

# Diacana<sup>TM</sup>

Canagliflozin

## COMPOSITION

Each film coated tablet contains Canagliflozin Hemihydrate INN equivalent to Canagliflozin 100 mg.

## PHARMACOLOGY

Canagliflozin is an inhibitor of subtype-2 sodium-glucose co-transport protein (SGLT-2), which is responsible for at least 90% of the glucose reabsorption in the kidney. Blocking this transporter reduces the reabsorption of glucose from renal tubules, leading to more excretion of glucose in urine.

## INDICATIONS

**Diacana** 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 is 100 mg once daily, taken before the first meal of the day. Dose can be increased to 300 mg once daily who have CrCl  $\geq$ 60 ml/min or who requires additional glycemic control. No dose adjustment is required for mild renal impairment. For moderate renal impairment (CrCl 45-60 ml/min), **Diacana** 100 mg is recommended.

## CONTRAINDICATIONS

History of serious hypersensitivity reaction to Canagliflozin, severe renal impairment, End Stage Renal Disease (ESRD), or on dialysis patients.

## WARNING AND PRECAUTION

Not for the treatment of type-1 diabetes mellitus or diabetic ketoacidosis. The risk of necrotizing fasciitis of the perineum/Fournier's gangrene is very rare. Consult with doctor immediately if you experience any symptoms of tenderness, redness or swelling of the genitals or the area from the genitals back to the rectum and have a fever above 100.4<sup>o</sup> F.

## SIDE EFFECTS

The most common adverse reactions of Canagliflozin are female genital mycotic infections, urinary tract infection and increased urination. Other side effects of Canagliflozin include low blood pressure, increases potassium blood levels (hyperkalemia), low blood glucose and increases Low-Density Lipoprotein Cholesterol (LDL-C).

## USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies on pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. For nursing mother discontinue drug or nursing.

## USE IN CHILDREN AND ADOLESCENTS

Safety and effectiveness of Canagliflozin in paediatric patients under 18 years of age have not been established. Adverse reactions related to reduced intravascular volume with Canagliflozin have been seen in patients 65 years or older.

## DRUG INTERACTIONS

**UGT inducers (e.g. Rifampin, Phenytoin):** Canagliflozin exposure is reduced. Consider increasing dose from 100 mg to 300 mg.

**Digoxin:** Canagliflozin may slightly increase the concentration of digoxin in the body when both drugs are being taken.

## OVERDOSAGE

For overdose, contact Poison Control and administer standard support measures. Canagliflozin is minimally removed by dialysis and is not expected to be effectively removed by peritoneal dialysis.

## STORAGE

Store below 30<sup>o</sup>C temperature in a cool & dry place. Protect from light & moisture. Keep out of the reach of children.

## HOW SUPPLIED

Each box contains 10 tablets in Alu-Alu blister pack.