inpefa®

sotagliflozin tablets

INPEFA 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

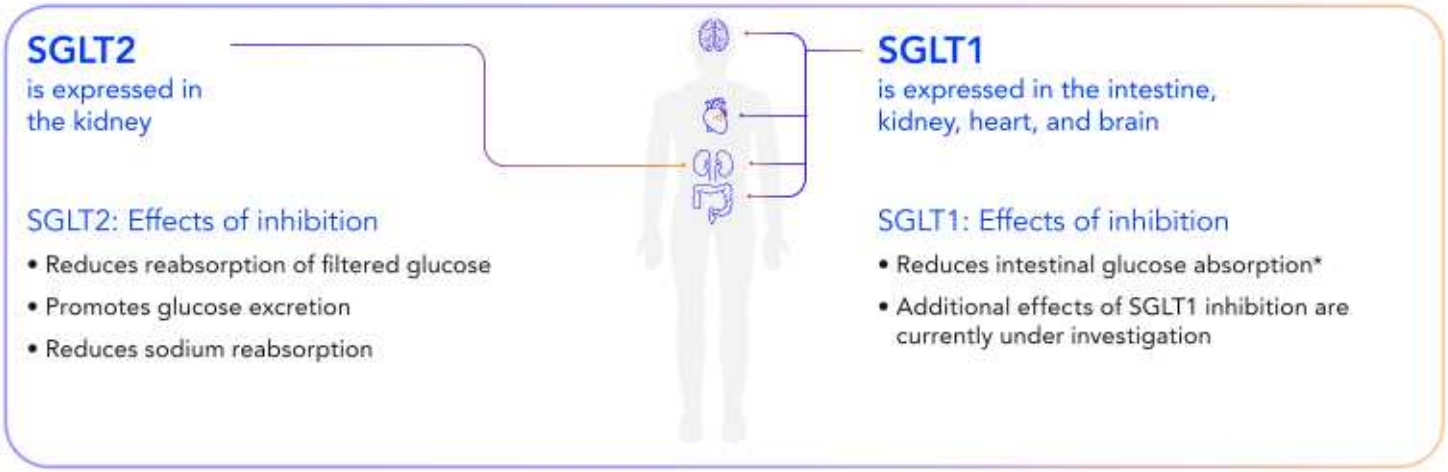
IMPORTANT SAFETY INFORMATION

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

Please see Important Safety Information throughout, and click here for full Prescribing Information.

INPEFA is the only SGLT2 inhibitor with SGLT1 inhibition activity that was uniquely recognized in the clinical pharmacology section of its FDA label[1-3]

The mechanism for cardiovascular benefit for INPEFA has not been established.[1]



INITIATION OF GDMT, INCLUDING INPEFA, IS RECOMMENDED PRIOR TO HOSPITAL DISCHARGE[4]

AHA/ACC/HFSA JOINT GUIDELINES[a]

State that initiating GDMT **once stabilized and before discharge** is recommended and optimizing GDMT is a key component of a transitional care plan for patients with HF

Extending benefits of SGLTi: The SOLOIST-WHF trial extends the benefits of SGLTi to patients with diabetes and acutely decompensated HF

GDMT optimization during hospitalization: In SOLOIST-WHF, initiation of **INPEFA** before or shortly after discharge reduced the risk of cardiovascular mortality and hospitalization

*Which likely contributes to diarrhea.

ACC=American College of Cardiology; AHA=American Heart Association; GDMT=guideline-directed medical therapy; HF=heart failure; HFSA=Heart Failure Society of America.

References: 1. INPEFA Prescribing Information. Lexicon Pharmaceuticals. 2023. **2.** Song P, Onishi A, Koepsell H, Vallon V. Sodium glucose cotransporter SGLT1 as a therapeutic target in diabetes mellitus. *Expert Opin Ther Targets*. 2016;20(9):1109-1125. **3.** Lapuerta P, Zambrowicz B, Strumph P, Sands A. Development of sotagliflozin, a dual sodium-dependent glucose transporter 1/2 inhibitor. *Diab Vasc Dis Res*. 2015;12(2):101-110. **4.** Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18):e895-e1032.

