POWER FORWARD

With STEGLATRO™ (ertugliflozin)

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[1]

Steglatro™ (ertugliflozin)

5 mg ertugliflozin

15 mg ertugliflozin

ONCE DAILY DOSING, TAKEN IN THE MORNING with or without food[1]

The recommended starting dose of Steglatro is 5 mg once daily. In patients tolerating ertugliflozin 5 mg once daily, the dose can be increased to 15 mg once daily if additional glycaemic control is needed.[1]

Steglujan™ (ertugliflozin and sitagliptin)

5 mg/100 mg ertugliflozin sitagliptin

15 mg/100 mg ertugliflozin sitagliptin

ONCE DAILY DOSING, TAKEN IN THE MORNING with or without food[2]

The recommended starting dose of Steglujan is 5 mg ertugliflozin/100mg sitagliptin once daily. In patients tolerating the starting dose, the dose may be increased to 15 mg ertugliflozin/100 mg sitagliptin, once daily, if additional glycaemic control is needed. For patients treated with ertugliflozin who are being switched to Steglujan, the dose of ertugliflozin can be maintained.[2]

REFERENCES:
1. Steglatro local product circular **2.** Steglujan local product circular

Steglatro™ (ertugliflozin)

Steglujan™ (ertugliflozin and sitagliptin)

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. Steglujan 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) When metformin and/or a sulphonylurea (SU) and one of the monocomponents of Steglujan do not provide adequate glycaemic control. b) In patients already being treated with the combination of ertugliflozin and sitagliptin as separate tablets.

CONTRAINDICATIONS:

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

WARNINGS AND PRECAUTIONS

Steglatro or Steglujan should not be used in patients with type 1 diabetes mellitus.

HYPOTENSION/VOLUME DEPLETION: Symptomatic hypotension may occur after initiating Steglatro / Steglujan, 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/ Steglujan, 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 / Steglujan should not be initiated in patients with an eGFR below 60 ml/min/1.73 m2 & should be discontinued when eGFR is persistently below 45ml/min/1.73 m2.

HYPOGLYCAEMIA WITH CONCOMITANT USE WITH INSULIN AND INSULIN SECRETAGOGUES: Both Ertugliflozin & Sitagliptin 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 or Sitagliptin 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.

ACUTE PANCREATITIS: Use of dipeptidyl peptidase-4 (DPP-4) inhibitors has been associated with a risk of developing acute pancreatitis. If pancreatitis is suspected, Steglujan and other potentially suspect medicinal products should be discontinued. Caution should be exercised in patients with a history of pancreatitis.

HYPERSENSITIVITY REACTIONS: Post-marketing reports of serious hypersensitivity reactions in patients treated with sitagliptin havebeen reported. If a hypersensitivity reaction is suspected, Steglujan should be discontinued.

BULLOUS PEMPHIGOID: There have been post-marketing reports of bullous pemphigoid in patients taking DPP-4 inhibitors including sitagliptin. If bullous pemphigoid is suspected, Steglujan should be discontinued.

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.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

• Digoxin: Sitagliptin had a small effect on plasma digoxin concentrations. Patients at risk of digoxin toxicity should be monitored for this when sitagliptin and digoxin are administered concomitantly.

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. Serious adverse reactions including pancreatitis and hypersensitivity reactions have been reported with Sitagliptin. Hypoglycaemia has also been reported in combination with sulphonylurea and insulin.

OTHERS

- Steglatro / Steglujan should not be used during pregnancy.
- Steglatro / Steglujan should not be used during breast-feeding.

Please read the full prescribing information before initiating Steglatro/ Steglujan.

MSD

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