

# Empavic

## Empagliflozin

### COMPOSITION

**Empavic 10 mg Tablet:** Each film coated tablet contains Empagliflozin INN 10 mg.

**Empavic 25 mg Tablet:** Each film coated tablet contains Empagliflozin INN 25 mg.

### PHARMACOLOGY

Empagliflozin is an inhibitor of Sodium-glucose co-transporter 2 (SGLT2). By inhibiting SGLT2, Empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose and thereby increases urinary glucose excretion.

### INDICATIONS

Empagliflozin 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 cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

### DOSAGE AND ADMINISTRATION

The recommended dose of Empagliflozin is 10 mg once daily in the morning, taken with or without food. In patients tolerating Empagliflozin, the dose may be increased to 25 mg. once daily. In patients with depletion, correcting this condition prior to initiation of Empagliflozin is recommended.

### SIDE-EFFECTS

The most common adverse reactions associated with Empagliflozin are urinary tract infections and female genital mycotic infections. Others common side effects includes dehydration, hypotension, weakness, dizziness and increased thirstiness.

### CONTRAINDICATIONS

Empagliflozin is contraindicated in patients with history of serious hypersensitivity reaction to Empagliflozin or any of its ingredients, severe renal impairment, end-stage renal disease, or dialysis.

### PRECAUTIONS

Assessment of renal function is recommended prior to initiation of Empagliflozin and periodically thereafter. Empagliflozin should not initiated in patients with an eGFR less than 45 ml/min/1.73m<sup>2</sup>. No dose adjustment is needed in patients with an eGFR greater than or equal to 45 ml/min/1.73m<sup>2</sup>.

The risk of necrotizing fasciitis of the perineum/Fournier's gangrene is very rare. Consult with doctor immediately if you experience any symptoms of tenderness, redness or swelling of the genitals or the area from the genitals back to the rectum and have a fever above 100.4°F.

### USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled studies of Empagliflozin in pregnant women. Empagliflozin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known if Empagliflozin is excreted in human milk. It is not recommended when breastfeeding.

### DRUG INTERACTIONS

Diuretics: Coadministration of Empagliflozin with diuretics enhances the potential for volume depletion. Insulin or Insulin Secretagogues: Coadministration of Empagliflozin with insulin or insulin secretagogues increases the risk for hypoglycemia.

### OVERDOSE

There were no reports of overdose during the clinical development program for Empagliflozin. Removal of Empagliflozin by hemodialysis has not been studied.

### STORAGE CONDITION

Keep in a cool & dry place (below 30°C), protected from light & moisture. Keep out of the reach of children.

### COMMERCIAL PACK

**Empavic 10 mg Tablet:** Each box contains 3X10 tablets in alu-alu blister pack.

**Empavic 25 mg Tablet:** Each box contains 3X10 tablets in alu-alu blister pack.

Manufactured by



**BIOPHARMA**

L I M I T E D

A-116, BSCIC, Industrial Estate  
TONGI, GAZIPUR, BANGLADESH

For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.