Steglatro (ertugliflozin)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Steglatro
- **Generic name:** Ertugliflozin
- **Pharmacological class:** Sodium-glucose co-transporter 2 (SGLT2) inhibitor
- **Strength and Formulation:** 5mg, 15mg; tabs
- **Manufacturer:** Merck & Co
- **How supplied:** Tabs—30, 90, 500
- **Legal Classification:** Rx

Indications

- Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- **Limitations of use:** not for treating type 1 diabetes mellitus or diabetic ketoacidosis

Dosage & Administration

- Take in the AM
- Initially 5mg once daily; if tolerated and need additional glycemic control; may increase to max 15mg once daily
- **Renal impairment:**
  - eGFR 30–<60mL/min/1.73m^2: do not initiate
  - persistently between 30–<60mL/min/1.73m^2: continued use is not recommended

Considerations for Special Populations

- **Pediatric:** <18yrs: not established
- **Pregnancy:** 2nd & 3rd trimesters: not recommended
- **Nursing mothers:** Not recommended
- **Elderly:** Reduced efficacy in renal impairment
- **Renal impairment:** See Dosage & Administration, Contraindications
- **Hepatic impairment:** Severe: not recommended

Contraindications

- Severe renal impairment (eGFR <30mL/min/1.73m^2), ESRD, or on dialysis

Warnings/Precautions

- Correct volume depletion before initiating
- **Monitor** for signs/symptoms of hypotension (esp. elderly, patients with renal impairment, low systolic BP, or on diuretics)
- Assess for **ketoacidosis** in presence of signs/symptoms of metabolic acidosis, regardless of blood glucose levels; discontinue if suspected, evaluate and treat; consider risk factors before initiation (eg, pancreatic insulin deficiency, caloric restriction, alcohol abuse)

Warnings/Precautions

- Evaluate **renal function** prior to starting and monitor periodically thereafter
- Risk of acute kidney injury in hypovolemia, chronic renal insufficiency, CHF, and concomitant drugs (eg, diuretics, ACEIs, ARBs, NSAIDs)
- Consider temporarily discontinuing in reduced oral intake or fluid losses; monitor for acute kidney injury; discontinue and treat if occurs
- Increased risk of genital mycotic infections or UTIs; monitor and treat if occurs

Warnings/Precautions

- History of prior amputation, peripheral vascular disease, neuropathy, diabetic foot ulcers
- Monitor for sign/symptoms of infection (including osteomyelitis), new pain/tenderness, sores or ulcers involving the lower limbs; discontinue if occur
- Monitor for increases in LDL-C; treat if occur

Interactions

- Consider a lower dose of concomitant insulin/insulin secretagogue to reduce risk of **hypoglycemia**
- **Hypotension** with concomitant diuretics
- May cause false (+) urine glucose tests or unreliable measurements of 1,5-AG assay; use alternative methods to monitor glycemic control

Adverse Reactions

- Female genital mycotic infections
- UTIs
- Headache
- Vaginal pruritus
- Increased urination
- Nasopharyngitis
- Back pain
- Weight decrease
- Thirst
- Volume depletion
- Renal impairment
- Ketoacidosis
- Amputation
- Hypoglycemia
- Urosepsis
- Pyelonephritis

Mechanism of Action

- By inhibiting SGLT2, **ertugliflozin** reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion

Clinical Studies

- Steglatro was studied in 7 multicenter, randomized, double-blind, placebo- or active comparator-controlled, clinical studies (N=4,863) in patients with type 2 diabetes mellitus
- Steglatro was also studied in combination with antidiabetic medications (insulin and a sulfonylurea) in patients with type 2 diabetes mellitus with moderate renal impairment

Clinical Studies

- The safety and efficacy of Steglatro **monotherapy** was evaluated in patients inadequately controlled on diet and exercise
- Study patients were randomized to placebo, Steglatro 5mg or Steglatro 15mg once daily

Clinical Studies

- At Week 26, treatment with Steglatro 5mg and 15mg led to statistically significant **reductions in HbA1c** vs placebo (−0.7% and −0.8% vs −0.2%, respectively)
- Also, more Steglatro-treated patients achieved **HbA1c <7%** vs placebo (30.1% and 38.8% vs 16.9%, respectively)

Clinical Studies

- The safety and efficacy of Steglatro as **add-on to metformin** was evaluated in patients inadequately controlled on metformin
- Study patients were randomized to placebo, Steglatro 5mg or Steglatro 15mg once daily plus background metformin

Clinical Studies

- At Week 26, treatment with Steglatro 5mg and 15mg led to statistically significant **reductions in HbA1c** vs placebo (−0.7% and −0.9% vs −0.2%, respectively)
- Also, more Steglatro-treated patients achieved **HbA1c <7%** vs placebo (36.3% and 43.3% vs 18.4%, respectively)

Clinical Studies

- In patients with type 2 diabetes mellitus and moderate renal impairment, treatment with Steglatro did not result in a reduction in HbA1c vs placebo
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/steglatro/drug/34790/