# Canaglif™

Canagliflozin

**COMPOSITION**
**Canaglif**™ 100 Tablet**:** Each tablet contains Canagliflozin 100 mg as Canagliflozin Hemihydrate INN.

**PHARMACOLOGY**
**Canaglif**™ is a Sodium-glucose co-transporter 2 (SGLT2) inhibitor. 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, Canagliflozin reduces reabsorption of filtered glucose and lowers the renal threshold for glucose ($RT_G$), and thereby increases urinary glucose excretion.

**INDICATION**
**Canaglif**™ is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus.

**DOSAGE AND ADMINISTRATION**
The recommended starting dose of **Canaglif**™ is 100 mg once daily, taken before the first meal of the day. Dose can be increased to 300 mg once daily in patients tolerating **Canaglif**™ 100 mg once daily who have an eGFR of 60 mL/min/1.73 $m^2$ or greater and require additional glycemic control. If the eGFR of Patients is 45 to 60 mL/min/1.73 $m^2$, the dose of **Canaglif**™ should be 100 mg once daily.

**SIDE EFFECTS**
Dehydration, Vaginal yeast infection, Yeast infection of the penis (balanitis or balanoposthitis).

**ADVERSE REACTIONS**
Hypotension, impairment in renal function, hyperkalemia, hypoglycemia with concomitant use with, insulin and insulin secretagogues, genital mycotic infections, hypersensitivity reactions, increases in Low-Density Lipoprotein (LDL-C)

**WARNINGS**
*Hypotension:* Before initiating Canagliflozin, assess volume status and correct hypovolemia in patients with renal impairment, the elderly, in patients with low systolic blood pressure, or if on diuretics, ACEi (Angiotensin converting enzyme inhibitor), or ARB (Angiotensin receptor blocker). Monitor for signs and symptoms during therapy.
*Impairment in Renal Function:* Monitor renal function during therapy. More frequent monitoring is recommended in patients with eGFR below 60 mL/min/1.73 $m^2$. Do not initiate Canagliflozin if eGFR is below 45 mL/min/1.73 $m^2$.
*Hyperkalemia:* Monitor potassium levels in patients with impaired renal function and in patients predisposed to hyperkalemia.
*Hypoglycemia:* Consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia when used in combination with Canagliflozin.

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

**USE IN PREGNANCY AND LACTATION**
*Pregnancy:* Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Canagliflozin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
*Nursing Mothers:* It is not known if Canagliflozin passes into breast milk. Discontinue drug or nursing.

**GERIATRIC USE**
Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with Canagliflozin (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration).

**PEDIATRIC USE**
Safety and effectiveness of Canagliflozin in pediatric patients under 18 years of age have not been established.

**CONTRAINDICATIONS**
History of a serious hypersensitivity reaction to Canagliflozin, Severe renal impairment (eGFR less than 30 mL/min/1.73 $m^2$), end stage renal disease or patients on dialysis.

**DRUG INTERACTIONS**
*UGT enzyme inducers:* The efficacy of Canagliflozin may be reduced when Co-administered with UGT enzyme inducers (e.g., with rifampin, phenytoin,phenobarbital, ritonavir). There was an increase in the area AUC and mean peak drug concentration ($C_{max}$) of digoxin (20% and 36%, respectively) when co-administered with Canagliflozin.

**STORAGE**
Protect from light and moisture. Store below 30°C. Keep medicine out of the reach of children.

**HOW SUPPLIED**
**Canaglif**™ 100 Tablet: Each box contains 10 tablets in blister pack.

Manufactured by
**SQUARE**
**PHARMACEUTICALS LTD.**
**BANGLADESH**