

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

Dapagliflozin 10mg + Vildagliptin 100mg Tablet

**Dosage Form:** Tablet

**Composition:**

Each film-coated tablet contains:

- Dapagliflozin Propanediol Monohydrate IP 10 mg
  - Vildagliptin IP 100 mg
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**Description**

This tablet is a fixed-dose combination of Dapagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor, and Vildagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor. It is used for the management of type 2 diabetes mellitus in patients inadequately controlled on monotherapy. The combination provides complementary mechanisms of action, addressing both fasting and post-prandial hyperglycemia, and supports sustained glycemic control.

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**Indications**

Indicated for:

- Type 2 diabetes mellitus
- Patients inadequately controlled on monotherapy with either Dapagliflozin or Vildagliptin

It helps in reducing blood glucose levels, improving insulin secretion in a glucose-dependent manner, and increasing urinary glucose excretion, thereby improving overall glycemic stability.

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**Dosage & Administration**

- Dosage should be as directed by the physician.
  - Swallow the tablet whole with water, preferably with meals.
  - Do not crush, chew, or split the tablet.
  - Regular monitoring of blood glucose, renal function, and liver function is recommended.
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**Pharmacological Action**

- **Dapagliflozin:** Selectively inhibits SGLT2 in the renal proximal tubules, reducing glucose reabsorption and increasing urinary glucose excretion. This mechanism lowers plasma glucose independently of insulin.
- **Vildagliptin:** Inhibits DPP-4 enzyme, prolonging the activity of incretin hormones (GLP-1 and GIP). This enhances glucose-dependent insulin secretion and suppresses glucagon release, improving post-prandial glucose regulation.

The combination provides synergistic glycemic control via renal glucose excretion and incretin-mediated insulin modulation.

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## Side Effects

Common side effects may include:

- Increased urination
  - Urinary tract infections
  - Genital infections
  - Mild gastrointestinal discomfort
  - Headache
  - Hypoglycemia (especially when combined with other antidiabetic agents)
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## Precautions & Warnings

- Use with caution in patients with renal or hepatic impairment
  - Monitor for hypoglycemia, particularly in elderly patients
  - Not indicated for type 1 diabetes mellitus or diabetic ketoacidosis
  - Therapy should be under strict medical supervision
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## Drug Interactions

- Concomitant use with insulin or insulin secretagogues may increase hypoglycemia risk
  - Caution with drugs affecting renal function or CYP450 metabolism
  - Consult a physician before combining with other antidiabetic medications
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## Storage

- Store below 25°C in a cool, dry place
- Protect from light and moisture