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.

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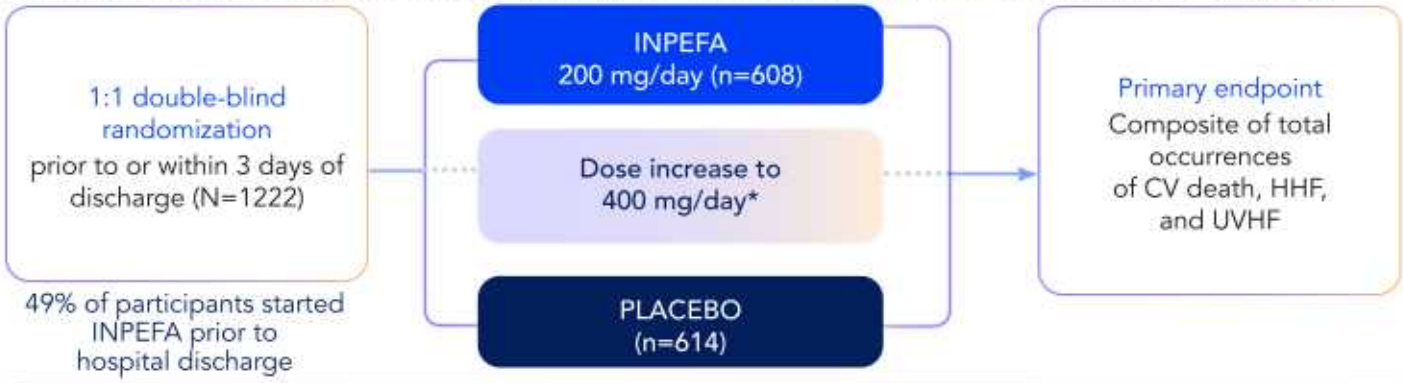
Clinical trial design: SOLOIST-WHF

Clinical outcomes in patients with type 2 diabetes post worsening HF[1]

A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP, MULTICENTER STUDY IN PATIENTS WITH T2DM ADMITTED FOR A WHF EVENT



Key inclusion criteria[2]
- T2DM
- Admitted to the hospital, heart failure unit, infusion center, or emergency department for WHF

Stabilization
- Off oxygen, transitioning to oral diuretics
- Elevated BNP or NT-proBNP

Key exclusion criteria
- End-stage HF
- Recent ACS, stroke, PCI, or CABS
- eGFR <30 mL/min/1.73 m^2

Secondary endpoints[2]
- Hospitalizations and urgent visits for heart failure†
- Deaths from cardiovascular causes†
- Deaths from cardiovascular causes, hospitalizations for heart failure, nonfatal myocardial infarctions, and nonfatal strokes†
- Deaths from cardiovascular causes, hospitalizations and urgent visits for heart failure, and events of heart failure during hospitalization†
- Deaths from any cause†
- Least-squares mean change in KCCQ-12 score to month 4
- Least-squares mean change in estimated GFR—mL/min/1.73 m^2

*Placebo or INPEFA dose could be increased as tolerated, at the discretion of the investigator.
†Total number of events (rate). Calculated as the number of events per 100 person-years of follow-up.
ACS=acute coronary syndrome; BNP=B-type natriuretic peptide; CABS=coronary artery bypass surgery; CV=cardiovascular; eGFR=estimated glomerular filtration rate; HHF=hospitalization for heart failure; KCCQ-12=Kansas City Cardiomyopathy Questionnaire-12 item; MI=myocardial infarction; NT-proBNP=N-terminal pro-BNP; PCI=percutaneous coronary intervention; UVHF=urgent visits for heart failure; WHF=worsening heart failure.

