Eltero™

Ertugliflozin

Presentation
Eltero™ 5: Each film coated tablet contains Ertugliflozin L-Pyroglutamic Acid INN equivalent to Ertugliflozin 5 mg.
Eltero™15: Each film coated tablet contains Ertugliflozin L-Pyroglutamic Acid INN equivalent to Ertugliflozin 15 mg.

Description
SGLT2 is the predominant transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. Ertugliflozin is an inhibitor of SGLT2. By inhibiting SGLT2, ertugliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

Indications
Ertugliflozin is a sodium glucose co-transporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dosage and Administration
Recommended starting dose is 5 mg once daily, taken in the morning, with or without food. Increase dose to 15 mg once daily in those tolerating Ertugliflozin and needing additional glycemic control. Assess renal function before initiating Ertugliflozin and periodically thereafter.
• Do not use in patients with an estimated glomerular filtration rate (eGFR) below 30 mL/minute/1.73 m^2
• Initiation is not recommended in patients with an eGFR of 30 to less than 60 mL/minute/1.73 m^2
• Continued use is not recommended in patients with an eGFR persistently between 30 and less than 60 mL/min/1.73 m^2.

Side-effects
Dehydration, vaginal yeast infection, yeast infection of the penis, urinary tract infection and female genital mycotic infections, diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, headache etc.

Contraindications
Severe renal impairment, end-stage renal disease, or dialysis. History of serious hypersensitivity reaction to Ertugliflozin.

Warning:
The risk of necrotizing fasciitis of the perineum/Fournier's gangrene.

Precautions
• Hypotension: May occur particularly in patients with renal impairment, the elderly, or patients on diuretics. Before initiating, assess and correct volume status. Monitor for signs and symptoms during therapy.

• Ketoacidosis: Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue, evaluate, and treat promptly. Before initiating, consider risk factors for ketoacidosis. Patients may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis.

• Acute Kidney Injury and Impairment in Renal Function: Consider temporarily discontinuing in settings of reduced oral intake or fluid losses. If acute kidney injury occurs, discontinue and promptly treat. Monitor renal function.

• Urosepsis and Pyelonephritis: Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated.

• Lower Limb Amputation: Before initiating, consider factors that may increase risk of amputation. Monitor patients for infections or ulcers of lower limbs, and discontinue if these occur.

• Hypoglycemia: Consider a lower dose of insulin or insulin secretagogue to reduce risk of hypoglycemia when used in combination.

• Genital Mycotic Infections: Monitor and treat if indicated.

• Increased LDL-C: Monitor and treat as appropriate.

Use in Specific Populations
• Pregnancy: Advise females of the potential risk to a fetus especially during the second and third trimesters.
• Lactation: Breastfeeding not recommended.
• Geriatrics: Higher incidence of adverse reactions related to reduced intravascular volume.
• Renal Impairment: Higher incidence of adverse reactions related to reduced intravascular volume and renal function.

Drug Interactions
Concomitant use with Insulin and Insulin Secretagogues Ertugliflozin may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue. Therefore, a-lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with Ertugliflozin.

Positive Urine Glucose Test:
Monitoring glycemic control with urine glucose tests is not recommended patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. Use alternative methods to monitor glycemic control.

Interference With 1,5-anhydroglucitol (1,5-AG) Assay:
Monitoring glycemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control.

Overdose
In the event of an overdose with Ertugliflozin, contact the Poison Control Center. Employ the usual supportive measures as dictated by the patient's clinical status. Removal of Ertugliflozin by hemodialysis has not been studied.

Storage condition
Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Pack
Eltero™ 5: Each box contains 3 blister strips of 10 tablets.
Eltero™ 15: Each box contains 2 blister strips of 10 tablets.

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