



Sitagliptin & Metformin Hydrochloride Tablets

Sitaklein-M 50/500

Product Overview

Product Name: **Sitaklein-M 50/500**

Formulation: Sitagliptin & Metformin Hydrochloride Tablets

Strength: Sitagliptin 50 mg + Metformin Hydrochloride 500 mg

Dosage Form: Film-Coated Tablets

Composition per Tablet

Each film-coated tablet contains:

- Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin ... 50 mg
- Metformin Hydrochloride IP ... 500 mg
- Excipients ... q.s.

DESCRIPTION

Sitaklein-M 50/500 is a fixed-dose combination of Sitagliptin and Metformin Hydrochloride used for the management of Type 2 Diabetes Mellitus. Sitagliptin is a DPP-4 (Dipeptidyl Peptidase-4) inhibitor that enhances the body's natural incretin hormones, increasing insulin release and decreasing glucagon secretion in a glucose-dependent manner. Metformin reduces hepatic glucose production, decreases intestinal glucose absorption, and improves insulin sensitivity. Together, they provide effective glycemic control when used along with diet and exercise.

INDICATIONS:

Used in the management of:

- Type 2 Diabetes Mellitus in adults.
- Improvement of fasting and postprandial blood glucose levels.
- Patients inadequately controlled with diet and exercise or metformin alone.
- Long-term glycemic control as part of comprehensive diabetes management.

Dosage & Administration



Adults:

One tablet once or twice daily, or as directed by the physician.

Should be taken with meals to reduce gastrointestinal side effects associated with Metformin.

Do not exceed the recommended dosage without medical supervision.

CONTRAINDICATIONS

- Hypersensitivity to Sitagliptin, Metformin, or any component of the formulation.
- Type 1 Diabetes Mellitus.
- Diabetic ketoacidosis.
- Severe renal impairment.
- Metabolic acidosis, including lactic acidosis.
- Severe hepatic impairment unless advised by a physician.

PRECAUTIONS

- Monitor blood glucose, HbA1c, and renal function regularly.
- Assess kidney function before initiating therapy and periodically thereafter.
- Use with caution in elderly patients and those with renal or hepatic impairment.
- Avoid excessive alcohol consumption while taking this medication.
- Temporarily discontinue before major surgery or administration of iodinated contrast media, as advised by the physician.

SIDE EFFECTS

Common:

- Nausea
- Diarrhea
- Abdominal discomfort
- Headache
- Upper respiratory tract infection
- Nasopharyngitis

RARE:

- Hypoglycemia (especially when used with insulin or sulfonylureas).
- Pancreatitis.
- Lactic acidosis (rare but serious, associated with Metformin).
- Allergic reactions including rash or angioedema.



STORAGE INSTRUCTIONS

Store in a cool, dry place below 25°C.
Protect from direct sunlight and moisture.
Keep out of reach of children.

PRESENTATION

Alu Alu pack containing 10 × 10 tablets.

SCHEDULE

Schedule H Prescription Drug – To be sold by retail on the prescription of a Registered Medical Practitioner only.

Warning: Schedule H drug – Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Made in India for:



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