inpefa™
sotagliflozin tablets

INPEFA™ (SOTAGLIFLOZIN) ORDER SET

Please see Important Safety Information on page 3 and click here for full Prescribing Information.

EXAMPLE ONLY ORDER SET: PROVIDED FOR EDUCATIONAL PURPOSES ONLY
Requires review and approval by clinician and pharmacy and/or any required hospital committees prior to adopting or using any portion of this example order set

INDICATION

INPEFA™ (sotagliflozin) is indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with:

- heart failure or
- type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors

SYMBOL KEY

☑ Pre-selected checkbox ☐ Checkbox

PRIOR AUTHORIZATION[1]

☑ Ensure authorization completed for outpatient continuation of medication.

MEDICAL DECISION-MAKING/PRECAUTIONS[1]

☑ **Diabetic Ketoacidosis in Patients with Type 1 Diabetes Mellitus and Other Ketoacidosis:** Consider ketone monitoring in patients with type 1 diabetes mellitus and consider ketone monitoring in others at risk for ketoacidosis, as indicated. Assess for ketoacidosis regardless of presenting blood glucose levels and discontinue INPEFA if ketoacidosis is suspected. Monitor patients for resolution of ketoacidosis before restarting.

☑ **Volume Depletion:** Before initiating sotagliflozin, assess, and if necessary, correct volume status in patients with renal impairment, the elderly, in patients with low systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms of hypotension during therapy.

☑ **Urosepsis and Pyelonephritis:** Monitor for signs and symptoms during therapy and treat promptly, as indicated.

☑ **Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues:** Before initiating sotagliflozin, assess concomitant use that may increase the risk of hypoglycemia. Lower dose of insulin or insulin secretagogue may be required.

☑ **Necrotizing Fasciitis of the Perineum (Fournier's Gangrene):** Assess patients who present with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, discontinue sotagliflozin, evaluate, and treat urgently.

☑ **Genital Mycotic Infections:** Monitor and treat as appropriate.

☑ **Renal Function:** No dose adjustment required for patients with an eGFR ≥25 mL/min/1.73 m^2. Data are insufficient to provide a dosing recommendation for initiation of treatment in patients with eGFR <25 mL/min/1.73 m^2. In clinical studies, patients were discontinued if eGFR fell below 15 mL/min/1.73 m^2 or they were initiated on chronic dialysis.

MEDICATION DOSING[1]

☐ ***INPEFA 200 mg by mouth once daily (recommended starting dose) to be given not more than one hour before the first meal of the day.***

☐ ***INPEFA 400 mg by mouth once daily (for patients tolerating 200 mg by mouth daily after at least 2 weeks).***

☑ ***Swallow tablets whole. Do not cut, crush, or chew.***

☑ ***If a dose is missed by more than 6 hours, take the next dose as prescribed the next day.***

Important Safety Information

INDICATION

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- heart failure or
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IMPORTANT SAFETY INFORMATION

Dosing: Assess renal function and volume status and, if necessary, correct volume depletion prior to initiation of INPEFA. INPEFA dosing for patients with decompensated heart failure may begin when patients are hemodynamically stable, including when hospitalized or immediately upon discharge.

Contraindications: INPEFA is contraindicated in patients with a history of serious hypersensitivity reaction to INPEFA.

Warnings and Precautions:

- **Ketoacidosis:** INPEFA increases the risk of ketoacidosis in patients with type 1 diabetes mellitus (T1DM). Type 2 diabetes mellitus (T2DM) and pancreatic disorders are also risk factors. The risk of ketoacidosis may be greater with higher doses. There have been postmarketing reports of fatal events of ketoacidosis in patients with type 2 diabetes using sodium glucose transporter 2 (SGLT2) inhibitors. Before initiating INPEFA, assess risk factors for ketoacidosis. Consider ketone monitoring in patients with T1DM and consider ketone monitoring in others at risk for ketoacidosis and educate patients on the signs/symptoms of ketoacidosis. Patients receiving INPEFA may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis. INPEFA is not indicated for glycemic control. Assess patients who present with signs and symptoms of metabolic acidosis or ketoacidosis, regardless of blood glucose level. If suspected, discontinue INPEFA, evaluate, and treat promptly. Monitor patients for resolution of ketoacidosis before restarting INPEFA.
- **Volume Depletion:** INPEFA can cause intravascular volume depletion which may sometimes manifest as symptomatic hypotension or acute transient changes in creatinine. There have been postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis, in patients with type 2 diabetes mellitus receiving SGLT2 inhibitors. Patients with impaired renal function (eGFR < 60 mL/min/1.73 m^2), elderly patients, or patients on loop diuretics may be at increased risk for volume depletion or hypotension. Before initiating INPEFA in patients with one or more of these characteristics, assess volume status and renal function, and monitor for signs and symptoms of hypotension during therapy.
- **Urosepsis and Pyelonephritis:** Treatment with SGLT2 inhibitors, including INPEFA, increases the risk for urinary tract infections. Serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization have been reported. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly.
- **Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues:** Insulin and insulin secretagogues are known to cause hypoglycemia. INPEFA may increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used with INPEFA.
- **Necrotizing Fasciitis of the Perineum (Fournier's Gangrene):** Reports of Fournier's Gangrene, a rare but serious and life-threatening necrotizing infection requiring urgent surgical intervention, have been identified in postmarketing surveillance in patients with diabetes mellitus receiving SGLT2 inhibitors. Assess patients who present with pain, tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, start treatment immediately with broad-spectrum antibiotics and, if necessary, surgical debridement. Discontinue INPEFA, closely monitor patient signs and symptoms, and provide appropriate alternative therapy for heart failure.
- **Genital Mycotic Infections:** INPEFA increases the risk of genital mycotic infections. Monitor and treat as appropriate.
- **Urinary Glucose Test and 1,5-anhydroglucitol (1,5-AG) Assay:** These are not reliable for patients taking SGLT2 inhibitors. Use alternative testing methods to monitor glucose levels.
- **Common Adverse Reactions:** The most commonly reported adverse reactions (incidence ≥5%) were urinary tract infection, volume depletion, diarrhea, and hypoglycemia.

Drug Interactions:

- **Digoxin:** Monitor patients appropriately as there is an increase in the exposure of digoxin when coadministered with INPEFA 400 mg.
- **Uridine 5'-diphospho-glucuronosyltransferase (UGT) Inducer:** The coadministration of rifampicin, an inducer of UGTs, with sotagliflozin resulted in a decrease in the exposure of sotagliflozin.
- **Lithium:** Concomitant use of an SGLT2 inhibitor with lithium may decrease serum lithium concentrations. Monitor serum lithium concentration more frequently during INPEFA initiation and with dosage changes.

Use in Specific Populations:

- **Pregnancy and Lactation:** INPEFA is not recommended during the second and third trimesters of pregnancy, nor while breastfeeding.
- **Geriatric Use:** No INPEFA dosage change is recommended based on age. No overall differences in efficacy were detected between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Elderly patients may be at increased risk for volume depletion adverse reactions, including hypotension.
- **Renal Impairment:** INPEFA was evaluated in patients with chronic kidney disease (eGFR 25 to 60 mL/min/1.73 m^2) and in patients with heart failure with eGFR < 60 mL/min/1.73 m^2. The safety profile of INPEFA across eGFR subgroups in these studies was consistent with the known safety profile. There was an increase in volume-related adverse events (e.g., hypotension, dizziness) in patients with eGFR < 30 mL/min/1.73 m^2 relative to the overall safety population. Efficacy and safety studies with INPEFA did not enroll patients with an eGFR less than 25 mL/min/1.73 m^2 or on dialysis. After starting therapy in the studies, patients were discontinued if eGFR fell below 15 mL/min/1.73 m^2 or were initiated on chronic dialysis.
- **Hepatic Impairment:** INPEFA is not recommended in patients with moderate or severe hepatic impairment.

For more information, see full Prescribing Information.

Reference: 1. INPEFA Prescribing Information. Lexicon Pharmaceuticals. 2023.

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