References: 1. INPEFA Prescribing Information. Lexicon Pharmaceuticals. 2023. **2.** Bhatt DL, Szarek M, Steg PG, et al; SOLOIST-WHF Trial Investigators. Sotagliflozin in patients with diabetes and recent worsening heart failure. *N Engl J Med.* 2021;384(2):117-128.

IMPORTANT SAFETY INFORMATION

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.

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Clinical trial design: SOLOIST-WHF

Select baseline characteristics[1]

Patient demographics and characteristics

Median age (years)	70
Female (%)	34
Race or ethnic group (%) White Black Asian, other, or unknown	 93 4 3
Median A1C (%)	7.1
Median BMI (kg/m^2)	31
Median KCCQ-12 score	41
Median estimated GFR (mL/min/1.73 m^2)	50
Left ventricular ejection fraction (LVEF) Median value (%)	35 79% of patients with LVEF <50%
Median NT-proBNP (pg/mL)	1806

At baseline, 91% were treated with inhibitors of the renin-angiotensin-aldosterone system, 92% with a beta blocker, 95% with a loop diuretic, and 10% with another diuretic.

At baseline, 86% of patients were treated with at least one antihyperglycemic agent.

BMI=body mass index; NT-proBNP=N-terminal pro B-type natriuretic peptide.

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

IMPORTANT SAFETY INFORMATION
Warnings and Precautions (cont'd)
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.

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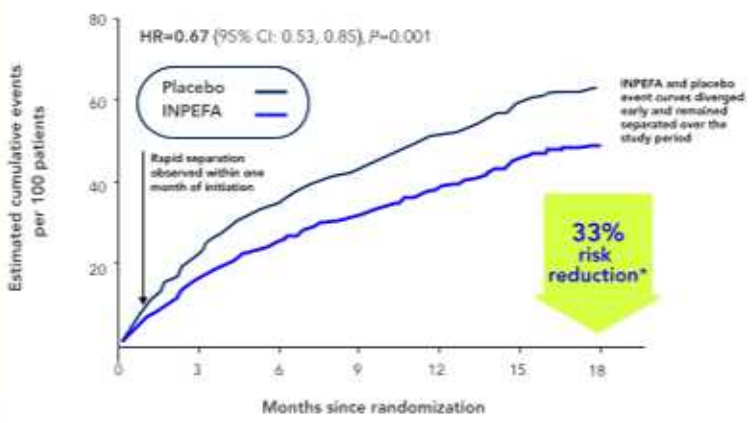
Efficacy results: SOLOIST-WHF

33% risk reduction in the composite of CV deaths, hospitalizations, and urgent visits for HF across LVEF*

Primary endpoint[1,2]

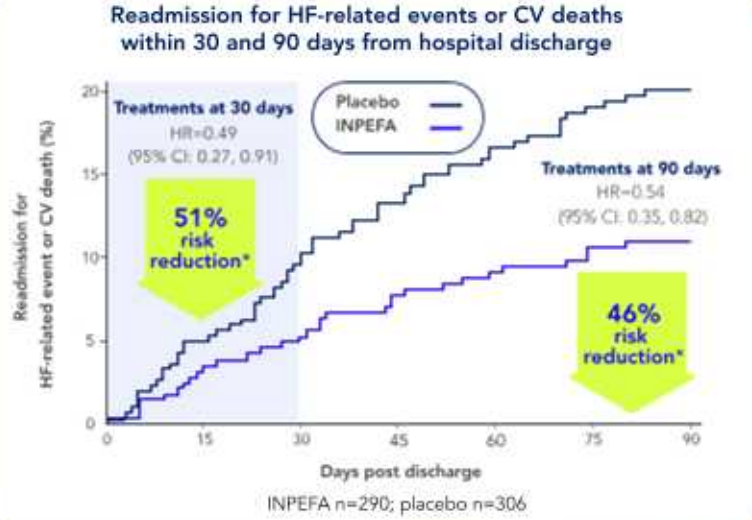


NNT OF 4

Number needed to treat to prevent 1 primary composite event of CV death, hospitalization for HF, and urgent HF visit[1]

