Only for the use of Medical Professionals

Glycema®

Dapagliflozin

Description

Glycema® is a preparation of Dapagliflozin, which is an inhibitor of Sodium-glucose co-transporter 2 (SGLT2). Sodium-glucose co-transporter 2 (SGLT2), expressed in the proximal renal tubules, is responsible for the majority of the reabsorption of filtered glucose from the tubular lumen. By inhibiting SGLT2, Dapagliflozin reduces reabsorption of filtered glucose and lowers the renal threshold for glucose (RTG), and thereby increases urinary glucose excretion.

Indications

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

Dosage and administration

Adults

The recommended starting dose of **Glycema®** 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.

Patients with Renal Impairment: 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 m2.

No dose adjustment is needed in patients with mild renal impairment (eGFR of 60 mL/min/1.73 m2 or greater). Dapagliflozin should be discontinued when eGFR is persistently less than 60 mL/min/1.73 m2.

Children

The safety and efficacy of Dapagliflozin in children and adolescents (<18 years) have not been established.

Use in pregnancy & lactation

Pregnancy

Dapagliflozin is pregnancy category C. There are no adequate data and well controlled studies on the use of Dapagliflozin in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

It is not known whether Dapagliflozin is excreted in human milk. However, Dapagliflozin should not be used during lactation.

Side effects
The most common side effects of Dapagliflozin includes hypotension, ketoacidosis, acute kidney injury and impairment in renal function, urosepsis and pyelonephritis, hypoglycemia with concomitant use with insulin and insulin secretagogues, genital mycotic infections, increases in low-density lipoprotein cholesterol (LDL-C), nasopharyngitis, urinary tract infection and bladder cancer.

Contraindications
This product is contraindicated in patients with known hypersensitivity to Dapagliflozin or to any of the excipients. It is also contraindicated in severe renal impairment, end-stage renal diseases or patients on dialysis.

Warning & Precautions
Hypotension: Before initiating Dapagliflozin, assess volume status and correct hypovolemia in the elderly, in patients with renal impairment or low systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms during therapy.
Impairment in renal function: Monitor renal function during therapy.
Hypoglycemia: In patients taking insulin or an insulin secretagogue with Dapagliflozin, consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia.
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.
Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Dapagliflozin or any other antidiabetic drug.

Drug interactions
Dapagliflozin can interact and may add to the diuretic effect of thiazide and loop diuretics and increase the risk of dehydration and hypotension. Insulin and insulin secretagogues, such as sulphonylureas, cause hypoglycemia. Therefore, a lower dose of insulin or an insulin secretagogue may be required to reduce the risk of hypoglycaemia when used in combination with Dapagliflozin. It may have interaction with antihypertensives, pioglitazone, agents that affect renal function (e.g., ACE inhibitors, angiotensin II antagonists), GLP-1 agonists, valsartan, rifampin, mefenamic acid.

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

Pharmaceutical precautions
Store in a cool (below 30°C) & dry place protected from light. Keep away from the reach of children.

Presentation

Glycema®5 tablet: Each coated tablet contains Dapagliflozin Propanediol Monohydrate INN 6.151 mg equivalent to Dapagliflozin 5 mg.

Glycema®10 tablet: Each coated tablet contains Dapagliflozin Propanediol Monohydrate INN 12.302 mg equivalent to Dapagliflozin 10 mg.

Package quantities

Glycema®5 tablet: Carton of 30 tablets in blister pack.

Glycema®10 tablet: Carton of 20 tablets in blister pack.

® Registered Trade Mark

ACI Limited

Godnyl, Narayanganj, Bangladesh