MEDICATION GUIDE
INPEFA® (in peh' fah**)**
(sotagliflozin)
tablets, for oral use

What is the most important information I should know about INPEFA?

INPEFA can cause serious side effects, including:

- **Ketoacidosis (acidic blood with increased ketones in your blood or urine).** Ketoacidosis has happened in people who have type 1 or type 2 diabetes during treatment with INPEFA. Ketoacidosis can happen with INPEFA even if your blood sugar is not high. Your healthcare provider may ask you to periodically check ketones in your urine or blood. Ketoacidosis can also happen in people who are sick or who have surgery during treatment with INPEFA. Ketoacidosis is a serious condition which needs to be treated in a hospital. Ketoacidosis may lead to death.
  - **Stop taking INPEFA and call your healthcare provider or get medical help right away if you get any of the following symptoms. If possible, check for ketones in your urine or blood, even if your blood sugar is less than 250 mg/dL:**
    - nausea
    - vomiting
    - trouble breathing
    - stomach-area (abdominal) pain
    - tiredness
    - ketones in your urine or blood
- **Dehydration.** INPEFA can cause some people to become dehydrated (the loss of body water and salt). Dehydration may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension). There have been reports of sudden kidney injury due to dehydration in people with type 2 diabetes who are taking a medicine that works like INPEFA.

  You may be at higher risk of dehydration if you:
  - take medicines to lower your blood pressure, including water pills (diuretics)
  - are 65 years of age or older
  - are on a low salt diet
  - have kidney problems

  Talk to your healthcare provider about what you can do to prevent dehydration including how much fluid you should drink on a daily basis. Call your healthcare provider right away if you reduce the amount of food or liquid you drink, for example if you cannot eat or you start to lose liquids from your body, for example from vomiting, diarrhea, or being in the sun too long.

See **"What are the possible side effects of INPEFA?"** for more information about side effects.

What is INPEFA?

INPEFA is a prescription medicine used to reduce the risk of death due to heart problems (cardiovascular death), hospitalization for heart failure, and urgent visits to the doctor for heart failure in adults with:

- heart failure (when the heart is weak and cannot pump enough blood to the rest of your body), **or**
- type 2 diabetes, chronic kidney disease, and other cardiovascular risk factors.

It is not known if INPEFA is safe and effective in children under 18 years of age.

Do not take INPEFA if you:

- are allergic to sotagliflozin or any of the ingredients in INPEFA. See the end of this Medication Guide for a list of ingredients in INPEFA. Symptoms of a **serious** allergic reaction to INPEFA may include:
  - skin rash
  - raised red patches on your skin (hives)
  - swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing

  If you have any of these symptoms, stop taking INPEFA and call your healthcare provider or go to the nearest hospital emergency room right away.

Before taking INPEFA, tell your healthcare provider about all of your medical conditions, including if you:

- have type 1 diabetes or have had diabetic ketoacidosis.
- are going to have surgery or a procedure that requires fasting. Your healthcare provider may stop your INPEFA for at least 3 days before you have surgery. Talk to your healthcare provider if you are having surgery about when to stop taking INPEFA and when to start it again.
- are eating less or there is a change in your diet.
- have or have had problems with your pancreas, including pancreatitis or surgery on your pancreas.
- drink alcohol very often or drink a lot of alcohol over a short period ("binge" drinking).
- have a history of urinary tract infections or problems urinating.
- have a history of infection of the vagina or penis.
- have kidney or liver problems.

- are pregnant or plan to become pregnant. INPEFA may harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with INPEFA. Your healthcare provider may switch you to a different medicine.
- are breastfeeding or plan to breastfeed. It is not known if INPEFA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with INPEFA. You should not breastfeed during treatment with INPEFA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. INPEFA may affect the way other medicines work, and other medicines may affect how INPEFA works.

How should I take INPEFA?