Calculation: The rate of primary endpoint events was 51.3 events per 100 patient-years in the INPEFA group and 76.4 events per 100 patient-years in the placebo group. Absolute difference 76.4–51.3=25.1. NNT=1/ARR=1/0.25=4.[3]

Post hoc analysis[4]



In patients initiated on or before discharge

>50% risk reduction* in readmission for HF-related event or CV death within 30 days†

Limitations of analysis: This post hoc analysis occurred after the protocol-specified final analysis. No formal statistical testing was planned for this analysis; therefore, no conclusions can be drawn. These data are not in the prescribing information, and results should be interpreted with caution.

*Relative risk reduction.
†Patients included in this analysis received INPEFA prior to or at discharge in either the hospital or urgent care setting.
ARR=absolute risk reduction; CI=confidence interval; HR=hazard ratio; NNT=number needed to treat.

References: 1. Verma S, Anker SD, Butler J, Bhatt DL. Early initiation of sodium-glucose cotransporter 2 inhibitors is important, irrespective of ejection fraction: SOLOIST-WHF in perspective. *ESC Heart Fail.* 2020;7(6):3261-3267. **2.** INPEFA Prescribing Information. Lexicon Pharmaceuticals. 2023. **3.** Bhatt DL, Szarek M, Steg PG, et al; SOLOIST-WHF Trial Investigators. Sotagliflozin in patients with diabetes and recent worsening heart failure. *N Engl J Med.* 2021;384(2):117-128. **4.** Pitt B, Bhatt DL, Szarek M, et al. Effect of sotagliflozin on early mortality and heart failure-related events. *JACC Heart Fail.* 2023;11(8 Pt 1):879-889.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

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.

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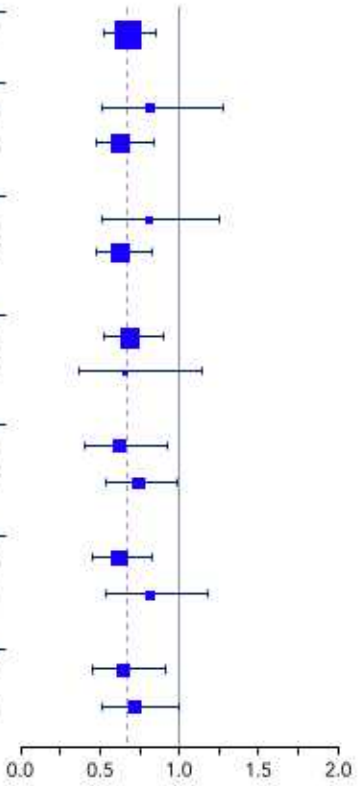
Primary endpoint: SOLOIST-WHF

Primary endpoint results across subgroups[1]

Subgroup	Patients	Events per 100 PY: INPEFA	Events per 100 PY: Placebo	HR (95% CI)
Overall	1222	51.3	76.4	0.67 (0.53, 0.85)
Sex				
Female	412	42.0	51.9	0.81 (0.51, 1.27)
Male	810	56.1	89.6	0.62 (0.47, 0.83)
Age (years)				
<65	364	57.4	71.0	0.80 (0.51, 1.24)
≥65	858	48.3	78.6	0.62 (0.47, 0.83)
LVEF at screening (%)				
<50	955	53.7	79.9	0.68 (0.52, 0.89)
≥50	265	43.4	65.7	0.65 (0.37, 1.14)
Baseline NT-proBNP (pg/mL)				
≤ median (1806)	600	34.6	57.4	0.61 (0.40, 0.92)
> median (1806)	600	68.1	94.2	0.73 (0.54, 0.98)
MRA use at baseline				
Yes	788	47.4	76.1	0.61 (0.45, 0.83)
No	434	59.1	76.9	0.80 (0.54, 1.17)
Timing of first dose				
Post-discharge	620	50.3	76.9	0.64 (0.45, 0.91)
Prior to or at discharge	596	52.0	75.9	0.71 (0.51, 0.99)



Primary composite endpoint was based on investigator-reported events in all randomized patients, analyzed according to the treatment group allocated by randomization. Discharge may have been from hospital or urgent treatment facility where urgent heart failure visit occurred. Note: The figure above presents effects in various subgroups all of which are baseline characteristics and all of which were prespecified. The 95% confidence limits that are shown do not take into account how many comparisons were made, nor do they reflect the effect of a particular factor after adjustment for all other factors. Apparent homogeneity or heterogeneity among groups should not be overinterpreted.

