84, 18 Junction Lashibi,

Spintex Road,

Accra

8. Marketing Authorization Number

FDA/SD.245-122301

9. Date of first authorization or renewal

04/12/2024

10. Date of revision of the text

June 2025