DAPAGLIP™

Dapagliflozin 5 & 10 mg

1246

Presentation

Dapaglip™ 5: Each tablet contains Dapagliflozin Propanediol Monohydrate INN equivalent to Dapagliflozin 5 mg. Dapaglip™ 10: Each tablet contains Dapagliflozin Propanediol Monohydrate INN equivalent to Dapagliflozin 10 mg.

Description

Dapagliflozin is an inhibitor of Sodium-Glucose Cotransporter 2 (SGLT2). By inhibiting SGLT2, Dapagliflozin reduces reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion. Thus reduces blood sugar levels.

Indications

Dapagliflozin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dosage and administration

The recommended starting dose of Dapagliflozin is 5 mg once daily, taken in the morning, with or without food. In patients tolerating Dapagliflozin 5 mg once daily who require additional glycemic control, the dose can be increased to 10 mg once daily.

Assessment of renal function is recommended prior to initiation of Dapagliflozin therapy and periodically thereafter. Dapagliflozin should not be initiated in patients with an eGFR less than 60 mL/min/1.73 m^2. No dose adjustment is needed in patients with mild renal impairment (eGFR of 60 mL/min/1.73 m^2 or greater). Dapagliflozin should be discontinued when eGFR is persistently less than 60 mL/min/1.73 m^2.

Use in Pregnancy and Lactation

Pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing Mothers: Discontinue Dapagliflozin or discontinue nursing.

Side-effects

Hypotension, impairment in renal function, hypoglycemia with concomitant use with insulin and insulin secretagogues, genital mycotic infections, increases in Low-Density Lipoprotein Cholesterol (LDL-C).

Contraindications

History of serious hypersensitivity reaction to Dapagliflozin. Severe renal impairment, end-stage renal disease, or dialysis, diabetic ketoacidosis, type-1 diabetes.

Warning:

The risk of necrotizing fasciitis of the perineum/Fournier's gangrene.

Precautions

Hypotension: Before initiating Dapagliflozin, volume status should be assessed and correction on hypovolemia should be made in the elderly, in patients with renal impairment or low systolic blood pressure, and in patients on diuretics. *Impairment in renal function:* Monitoring renal function is needed during therapy. *Hypoglycemia:* In patients taking insulin or an insulin secretagogue with Dapagliflozin, lower dose of insulin or the insulin secretagogue is considered to reduce the risk of hypoglycemia. *Genital mycotic infections:* Monitoring and treatment should be done if indicated. *Increased LDL-C:* Monitoring and treatment should be as per standard of care. *Bladder Cancer:* An imbalance in bladder cancers was observed in clinical trials. Dapagliflozin should not be used in patients with active bladder cancer and should be used with caution in patients with a prior history of bladder cancer.

Drug interactions

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

Overdose

There were no reports of overdose during the clinical development program for Dapagliflozin. The removal of Dapagliflozin by hemodialysis has not been studied.

Storage condition

Do not store above 30° C. Keep out of the reach of children.

Commercial pack

Dapaglip™5: Each box contains 3 blister strips of 10 tablets. Dapaglip™10: Each box contains 2 blister strips of 10 tablets.

Manufactured by
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Savar, Dhaka, Bangladesh
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