Consistent treatment effect was observed across subgroups[1]

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

IMPORTANT SAFETY INFORMATION
Warnings and Precautions (cont'd)
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.

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Primary and secondary endpoints: SOLOIST-WHF

Results overview[1,2]

ADDITIONAL PRIMARY AND KEY SECONDARY ENDPOINT RESULTS

Treatment effect for primary composite, components, and key secondary endpoints

	Event rates per 100 patient-years		
	INPEFA n=608	Placebo n=614	Hazard ratio (95% CI)
Primary endpoint*			
Total occurrence of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit†	51.3	76.4	0.67 (0.53, 0.85) *P*=0.001
Primary endpoint components			
Cardiovascular death‡,§	8.4	9.4	0.84 (0.58, 1.23)
Hospitalization for heart failure	33.7	51.9	0.65 (0.49, 0.87)
Urgent heart failure visit	6.9	12.1	0.60 (0.34, 1.06)
Secondary endpoint‡			
Hospitalization for heart failure and urgent heart failure visit§	40.6	63.9	0.64 (0.50, 0.84) *P*=0.0009

*Based on investigator-reported events in all randomized patients, analyzed according to the treatment group allocated by randomization.
†Predefined primary endpoint.
‡Predefined secondary endpoint and tested with multiplicity control.
§Time-to-event analysis was performed; event rates are percentages of patients with events.

Secondary endpoint results (investigator-reported) — ITT population

Endpoints‖	INPEFA n=608	Placebo n=614	Hazard ratio (95% CI)
CV death, HHF, non-fatal MI, and non-fatal stroke¶	244 (51.1)	321 (69.1)	0.73 (0.57, 0.94)
CV death, HHF, UVHF, and HF while hospitalized¶	263 (55.0)	375 (80.7)	0.68 (0.54, 0.86)
All-cause mortality#	65 (10.7)	76 (12.4)	0.82 (0.59, 1.14)
Change in KCCQ-12 score from Baseline to Month 4**	17.7	14.0	3.75 (0.94, 6.56)**
Change in eGFR (mL/min/1.73 m^2) from Week 4 to end of study**	-0.20	-2.22	2.02 (0.51, 3.53)**

‖Endpoints are presented in order of hierarchical testing.
¶Total occurrences analysis; results are total number of events (event rate per 100 patient-years); event rate is calculated as the cumulative number of events / [cumulative duration at risk (years) / 100].
#Time-to-event analysis; results are number of patients with an event (percentage of patients with an event).
**Change from Baseline analysis; results are LS mean change and between-group difference (95% CI) in LS mean change.

References: 1. INPEFA Prescribing Information. Lexicon Pharmaceuticals. 2023. **2.** Lexicon Pharmaceuticals. SOLOIST-WHF Clinical Study Report. December 15, 2021.

IMPORTANT SAFETY INFORMATION
Warnings and Precautions (cont'd)
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.

