
Reference:
Steglatro local Summary of product characteristics.

## SELECTED SAFETY INFORMATION

**THERAPEUTIC INDICATIONS** Steglatro is indicated in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: a) As monotherapy in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications. b) In addition to other medicinal products for the treatment of diabetes. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS** Steglatro should not be used in patients with type 1 diabetes mellitus. **Hypotension/Volume depletion:** Symptomatic hypotension may occur after initiating Steglatro, particularly in patients with impaired renal function, elderly patients, patients on diuretics, or patients on anti-hypertensive therapy with a history of hypotension. Before initiating Steglatro, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms after initiating therapy. **Diabetic ketoacidosis:** Cases have been reported in clinical trials with ertugliflozin. Treatment should be interrupted in patients who are hospitalised for major surgical procedures or acute serious medical illnesses. Restarting SGLT2 inhibitor treatment in patients with previous DKA while on SGLT2 inhibitor treatment is not recommended, unless another clear precipitating factor is identified and resolved. **Lower limb amputations:** Cases of lower limb amputation (primarily of the toe) has been observed in patients treated with ertugliflozin. Before initiating ertugliflozin, consider factors in the patient history that may increase the risk for amputation. Stop treatment with ertugliflozin in patients who develop events which may precede amputation. **Impairment in renal function:** Steglatro should not be initiated in patients with an eGFR below 60 ml/min/1.73 $m^2$ & should be discontinued when eGFR is persistently below 45 ml/min/1.73 $m^2$. **Hypoglycaemia with concomitant use with insulin and insulin secretagogues:** Ertugliflozin may increase the risk of hypoglycaemia when used in combination with insulin and/or an insulin secretagogue. **Genital mycotic infections:** Ertugliflozin increases the risk of genital mycotic infections. **Necrotising fasciitis of the perineum (Fournier's gangrene):** Post-marketing cases of necrotising fasciitis of the perineum, (also known as Fournier's gangrene), have been reported in female and male patients taking SGLT2 inhibitors. **Elderly patients:** Elderly patients may be at an increased risk of volume depletion. **Cardiac failure:** Experience in New York Heart Association (NYHA) class I-II is limited, and there is no experience in clinical studies with ertugliflozin in NYHA class III-IV. **Urine laboratory assessments:** Due to its mechanism of action, patients taking Ertugliflozin will test positive for glucose in their urine. Alternative methods should be used to monitor glycaemic control. **Interference with 1,5-anhydroglucitol (1,5-AG) assay:** Monitoring glycaemic control with 1,5-AG assay is not recommended. **Lactose:** Steglatro tablets contain lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take Steglatro. **UNDESIRABLE EFFECTS** The most commonly reported adverse reactions with Ertugliflozin were vulvovaginal mycotic infection and other female genital mycotic infections. Serious diabetic ketoacidosis occurred rarely. Hypoglycemia has also been reported. **OTHERS** Steglatro should not be used during pregnancy or breast-feeding.

MSD


In case you need any update or you have an inquiry or need to report an adverse reaction, you can contact:
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Steglatro™
(ertugliflozin)