

Brand Name: DEPAZIN M 500

Composition: Dapagliflozin 10 mg & Metformin Hydrochloride (ER) IP 500 mg

Dosage Form: TABLET

Category: Oral Antidiabetic (SGLT2 Inhibitor + Biguanide Combination)

Packaging Type: ALU-ALU

Packaging: 10 x 10

Brief Product Information:

DEPAZIN M 500 is an oral anti-diabetic combination tablet manufactured by **AstraEureka Pharmaceutical**, a trusted **manufacturer of composition** combining **Dapagliflozin** and **Metformin**. This fixed-dose combination is indicated for the management of Type 2 Diabetes Mellitus. It works synergistically to improve glycemic control by reducing glucose reabsorption in the kidneys and improving insulin sensitivity.

Composition:

Each film-coated tablet contains:

Dapagliflozin Propanediol Monohydrate
equivalent to Dapagliflozin.....10 mg
Metformin Hydrochloride IP.....500 mg
Excipients.....q.s.

Key Ingredients:

1. **Dapagliflozin 10 mg:** A Sodium-Glucose Co-Transporter 2 (SGLT2) inhibitor that helps lower blood sugar by promoting urinary glucose excretion.
2. **Metformin Hydrochloride 500 mg:** A biguanide that reduces hepatic glucose production and enhances peripheral insulin sensitivity.
3. **Pharmaceutical Excipients:** Provide stability, uniformity, and proper tablet formulation.

Key Benefits:

1. Dual mechanism of action provides better blood sugar control.
2. Aids in weight loss or weight maintenance.
3. Low risk of hypoglycemia when used alone.
4. Improves HbA1c levels and fasting plasma glucose.
5. Helps delay diabetes-related complications.
6. Convenient once or twice-daily oral dosage.

Indications:

1. Type 2 Diabetes Mellitus (T2DM) in adults
2. As an adjunct to diet and exercise when monotherapy with either component does not provide adequate glycemic control
3. Can be used in combination with other anti-diabetic agents when necessary

Directions for Use:

1. Take the tablet whole with water, preferably with meals to reduce gastrointestinal side effects.
2. Do not crush, split, or chew the tablet.
3. Take at the same time each day for best results.
4. Follow the dosing schedule prescribed by the healthcare provider.

Doses and Administration:

1. **Recommended Dose:** One tablet once or twice daily depending on individual glycemic response and physician's recommendation
2. Dose may be adjusted based on patient response, renal function, and tolerance
3. Maximum daily dose of Metformin should not exceed 2000 mg
4. Monitor blood glucose regularly during therapy

Safety Information:

1. Periodic monitoring of renal function, liver function, and blood glucose levels is recommended
2. Inform the doctor about any history of kidney or heart disease before use
3. Ensure adequate hydration to reduce the risk of dehydration
4. Avoid alcohol while on Metformin as it may increase the risk of lactic acidosis
5. Use with caution in elderly patients and those with impaired renal function

Mechanism of Action:

- **Dapagliflozin:** Inhibits SGLT2 in the proximal renal tubules, reducing glucose reabsorption and increasing urinary glucose excretion, thereby lowering blood glucose levels.
- **Metformin:** Suppresses hepatic gluconeogenesis, decreases intestinal glucose absorption, and improves insulin sensitivity in peripheral tissues.
- Together, they target different mechanisms to achieve better glycemic control with complementary effects.

Contraindications:

1. Hypersensitivity to Dapagliflozin, Metformin, or any excipient
2. Patients with Type 1 Diabetes Mellitus or diabetic ketoacidosis
3. Severe renal impairment (eGFR <30 mL/min/1.73 m²)
4. Acute or chronic metabolic acidosis (including lactic acidosis)
5. Severe hepatic impairment

Side Effects:

1. Common: Urinary tract infections, genital fungal infections, increased urination, nausea, diarrhea
2. Less common: Lactic acidosis (rare but serious), dehydration, hypotension
3. Rare: Hypoglycemia (when used with sulfonylureas or insulin), vitamin B12 deficiency with long-term Metformin use
4. Discontinue and seek immediate care in case of signs of lactic acidosis or severe dehydration

Important Notice:

- DEPAZIN M 500 is a **prescription-only** medicine
- Not for use in patients with Type 1 diabetes or diabetic ketoacidosis
- Regular monitoring and medical supervision are essential
- Maintain proper hydration and avoid alcohol consumption
- Do not discontinue or alter dosage without medical advice

Storage Condition:

1. Store in a cool, dry place below 25°C
2. Protect from light, heat, and moisture
3. Keep out of reach of children
4. Do not use if the tablet strip is torn or expired

Packing Information:

- **Primary Packaging:** Alu-Alu strip
- **Quantity:** 10 tablets per strip
- **Secondary Packaging:** 10 strips per box (10 x 10)