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Safety and tolerability

SAFETY AND TOLERABILITY PROFILE OF INPEFA ACROSS PATIENT POPULATIONS IN BOTH SOLOIST-WHF AND SCORED*

Adverse events reported in ≥2% of patients treated with INPEFA in either SOLOIST-WHF or SCORED[1]

	SOLOIST-WHF (N=1216)		SCORED (N=10,577)	
Adverse event	**INPEFA % (n=605)**	**Placebo % (n=611)**	**INPEFA % (n=5291)**	**Placebo % (n=5286)**
Urinary tract infection	8.6	7.2	11.5	11.0
Volume depletion	9.3	8.8	5.2	4.0
Diarrhea	6.9	4.1	8.4	6.0
Hypoglycemia	4.3	2.8	7.7	7.9
Dizziness	2.6	2.5	3.3	2.8
Genital mycotic infection	0.8	0.2	2.4	0.9

- Adverse events that were reported in ≥5% of patients in both trials included urinary tract infection, volume depletion, diarrhea, and hypoglycemia

Adverse events that led to discontinuation occurred in[1]:
- 5.6% of INPEFA patients vs 5.4% of placebo patients in SOLOIST-WHF
- 5.0% of INPEFA patients vs 4.5% of placebo patients in SCORED

*The SCORED (Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes Mellitus, Cardiovascular Risk Factors and Moderately Impaired Renal Function) study (NCT03315143) was a randomized, double-blind, placebo-controlled, parallel-group, multicenter study in patients with type 2 diabetes mellitus (A1C >7%), chronic kidney disease (eGFR 25 to 60 mL/min/1.73 m^2), and additional cardiovascular risk factors such as a history of heart failure, obesity, dyslipidemia, hypertension, or elevated cardiac and inflammatory biomarkers to determine if INPEFA reduces the risk of total occurrence of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit. Of the 10,584 randomized patients, 5292 were randomized to INPEFA and 5292 to placebo.

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

IMPORTANT SAFETY INFORMATION

Drug Interactions (cont'd):
- **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.

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INPEFA is available as a convenient, once-daily tablet[1]

The recommended starting dose of INPEFA is 200 mg one hour before the first meal of the day

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

IMPORTANT SAFETY INFORMATION

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.

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Ordering information

INPEFA IS BEING DISTRIBUTED THROUGH THE FOLLOWING AUTHORIZED WHOLESALERS

PRODUCT ORDERING

Wholesaler	Item code
AmerisourceBergen	10280309
Cardinal Health	5852876
McKesson	2818995
Morris & Dickson	289587
Mutual Drug	473447
Smith Drug Company	981456
Value Drug Company	247889

NDC FOR INPEFA

INPEFA 200 mg tablets

Bottle size (tablets)	NDC
30	70183-220-30

inpefa TOGETHER
YOUR PATIENT JOURNEY PARTNER

Patient support with INPEFA Together™

INPEFA Together™ works with the HCP office and patients to verify insurance coverage, initiate prior authorization, and find the lowest available out-of-pocket options.*

OUR OFFERINGS

ACCESS

- Benefits investigation and prior authorization support
- Guidance over the first month of prescription to facilitate refills

FINANCIAL SUPPORT

- Regardless of insurance type, patients are eligible to receive their first 30-day supply at no cost
  - Vouchers may be found through EHR platforms associated with the prescriptions
  - If the voucher does not appear in the EHR, the patient may be enrolled here
  - The patient must activate the voucher prior to visiting the pharmacy

- Eligible patients with commercial insurance may pay as little as $10 through our Copay Program, with up to $2,600 in costs covered per year†
  - The copay program will be automatically applied for eligible patients who utilized the voucher. No action required
  - Your patients may also enroll in copay assistance directly by contacting INPEFA Together™

For more information, visit INPEFAhcp.com/savings-and-resources.

*Based on the patient's coverage status.
†Patients who are uninsured or underinsured may qualify for our Patient Assistance Program.
EHR=electronic health record.

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inpefa TOGETHER
YOUR PATIENT JOURNEY PARTNER

Enrollment and next steps

GETTING PATIENTS STARTED IN 3 EASY STEPS

1. The HCP provides the patient with a prescription and the 30-day voucher. They may enroll the patient here.
2. The HCP asks the patient to activate the voucher before picking up INPEFA at the pharmacy.
   - The activation of the voucher triggers INPEFA Together™ support for the patient
3. The HCP informs patients to take their voucher and prescription to their pharmacy as they normally would. The specialist may contact them to explain their benefit, including possible out-of-pocket costs and affordability options
   - INPEFA Together™ may also reach out to the HCP office to assist with prior authorizations or offer other support

Note: After the 30 days, the copay card will be automatically activated for eligible commercially insured patients: NO ACTION REQUIRED. The patient may pay as little as $0.

