GLIPATAB

EMPAGLIFLOZIN INN

Compositions:

Glipatab 10 Tablet: Each film coated tablet contains Empagliflozin INN 10 mg. Glipatab 25 Tablet: Each film coated tablet contains Empagliflozin INN 25 mg.

Pharmacology:

Empagliflozin is an inhibitor of Sodium-glucose co-transporter 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

Dosage And Administration:

The recommended dose of Glipatab 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.

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.

Warning And Precaution:

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/1.73m2. No dose adjustment is needed in patients with an eGFR greater than or equal to 45 mL/min/1.73m2.

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.

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 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.

Overdosage:

No data is available.

Storage:

Store in a cool (below 30°C) and dry place. Keep out of the reach of the children.

Packing:

Glipatab 10 Tablet: Each box contains 3 x 10 tablets in blister pack. Glipatab 25 Tablet: Each box contains 3 x 10 tablets in blister pack

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.