

Dipodart 10 Tablet

Dapagliflozin 10mg Tablets

Category:

SGLT2 Inhibitor (Antidiabetic)

Dosage Form:

Oral Tablet

Strength:

Dapagliflozin 10 mg per tablet

Description:

Dapagliflozin is a selective inhibitor of sodium-glucose cotransporter 2 (SGLT2). It works by blocking the reabsorption of glucose from the kidneys back into the bloodstream, leading to increased glucose excretion through urine. This helps to lower blood sugar levels in patients with type 2 diabetes. Additionally, Dapagliflozin has been shown to provide benefits in heart failure and chronic kidney disease (CKD) management.

Composition (per tablet):

- **Dapagliflozin: 10 mg**
- **Inactive ingredients:**
Microcrystalline cellulose, lactose monohydrate, magnesium stearate, and others (as excipients).

Indications:

1. Type 2 Diabetes Mellitus:

- Dapagliflozin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.
- It can be used alone or in combination with other antidiabetic medications (e.g., metformin, sulfonylureas, insulin) when those drugs do not provide adequate control.

2. Heart Failure:

- Dapagliflozin is approved for the treatment of heart failure with reduced ejection fraction (HFrEF), regardless of diabetes status, to reduce the risk of hospitalization and death from cardiovascular causes.

3. Chronic Kidney Disease (CKD):

- Dapagliflozin is used to reduce the risk of sustained decline in eGFR, end-stage kidney disease, and renal or cardiovascular death in patients with CKD.
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Mechanism of Action:

Dapagliflozin is an SGLT2 inhibitor that works by blocking the sodium-glucose cotransporter 2 in the kidneys, which is responsible for reabsorbing glucose from the urine back into the blood. By inhibiting

SGLT2, dapagliflozin increases glucose excretion through urine, thereby lowering blood sugar levels. In addition to its effects on blood glucose, dapagliflozin also has benefits on heart function and kidney health by reducing fluid retention, lowering blood pressure, and protecting kidney function.

Dosage and Administration:

- **For Type 2 Diabetes Mellitus:**
 - The recommended dose is 10 mg once daily, taken orally with or without food.
 - The dose can be increased or decreased based on individual response and the patient's tolerance.
- **For Heart Failure (HFrEF):**
 - The usual dose is 10 mg once daily.
 - It may be taken with or without food.
- **For Chronic Kidney Disease (CKD):**
 - The recommended dose is 10 mg once daily.
 - The dose should be adjusted according to kidney function and clinical response.

Note: If a dose is missed, it should be taken as soon as possible, unless it is almost time for the next dose. Do not take two doses to make up for a missed dose.

Contraindications:

- **Hypersensitivity: Known allergy to dapagliflozin or any of the excipients in the formulation.**

- **Severe Renal Impairment:**
Dapagliflozin is not recommended for patients with severe renal impairment (eGFR < 30 mL/min/1.73 m²) or in patients on dialysis.
 - **Diabetic Ketoacidosis (DKA):**
Dapagliflozin should not be used for patients with diabetic ketoacidosis.
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Precautions:

1. Renal Function:

- Dapagliflozin should be used with caution in patients with moderate renal impairment (eGFR 30-59 mL/min/1.73 m²), and it is contraindicated in severe renal impairment (eGFR < 30 mL/min/1.73 m²).
- Regular monitoring of kidney function is recommended during treatment.

2. Hypotension:

- Patients with low blood pressure (hypotension), including those with heart failure or on diuretics, may be at increased risk of dehydration and hypotension. Monitoring of blood pressure is recommended, especially during the initial treatment phase.

3. Urinary Tract Infections (UTIs):

- Dapagliflozin may increase the risk of UTIs and genital infections. Patients should be monitored for symptoms of infection and treated promptly.

4. Ketoacidosis:

- Dapagliflozin is associated with an increased risk of

diabetic ketoacidosis, particularly in patients with type 1 diabetes. Ketoacidosis should be considered in patients presenting with nausea, vomiting, abdominal pain, and fatigue.

5. Pregnancy and Breastfeeding:

- Dapagliflozin is contraindicated during pregnancy (Category D) and should be avoided in breastfeeding mothers unless absolutely necessary.
 - It should not be used in women who are pregnant or planning to become pregnant.
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Adverse Effects:

Common Side Effects:

- Urinary tract infections (UTIs)
- Genital fungal infections
- Increased urination
- Thirst
- Dehydration
- Dizziness or lightheadedness (especially when standing up quickly)

Serious Side Effects (Rare):

- Diabetic ketoacidosis (DKA)
 - Acute kidney injury
 - Hypotension
 - Hypoglycemia (when used with other antidiabetic medications)
 - Serious infections (e.g., urosepsis, pyelonephritis)
 - Allergic reactions (e.g., rash, swelling, difficulty breathing)
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Drug Interactions:

- 1. Diuretics (e.g., furosemide, hydrochlorothiazide):**
 - May increase the risk of dehydration and hypotension.
 - 2. Insulin and Insulin Secretagogues (e.g., sulfonylureas):**
 - May increase the risk of hypoglycemia. Dose adjustment of insulin or sulfonylureas may be necessary.
 - 3. Rifampicin (antibiotic):**
 - May reduce the effectiveness of dapagliflozin.
 - 4. ACE inhibitors and ARBs:**
 - Combined use with dapagliflozin may increase the risk of hypotension and renal dysfunction.
 - 5. Digoxin:**
 - Caution should be used when dapagliflozin is taken with digoxin, as it may increase the risk of digoxin toxicity.
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Storage Instructions:

- Store at room temperature (between 15°C to 30°C).
 - Keep away from moisture and direct sunlight.
 - Store in the original container, tightly closed.
 - Keep out of the reach of children.
 - Do not use after the expiration date mentioned on the packaging.
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Key Benefits:

- **Effective Blood Sugar Control:** Helps lower blood glucose levels, especially in patients with type 2 diabetes, leading to improved glycemic control.
 - **Cardiovascular Benefits:** Proven to reduce hospitalizations due to heart failure and improve heart function in patients with heart failure.
 - **Kidney Protection:** Slows the progression of chronic kidney disease and reduces the risk of kidney-related complications.
 - **Once-Daily Dosing:** Convenient 10 mg daily dosage, improving patient compliance.
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Note: Always follow your healthcare provider's instructions regarding dosage and administration. Regular monitoring of kidney function, blood pressure, and electrolytes is essential for patients taking dapagliflozin, particularly for those with heart failure or kidney disease.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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