For additional assistance, please call a dedicated INPEFA Together™ Specialist at 855-2-INPEFA or 855-246-7332, Monday to Friday, 8 AM to 8 PM.

For more information, visit INPEFAhcp.com/savings-and-resources.

INPEFA: an inhibitor of SGLT2 and SGLT1[1]

- Over a patient lifetime, hospitalizations are estimated to account for 80% of total direct costs of HF[2]
  - Nearly one-quarter (22%) of individuals with worsening HF are rehospitalized within 30 days of HHF, and two-thirds (67%) are rehospitalized within the year following HHF[3,4]

- Initiation of GDMT, including INPEFA, is recommended prior to hospital discharge[5]

- INPEFA has demonstrated[1,6,7]:
  - 33% risk reduction* in the primary composite of CV death, hospitalization for HF, and urgent HF visit, regardless of EF (HR=0.67 [95% CI: 0.53, 0.85], *P*=0.001) in patients initiated following hemodynamic stabilization from an acute compensation/WHF event
  - An NNT of 4 to prevent 1 primary composite event of CV death, hospitalization, and urgent HF visit
    - The rate of primary endpoint events was 51.3 events per 100 patient-years in the INPEFA group and 76.4 events per 100 patient-years in the placebo group. Absolute difference 76.4–51.3=25.1. NNT=1/ARR=1/0.25=4 patient-years
  - >50% risk reduction* in readmission for HF-related event or CV death within 30 days (HR=0.49 [95% CI: 0.27, 0.91])
    - **Limitations of analysis:** This post hoc analysis occurred after the protocol-specified final analysis. No formal statistical testing was planned for this analysis; therefore, no conclusions can be drawn. These data are not in the prescribing information, and results should be interpreted with caution

- In the SOLOIST-WHF study, 5.6% of patients in the INPEFA group and 5.4% of patients in the placebo group discontinued therapy due to adverse events (AEs)[1]
- In this study, most common adverse reactions (incidence ≥5%) were urinary tract infection, volume depletion, and diarrhea[1]

*Relative risk reduction.

References: 1. INPEFA Prescribing Information. Lexicon Pharmaceuticals. 2023. **2.** Heidenreich PA, Albert NM, Allen LA, et al. Forecasting the impact of heart failure in the United States. *Circ Heart Fail*. 2013;6(3):606-619. **3.** Kilgore M, Patel HK, Kielhorn A, Maya JF, Sharma P. Economic burden of hospitalizations of Medicare beneficiaries with heart failure. *Risk Manag Health Policy*. 2017;10:63-70. **4.** Dharmarajan K, Hsieh AF, Kulkarni VT, et al. Trajectories of risk after hospitalization for heart failure, acute myocardial infarction, or pneumonia: retrospective cohort study. *BMJ*. 2015;350:h411. **5.** Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18):e895-e1032. **6.** Verma S, Anker SD, Butler J, Bhatt DL. Early initiation of sodium-glucose cotransporter 2 inhibitors is important, irrespective of ejection fraction: SOLOIST-WHF in perspective. *ESC Heart Fail*. 2020;7(6):3261-3267. **7.** Pitt B, Bhatt DL, Szarek M, et al. Effect of sotagliflozin on early mortality and heart failure-related events. *JACC Heart Fail*. 2023;11(8 Pt 1):879-889.

IMPORTANT SAFETY INFORMATION
Use in Specific Populations (cont'd):
- **Hepatic Impairment:** INPEFA is not recommended in patients with moderate or severe hepatic impairment.

Please see Important Safety Information throughout, and click here for full Prescribing Information.

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