

# Istalab DM 500 Tablet

## Composition (per film-coated extended-release tablet):

- **Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin** – 10 mg
- **Metformin Hydrochloride (Extended Release)** – 500 mg
- **Sitagliptin Phosphate Monohydrate eq. to Sitagliptin** – 100 mg

## Description:

Istalab DM 500 Tablet is a fixed-dose combination of three oral antidiabetic agents: Dapagliflozin, Metformin (ER), and Sitagliptin. This combination offers a complementary mechanism of action targeting multiple pathways of glucose regulation in patients with type 2 diabetes mellitus. Dapagliflozin is a sodium-glucose co-transporter 2 (SGLT2) inhibitor, Metformin is a biguanide that improves insulin sensitivity and reduces hepatic glucose output, and Sitagliptin is a DPP-4 inhibitor that enhances incretin hormone activity, promoting glucose-dependent insulin release and suppressing glucagon.

## Indications:

- Type 2 Diabetes Mellitus (as an adjunct to diet and exercise)
- Patients inadequately controlled on monotherapy or dual therapy with any of the included agents

## Mechanism of Action:

- **Dapagliflozin** reduces renal glucose reabsorption, leading to glycosuria and lower blood glucose levels.
- **Metformin** decreases hepatic glucose production and increases peripheral insulin sensitivity.
- **Sitagliptin** inhibits the DPP-4 enzyme, increasing endogenous incretin levels, which helps regulate insulin and glucagon secretion in a glucose-dependent manner.

## Dosage and Administration:

- One tablet once or twice daily or as directed by the physician.
- To be taken with food to minimize gastrointestinal side effects associated with Metformin.

## Contraindications:

- Hypersensitivity to any of the active ingredients
- Severe renal impairment (eGFR <30 mL/min/1.73 m<sup>2</sup>)
- Diabetic ketoacidosis
- Acute or chronic metabolic acidosis

## Precautions:

- Monitor renal function prior to and during treatment
- Use with caution in patients with cardiovascular disease or history of pancreatitis
- Risk of genital mycotic infections with SGLT2 inhibitors
- Educate patient on recognizing signs of lactic acidosis

**Side Effects:**

- Common: Urinary tract infections, genital infections, gastrointestinal disturbances, headache
- Rare: Hypoglycemia (when used with insulin or sulfonylureas), lactic acidosis, pancreatitis

**Storage:**

- Store in a cool, dry place below 30°C
- Protect from moisture and direct sunlight
- Keep out of reach of children

Manufactured in India for:



**Cafoli Lifecare Pvt. Ltd.**

**(An ISO 9001: 2015 Certified Co.)**

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