

DAPATAB

DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE INN

Compositions:

Dapatab-5 Tablet: Each tablet contains Dapagliflozin Propanediol Monohydrate INN equivalent to Dapagliflozin 5 mg. Dapatab-10 Tablet: Each tablet contains Dapagliflozin Propanediol Monohydrate INN equivalent to Dapagliflozin 10 mg.

Pharmacology:

Dapatab (Dapagliflozin) helps lower blood glucose levels by helping the body to filter more excess glucose out of the blood. Sodium-glucose co transporter2 (SGLT2), expressed in the proximal renal tubules, is responsible for the majority of the re-absorption of filtered glucose from the tubular lumen. Dapagliflozin is an inhibitor of SGLT2. By inhibiting SGLT2, Dapagliflozin reduces reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

Dosage And Administration:

- The recommended starting dose is 5 mg once daily, taken in the morning, with or without food.
- Dose can be increased to 10 mg once daily in patients who require additional glycemic control.
- Assess renal function before initiating Dapatab. Do not initiate Dapatab if eGFR is below 60 mL/min/1.73 m².
- Discontinue Dapatab if eGFR falls persistently below 60 mL/min/1.73 m².

Contraindications:

Contraindicated in patients with hypersensitivity to any component of this product.

Warning And Precaution:

Dapagliflozin is not recommended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Side Effects:

Dapagliflozin may cause female genital mycotic infections, nasopharyngitis and urinary tract infections

Use in Pregnancy and Lactation:

Pregnancy: There are no adequate well controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to fetus. Lactation: Discontinue Dapatab or discontinue nursing.

Drug Interaction:

Valsartan, Rifampin, Mefenamic acid either increase or decrease plasma concentration of Dapagliflozin. Dapagliflozin either increase or decrease plasma concentration of Bumetanide, Pioglitazone and Valsartan.

Overdosage:

There were no reports of overdose during the clinical development program for Dapagliflozin.

Storage:

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

Packing:

Dapatab-5 Tablet: Each box contains 3 x 10 tablets in blister pack. Dapatab-10 Tablet: Each box contains 2 x 10 tablets in blister pack.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.