Information For the User Dapagliflozin Propanediol Monohydrate 10mg + Vildagliptin I.P. 100mg Tablets

# Dapa V 10-100 SR

**Composition (per bilayered extended-release tablet):** Dapagliflozin Propanediol Monohydrate — 10 mg Vildagliptin I.P. — 100 mg

#### **Description:**

Dapa V 10/100 SR Tablet is a fixed-dose combination of a Sodium-Glucose Cotransporter-2 (SGLT2) inhibitor and a Dipeptidyl Peptidase-4 (DPP-4) inhibitor, formulated for sustained release. This dual therapy is intended to provide improved glycemic control in adult patients with type 2 diabetes mellitus (T2DM), especially when monotherapy does not offer adequate control. The extended-release formulation ensures prolonged therapeutic action and once-daily dosing convenience.

#### **Indications:**

Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It may be used as part of dual or triple oral therapy regimens.

#### **Mechanism of Action:**

**Dapagliflozin** reduces renal glucose reabsorption, increasing urinary glucose excretion and lowering blood glucose levels independently of insulin secretion.

**Vildagliptin** inhibits the enzyme DPP-4, which increases levels of incretin hormones (GLP-1 and GIP), enhancing insulin secretion and reducing glucagon levels in a glucose-dependent manner.

# **Dosage and Administration:**

One tablet once daily, preferably in the morning, or as directed by the physician. To be taken with or without food. Dosage adjustments may be required based on renal function or concurrent therapy.

# **Contraindications:**

Contraindicated in patients with:

- Hypersensitivity to dapagliflozin, vildagliptin, or any excipients
- Type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis
- Moderate to severe renal impairment without medical supervision

# Warnings and Precautions:

- Monitor renal function before and during treatment
- Caution in patients with cardiovascular disease, pancreatitis, or hepatic impairment
- Discontinue in case of suspected ketoacidosis or urinary tract infections
- Not recommended during pregnancy and lactation unless prescribed

# **Drug Interactions:**

- Risk of hypoglycemia when used with insulin or sulfonylureas
- Monitor when used with diuretics due to volume depletion risk
- No significant interactions with most commonly used medications

#### Side Effects:

Common side effects may include urinary tract infections, genital infections, nausea, headache, dizziness, or hypoglycemia when used with other antidiabetics. Rarely, elevated liver enzymes or signs of pancreatitis may occur.

## **Overdosage:**

In case of overdose, initiate symptomatic and supportive treatment. Monitor blood glucose levels and kidney function. No specific antidote is available.

# **Storage:**

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

Manufactured in India for:

