

**Dapaveldactin 5 mg<sup>®</sup> F.C.T**

**Dapaveldactin 10 mg<sup>®</sup> F.C.T**

**Dapagliflozin**

**1. INDICATIONS AND USAGE**

**1.1. Type 2 Diabetes Mellitus**

DAPAVELDACTIN<sup>®</sup> (dapagliflozin) is indicated:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors.
- To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.
- To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

**1.3. Limitations of Use**

- DAPAVELDACTIN<sup>®</sup> is not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients [see Warnings and Precautions (5.1)].
- DAPAVELDACTIN<sup>®</sup> is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 45 mL/min/1.73 m<sup>2</sup>. DAPAVELDACTIN<sup>®</sup> is likely to be ineffective in this setting based upon its mechanism of action.
- DAPAVELDACTIN<sup>®</sup> is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. DAPAVELDACTIN<sup>®</sup> is not expected to be effective in these populations.

*Dr/Hoda Nageh*  
9/1/2023

**2. DOSAGE AND ADMINISTRATION**

**2.1. Prior to Initiation of DAPAVELDACTIN<sup>®</sup>**

- Assess renal function prior to initiation of DAPAVELDACTIN<sup>®</sup> therapy and then as clinically indicated [see Warnings and Precautions (5.2)].
- Assess volume status and, if necessary, correct volume depletion prior to initiation of DAPAVELDACTIN<sup>®</sup> [see Warnings and Precautions (5.2) and Use in Specific Populations (8.5, 8.6)].

**2.2 Recommended Dosage**

- See Table 1 for dosage recommendations based on estimated glomerular filtration rate (eGFR).

**Table 1. DAPAVELDACTIN<sup>®</sup> Dosing Recommendations for Patients Based on Renal Function**

Table 1: Recommended Dosage eGFR (mL/min/1.73 m <sup>2</sup> )	Recommended Dose
eGFR 45 or greater	To improve glycemic control, the recommended starting dose is 5 mg orally once daily. Dose can be increased to 10 mg orally once daily for additional glycemic control*. For all other indications, the recommended starting dose is 10 mg orally once daily.
eGFR 25 to less than 45	10 mg orally once daily*.
eGFR less than 25	Initiation is not recommended; however, patients may continue 10 mg orally once daily to reduce the risk of eGFR decline, ESKD, CV death and hHF.
On dialysis	Contraindicated.

\* DAPAVELDACTIN<sup>®</sup> is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 45 mL/min/1.73 m<sup>2</sup>. DAPAVELDACTIN<sup>®</sup> is likely to be ineffective in this setting based upon its mechanism of action.

eGFR: Estimated glomerular filtration rate, hHF: hospitalization for heart failure, CV: Cardiovascular, ESKD: End Stage Kidney Disease

**3. DOSAGE FORMS AND STRENGTHS**

**DAPAVELDACTIN<sup>®</sup> 5 mg**

- Each film-coated tablet contains dapagliflozin propanediol monohydrate 6.15mg equivalent to 5 mg dapagliflozin.
- **DAPAVELDACTIN<sup>®</sup> 10 mg**  
Each film-coated tablet contains dapagliflozin propanediol monohydrate 12.30mg equivalent to 10 mg dapagliflozin

