

# Sucovil M

Vildagliptin & Metformin HCl

## Presentation

**Sucovil M 50/850 Tablet:** Each film coated tablet contains Vildagliptin INN 50 mg and Metformin HCl BP 850 mg.

**Sucovil M 50/500 Tablet:** Each film coated tablet contains Vildagliptin INN 50 mg and Metformin HCl BP 500 mg.

## Description

**Sucovil M** is a combination of Vildagliptin INN and Metformin hydrochloride BP. Vildagliptin is a potent and selective dipeptidyl-peptidase-4 (DPP-4) inhibitor that improves glycemic control by rapid and complete inhibition of DPP-4 activity. In patients with type 2 diabetes, administration of Vildagliptin inhibits the DPP-4 enzyme activity for a period of 24 hours. By increasing the endogenous levels of incretin hormones Vildagliptin enhances the sensitivity of beta cells to glucose, resulting in improved glucose-dependent insulin secretion. Metformin is a biguanide drug that decreases hepatic glucose production, decreases intestinal absorption of glucose, increases insulin sensitivity and enhances peripheral glucose uptake.

## Indication

**Sucovil M** is indicated in patients with type 2 diabetes who are unable to achieve sufficient glycemic control at their maximally tolerated dose of oral Metformin alone or who are already treated with the combination of Vildagliptin and Metformin as separate tablets.

## Dosage and administration

**Adults: Sucovil M** may be initiated twice daily, 1 tab in the morning and the other in the evening. The maximum daily dose is 100 mg Vildagliptin plus 2000 mg Metformin HCl. Taking this combination with or just after food may reduce gastrointestinal symptoms associated with Metformin.

## Contraindication

Combination of Vildagliptin & Metformin HCl is contraindicated in patients with hypersensitivity to the active substance or to any of its components, patients with renal impairment, patients with diabetic ketoacidosis, patients with type 1 diabetes.

## Side effect

The majority of adverse reactions are mild and transient, not requiring treatment discontinuations. Lactic acidosis can occur due to Metformin and rare cases of hepatic dysfunction. Some common side effects like tremor, headache, dizziness, nausea, hypoglycaemia, fatigue are seen.

## Use in Special Groups

**Use in Pregnancy:** There are no adequate and well-controlled studies in pregnant women. Therefore it should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

**Use in Lactation:** It is not known whether Vildagliptin is excreted in human milk. Due to lack of human data, Vildagliptin & Metformin combination should not be used during lactation.

**Use in Paediatric Patients:** The safety and effectiveness of combination of Vildagliptin & Metformin in paediatric patients have not been established. Therefore, it is not recommended for use in children below 18 years of age.

**Use in Geriatric Patients (> 65 Years):** As Metformin is excreted via the kidney and elderly patients have a tendency to decrease renal function, so elderly patients taking combination of Vildagliptin & Metformin should have their renal function monitored regularly. It should only be used in elderly patients with normal renal function.

## Precaution

Lactic acidosis can occur due to Metformin accumulation. If metabolic acidosis is suspected, treatment should be discontinued and the patient should be hospitalized immediately. Serum creatinine should be monitored at least once a year in patients with normal renal function and 2-4 times a year in patients with serum creatinine levels at the upper limit of normal and in elderly patients. Special caution should be exercised in elderly patients where renal function become impaired (e.g. when initiating antihypertensives, diuretics or NSAIDs). Vildagliptin & Metformin tablets should be discontinued 48 hours before elective surgery with general anaesthesia and should not usually be resumed earlier than 48 hours afterwards.

## Drug Interaction

In pharmacokinetic studies, no interactions were seen with pioglitazone, metformin, glibenclamide, digoxin, warfarin, amlodipine, ramipril, valsartan or simvastatin. As with other oral antidiabetic medicinal products the glucose-lowering effect of Vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics. Close monitoring of glycemic control is required, when cationic drugs are co-administered. glucocorticoids, beta-2 agonists, diuretics and ACE inhibitors may alter the blood glucose levels.

## Overdose

Symptoms of overdose may include muscle pain, fever, swelling in hands or feet, tingling or numbness in hands or feet, drowsiness, abdominal pain.

## Storage

Store in a cool & dry place and keep away from light. Keep out of the reach of children.

## Commercial Pack

**Sucovil M 50/850 Tablet:** Each box contains 3x6 tablets in Alu-Alu strips.

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Manufactured by:



**Globe Pharmaceuticals Ltd.**

Noakhali, Bangladesh