

Emlozin[®]

Empagliflozin

COMPOSITION:

Emlozin[®] 10 Tablet: Each film coated tablet contains Empagliflozin INN 10 mg.

Emlozin[®] 25 Tablet: Each film coated tablet contains Empagliflozin INN 25 mg.

PHARMACOLOGY:

Empagliflozin is an inhibitor of Sodium-glucose cotransporter-2 (SGLT2). SGLT2 is the predominant transporter responsible for reabsorption of glucose from the kidney back into the circulation. By inhibiting SGLT2,

Empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

INDICATION:

Emlozin[®] is indicated as,

- An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and

- To reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established

cardiovascular disease.

DOSE & ADMINISTRATION:

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

CONTRAINDICATION:

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.

WARNING AND PRECAUTION:

Assessment of renal function is recommended prior to initiation of Empagliflozin and periodically thereafter. Empagliflozin should not be initiated in patients with an eGFR less than 45 mL/min/1.73m². No dose adjustment

is needed in patients with an eGFR greater than or equal to 45 mL/min/1.73m². 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.

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

USE IN PREGNANCY & 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.

USE IN CHILDREN & ADOLESCENTS:

The safety and effectiveness of Emlozin[®] Tablet have not been established in children & adolescence.

DRUG INTERACTION:

Diuretics: Co-administration of Empagliflozin with diuretics resulted in increased urine volume.

Insulin or Insulin Secretagogues: Co-administration of Empagliflozin with insulin or insulin secretagogues increases the risk for hypoglycemia.

Positive Urine Glucose Test: Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. Use alternative methods to monitor glycemic control.

Interference with 1,5-anhydroglucitol (1,5-AG) Assay: Monitoring glycemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control.

OVERDOSE:

In the event of an overdose with Emlozin[®] the usual supportive measures (e.g., remove unabsorbed material from the GI tract, perform clinical monitoring, and institute supportive treatment) should be employed. Removal of Empagliflozin by hemodialysis has not been studied.

STORAGE:

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

PACKING:

Emlozin[®] 10 Tablet: Each box contains 2x15's tablets in Alu-Alu blister pack.

Emlozin[®] 25 Tablet: Each box contains 1x15's tablets in Alu-Alu blister pack.



Manufactured by

Team Pharmaceuticals Ltd.

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