Emfogen™

Empagliflozin Tablet

Presentation
Emfogen™ 10 : Each film coated tablet contains Empagliflozin INN 10 mg.
Emfogen™ 25 : Each film coated tablet contains Empagliflozin INN 25 mg.

Indications
Emfogen™ 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 & 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.

Side Effects
The most common adverse reactions associated with Empagliflozin (5% or greater incidence) are urinary tract infections and female genital mycotic infections.

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^2. No dose adjustment is needed in patients with an eGFR greater than or equal to 45 mL/min/1.73m^2.

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.

Drug Interactions
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 measurement of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control.

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.

Storage Conditions
Store in a cool (below 30°C) and dry place, away from light. Keep out of reach of children.

Commercial Pack
Emfogen™ 10 : Each box contains 2 blister packs of 10 Tablets.
Emfogen™ 25 : Each box contains 1 blister pack of 10 Tablets.

Manufactured by:
general GENERAL Pharmaceuticals Ltd.
Mouchak, Kaliakair, Gazipur, Bangladesh

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