- Take INPEFA exactly as your healthcare provider tells you to take it.
- Do not change your dose of INPEFA without talking to your healthcare provider.
- Take INPEFA by mouth 1 time each day no more than 1 hour before your first meal of the day.
- Swallow INPEFA tablets whole. Do not cut, crush, or chew.
- If you miss a dose of INPEFA by more than 6 hours after taking INPEFA, take your next dose at your next scheduled time the next day.
- INPEFA will cause your urine to test positive for glucose.
- Your healthcare provider may do certain blood tests before you start INPEFA and during your treatment as needed.
- If you take too much INPEFA, call your healthcare provider or local poison control center, or go to the nearest emergency room right away.

What are the possible side effects of INPEFA?

INPEFA can cause serious side effects, including:

- See "**What is the most important information I should know about INPEFA?**"
- **Serious urinary tract infections.** Serious urinary tract infections that may lead to hospitalization have happened in people who are taking INPEFA. Tell your healthcare provider if you have any signs or symptoms of a urinary tract infection such as a burning feeling when passing urine, a need to urinate often, the need to urinate right away, pain in the lower part of your stomach (pelvis), or blood in the urine. Sometimes people also may have a fever, back pain, nausea, or vomiting.
- **Low blood sugar (hypoglycemia).** If you take INPEFA with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take INPEFA. Signs and symptoms of low blood sugar may include:
  - headache
  - shaking or feeling jittery
  - irritability
  - fast heartbeat
  - weakness
  - drowsiness
  - sweating
  - confusion
  - dizziness
  - hunger
- **A rare but serious bacterial infection that causes damage to the tissue under the skin (necrotizing fasciitis) in the area between and around the anus and genitals (perineum).** Necrotizing fasciitis of the perineum has happened in women and men with diabetes who take INPEFA. Necrotizing fasciitis of the perineum may lead to hospitalization, may require multiple surgeries, and may lead to death. **Seek medical attention immediately if you have a fever or you are feeling very weak, tired, or uncomfortable (malaise) and you develop any of the following symptoms in the area between and around the anus and genitals:**
  - pain or tenderness
  - swelling
  - redness of skin (erythema)
- **Vaginal yeast infection.** Symptoms of a vaginal yeast infection include:
  - vaginal odor
  - white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese)
  - vaginal itching
- **Yeast infection of the penis (balanitis or balanoposthitis).** Swelling of an uncircumcised penis may develop that makes it difficult to pull back the skin around the tip of the penis. Other symptoms of yeast infection of the penis include:
  - redness, itching, or swelling of the penis
  - rash of the penis
  - foul smelling discharge from the penis
  - pain in the skin around the penis

Talk to your healthcare provider about what to do if you get symptoms of a yeast infection of the vagina or penis. Your healthcare provider may suggest you use an over-the-counter antifungal medicine. Talk to your healthcare provider right away if you use an over-the-counter antifungal medication and your symptoms do not go away.

The most common side effects of INPEFA include:

- urinary tract infection
- dehydration
- diarrhea
- low blood sugar levels

These are not all the possible side effects of INPEFA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store INPEFA?

- Store INPEFA at room temperature between 68°F to 77°F (20°C to 25°C).

Keep INPEFA and all medicines out of the reach of children.

General information about the safe and effective use of INPEFA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use INPEFA for a condition for which it is not prescribed. Do not give INPEFA to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about INPEFA that is written for health professionals.

What are the ingredients in INPEFA?

Active ingredient: sotagliflozin.

Inactive ingredients: The core of the tablet contains: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, and talc. The film coating for the 200 mg tablet contains: indigo carmine aluminum lake, polyethylene glycol, polyvinyl alcohol (partly hydrolyzed), talc, and titanium dioxide. The film coating for the 400 mg tablet contains: hypromellose, lactose monohydrate, titanium dioxide, triacetin, and yellow iron oxide. For tablets that are printed and not debossed, the ink contains: ammonium hydroxide, black iron oxide, isopropyl alcohol, N-butyl alcohol, propylene glycol, and shellac.

Manufactured for: Lexicon Pharmaceuticals, Inc. The Woodlands, TX, 77381.

For more information about INPEFA, go to www.lexpharma.com or call 1-855-330-2573.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued 01/2024