

Zein Film Coated Tablets



Composition: Each Zein (10-25) Film Coated Tablet contains: Empagliflozin (10-25) mg.

Mechanism of Action:

Empagliflozin is an inhibitor of the sodium-glucose co-transporter 2 (SGLT2), the predominant transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. By inhibiting SGLT2, empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

Pharmacokinetics:

After oral administration, peak plasma concentrations of empagliflozin reach after 1.5 hours. The apparent steady-state volume of distribution is about 73.8 liters. The terminal elimination half-life is 12.4 hours. No major metabolites of empagliflozin have been detected in plasma. The most abundant metabolites are the glucuronide conjugates. In healthy subjects, 95.6% of the drug is eliminated, in feces (41.2%) or urine (54.4%).

Indications:

Zein is used to:

- Treat type 2 diabetes in adult patients (aged 18 years and older) that cannot be controlled by diet and exercise alone.
- Reducing the risk of cardiovascular death in adult patients with type 2 diabetes who also suffer from cardiovascular disease.

Contraindications:

Hypersensitivity to the active substance or to any of the excipients.

Warnings & Precautions:

- Rare cases of ketoacidosis have been reported in patients with diabetes mellitus treated with SGLT2 inhibitors, including empagliflozin.

- Caution should be exercised in patients for whom an empagliflozin-induced drop in blood pressure could pose a risk.

- Cases of necrotising fasciitis of the perineum, (also known as Fournier's gangrene), have been reported in female and male patients with diabetes mellitus taking SGLT2 inhibitors.

- Hematocrit increase was observed with empagliflozin treatment.

- Patients who take Zein show positive results for glucose in the urine.

Pregnancy & Lactation:

Pregnancy: There are no data from the use of empagliflozin in pregnant women. It is preferable to avoid the use of Zein during pregnancy.

Lactation: Zein should not be used during breast-feeding.

Driving & Using Machines:

Zein has minor influence on the ability to drive and use machines. Patients should be advised to take precautions to avoid hypoglycemia while driving and using machines, particularly when Zein is used in combination with a sulfonylurea and/or insulin.

Drug Interactions:

- Insulin and insulin secretagogues, such as sulphonylureas, may increase the risk of hypoglycaemia.

- Empagliflozin may add to the diuretic effect of thiazide and loop diuretics and may increase the risk of dehydration and hypotension.

- Empagliflozin may increase the renal excretion of lithium, which may cause low levels of lithium in the blood. Serum lithium concentration should be monitored frequently when initiating empagliflozin therapy and when adjusting the dose.

Side Effects:

Common adverse reactions associated with Zein include: thirst, constipation, pruritus, rash, increased urination, urinary tract

infections and female genital mycotic infections, serum lipids increased.

Dosage & Administration:

Type 2 Diabetes mellitus:

- The recommended dose is 10 mg once daily in the morning, which may be taken with or without food, for monotherapy and combination therapy with other medications.

- For additional glycaemic control, dose may be increased to 25 mg in patients tolerating Zein.

Heart Failure:

- The recommended dose is 10 mg once daily.

- The maximum daily dose is 25 mg.

Renal Impairment:

In patients with type 2 diabetes mellitus, the glycaemic efficacy of empagliflozin is dependent on renal function. For dose adjustment recommendations according to eGFR or CrCL refer to table.

Table: Dose adjustment recommendations.

Indication	eGFR [ml/min/1.73 m ²] or CrCL [ml/min]	Total daily dose
Type 2 diabetes mellitus	≥ 60	Initiate with 10 mg. In patients tolerating 10 mg empagliflozin and requiring additional glycaemic control, the dose can be increased to 25 mg.
	45 to < 60	Initiate with 10 mg empagliflozin*. Continue with 10 mg empagliflozin.
	30 to < 45*	Initiate with 10 mg empagliflozin. Continue with 10 mg empagliflozin.
	< 30	Empagliflozin is not recommended.
Empagliflozin should not be used in patients with end stage renal disease (ESRD) or in patients on dialysis.		
Heart failure (with or without type 2 diabetes mellitus)	≥ 20	Recommended daily dose is 10 mg empagliflozin.
	< 20	Empagliflozin is not recommended.

+ patients with type 2 diabetes mellitus and established cardiovascular disease.

Overdose:

Symptoms: In clinical studies, single doses of up to 800 mg empagliflozin in healthy volunteers and multiple daily doses of up to 100 mg empagliflozin in patients with type 2 diabetes did not show any toxicity. Empagliflozin increased urine glucose excretion leading to an increase in urine volume. The observed increase in urine volume was not dose-dependent and is not of clinical significance.

Treatment: In the event of an overdose, treatment should be initiated as appropriate to the patient's clinical status.

Storage:

Store at a temperature below 30°C. Keep out of reach of children.

Packaging:

Each Zein (10-25) carton box contains 20 or 30 film coated tablets in two or three blister strips.

*A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
 - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
 - The doctor and the pharmacist prescribe in medicine, it's benefits and risks.
 - Do not repeat the same prescription without consulting your doctor.
 - KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN
 - Council of Arab Health Ministries, Union of Arab Pharmacists

الدواء مستحضر بوثر على صحتك واستعماله خلافاً لتعليمات مبروكك للخطر
إنه ينافي وصفة الطبيب، وطريقة الاستعمال الموصى بها وطبيباً وتعليمات الصيدلي
التي سرفها لك، فاطلب واصلها على البشائر إن في الدواء وبنته وخزونه.
لا تكرر صرف الدواء بدون وصفة طبية.
لا تكرر الأدوية بمقتضى أيدي الأطباء.
محلى وزراء الصحة العرب والاتحاد العرب.