# Elpida™ 200

Sotagliflozin Tablet

**Presentation**
Elpida™ 200: Each film coated tablet contains Sotagliflozin INN 200 mg.

**Description**
Sotagliflozin is an orally delivered dual inhibitor of SGLT1 and SGLT2. Sotagliflozin improves glycaemic and metabolic control through dual inhibition - local inhibition of SGLT1 in the gut and systemic SGLT2 inhibition in the proximal renal tubule. Inhibition of SGLT1 delays and reduces glucose absorption in the proximal intestine, resulting in a blunting and delay of postprandial hyperglycaemia. Inhibition of SGLT2 reduces renal glucose reabsorption and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

**Indications**
Sotagliflozin is indicated as an adjunct to insulin therapy to improve glycaemic control in adults with type 1 diabetes mellitus with a Body Mass Index (BMI) ≥ 27 kg/m$^2$, who have failed to achieve adequate glycaemic control despite optimal insulin therapy.

**Dosage and Administration**
Sotagliflozin is administered by the oral route. The recommended dose is 200 mg sotagliflozin once daily before the first meal of the day. After atleast three months, if additional glycaemic control is needed, in patients tolerating sotagliflozin 200 mg, the dose may be increased to 400 mg once daily.

**Side-effects**
Hypotension, renal impairment, hepatic impairment, genital mycotic infections, urinary tract infections, nausea, vomiting, or abdominal pain, excessive thirst, constantly feeling tired, high levels of ketones in urine tests or beta-hydroxybutyrate (BHB) in blood tests, difficulty breathing/rapid, deep breathing, difficulty paying attention, or confusion, rapid weight loss.

**Contraindications**
Hypersensitivity to the active substance or to any of the excipients

**Precautions**
*Hypotension:* Before initiating Sotagliflozin, volume status should be assessed and correction on hypovolemia should be made in the elderly, in patients with renal impairment, in patients with low systolic blood pressure and in patients on diuretics since Sotagliflozin causes intravascular volume contraction.

*Impairment in Renal Function:* Renal function should be evaluated prior to initiating Sotagliflozin and periodically. Initiation of sotagliflozin is not recommended when eGFR is less than 60 ml/min/1.73 m$^2$ and should be discontinued if eGFR is persistently less than 45 mL/min/1.73 m$^2$

*Hepatic impairment:* Sotagliflozin is not recommended in patients with moderate and severe hepatic impairment, as sotagliflozin exposure is increased in these patients.

*Genital mycotic infections:* Monitoring and treatment should be done as appropriate.
*Urinary tract infections:* Temporary interruption of Sotagliflozin should be considered when treating pyelonephritis and urosepsis.

**Use in Pregnancy and Lactation**
*Pregnancy:* There are no data from the use of Sotagliflozin in pregnant women.
*Lactation:* No data in humans are available on excretion of Sotagliflozin into milk.

**Drug Interaction**
Interaction studies conducted in healthy volunteers show that Sotagliflozin had no clinically relevant effect on the pharmacokinetics of metformin, metoprolol, midazolam and oral contraceptives.
Insulin: Insulin may increase the risk of hypoglycaemia. A lower dose of insulin may be required to minimize the risk of hypoglycaemia when used in combination with Sotagliflozin

**Over dosage**
Multiple doses of 800 mg once daily were administrated in healthy volunteers and these doses were well tolerated. In the event of an overdose, appropriate supportive treatment should be initiated as dictated by the patient's clinical status.The removal of Sotagliflozin by haemodialysis has not been studied.

**Storage**
Do not store above 30$^0$ C. Keep away from light and out of the reach of children.

**Commercial pack**
Elpida™ 200: Each box contains 1 blister strip of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
™ Trademark