STEGLATRO®▼
(ertugliflozin)

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SmPC) before prescribing.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (tel: 01992 467272).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Film-coated tablets containing 5 mg or 15 mg of ertugliflozin (as ertugliflozin L-pyroglutamic acid)

USES
Type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:
- as monotherapy in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications.
- with other anti-diabetic medicinal products.

DOSAGE AND ADMINISTRATION
Recommended starting dose is 5 mg once daily. Increase to 15 mg once daily if necessary. Assess renal function and correct volume depletion prior to initiation.
Renal impairment: Do not initiate in patients with eGFR <60ml/min/1.73m^2. Discontinue when eGFR persistently <45 ml/min/1.73 m^2.
Hepatic impairment: mild or moderate impairment: no dose adjustment required; severe impairment: not recommended. Elderly: ≥ 65 years: no dose adjustment required; ≥75 years: limited data. Children <18 years: no data.

CONTRA-INDICATIONS
Hypersensitivity to active substance or excipients.

PRECAUTIONS
Do not use in patients with type 1 diabetes. Symptomatic hypotension may occur upon initiation of therapy, particularly in patients with impaired renal function. Assess volume status prior to initiation. Consider temporary interruption of therapy if volume depletion occurs. Use with caution in patients at risk of DKA. If DKA is suspected or diagnosed, discontinue ertugliflozin. Interrupt therapy in patients hospitalised for major surgical procedures or acute serious medical illness until stabilised. A small increase in the risk of lower limb amputation (primarily of the toe) has been reported. Counsel all patients on routine preventative foot care and maintaining adequate hydration. Consider stopping treatment should lower-extremity skin ulcers, osteomyelitis or gangrene develop. Assess renal function prior to initiation of therapy and periodically thereafter. Discontinue ertugliflozin if eGFR falls persistently <45ml/min/1.73m^2. Monitor patients for genital mycotic infections and treat appropriately. No experience in NYHA class III-IV. Contains lactose monohydrate. Do not use in patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. Do not use urine glucose or 1,5-AG assay to monitor glycaemic control.
Drug interactions: Diuretics, insulin, sulphonyureas.
Pregnancy and lactation: Not recommended.

SIDE EFFECTS
Refer to SmPC for complete information on side-effects.
Very common (≥ 1/10): vulvovaginal mycotic infection and other female genital mycotic infections
Common (≥ 1/100 to < 1/10): Balanitis candida and other male genital mycotic infections, hypoglycaemia, volume depletion, increased urination, vulvovaginal pruritus, thirst, serum lipid changes, increased haemoglobin and BUN.
Uncommon (≥ 1/1,000 to <1/100): Dysuria, blood creatinine increased, glomerular filtration decreased.
Rare (≥1/10,000 to <1/1,000): DKA.

PACKAGE QUANTITIES AND BASIC NHS COST
5 mg x 28: £29.40
15 mg x 28: £29.40

Marketing Authorisation numbers
5 mg x 28: EU/1/18/1267/002
15 mg x 28: EU/1/18/1267/008

Marketing Authorisation Holder
Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

Legal category: POM

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