DAR DRUG ASSESSMENT REPORT **03 / 2020**

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dtbn

STEGLATRO®

ERTUGLIFLOZIN FOR TYPE 2 DIABETES MELLITUS

The Last Gliflozin

IMPORTANT THERAPEUTIC INNOVATION

MODEST THERAPEUTIC INNOVATION

SOME ADDED VALUE IN SPECIFIC SITUATIONS

NO THERAPEUTIC INNOVATION

INSUFFICIENT EVIDENCE

+ DATA SHEET

WHAT IS IT?

Oral antidiabetic agent.

INDICATION

Type 2 diabetes mellitus in adults, as combination therapy or as monotherapy in patients with intolerance or contraindication to metformin.

DOSAGE AND METHOD OF ADMINISTRATION

The recommended starting dose of ertugliflozin is 5 mg once daily and can be increased to 15 mg once daily with or without food.

SPECIAL POPULATIONS

Do not start with estimated glomerular filtration rate (eGFR)<60 ml/min/1.73 m2 (lower efficacy) and discontinued with eGFR <45 ml/min/1.73 m2.

EFFICACY

HbA1c reductions were between 0.43 and 1.16 at 26 or 52 weeks. In patients with moderate renal impairment, ertugliflozin is not more effective than placebo in HbA1c reductions. Body weight decreased between 1.6 kg and 4.3 kg (placebo-adjusted) was observed. In active-controlled trials, only 15 mg ertugliflozin + metformin has shown non-inferiority to metformin + glimepiride after 52 weeks of treatment, but the average dose of glimepiride was 3 mg / day and the percentage of missing values was 20%.

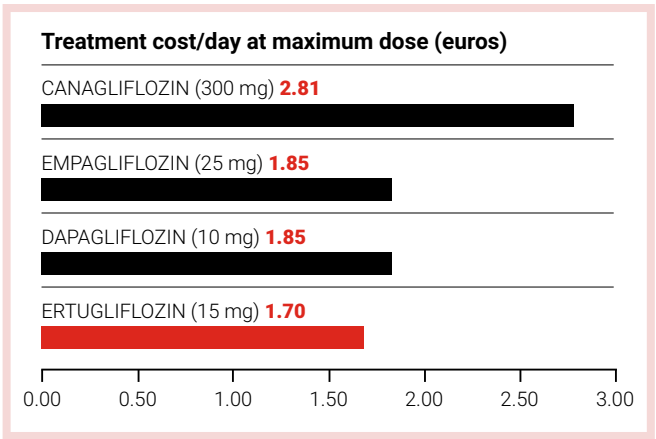
RISKS

The most commonly reported adverse effects were genital mycotic infections (dose-dependent), osmotic diuresis and hypoglycaemia. Because of the events observed with the drugs of the same group, caution is recommended with the risk of hypovolemia and dehydration, diabetic ketoacidosis, lower limb amputation, urinary tract infections. Use with caution in people who had serious heart disease or stroke and in elderly patients

PRESENTATIONS

Steglatro® 5mg 28 tablets (PVP+IVA: 47.46€)
Steglatro® 15mg 28 tablets (PVP+IVA: 47.46€)

REPORT [IN SPANISH]



Servicio Navarro de Salud Osasunbidea

INTERNATIONAL SOCIETY OF DRUG BULLETINS

The qualification has been assigned jointly by the New Medicines Evaluation Committees of Andalucia, Castilla y León, País Vasco, and Navarra. This information is subject to mo- difications depending on the evolution of scientific knowledge. Notify the suspicions of adverse reactions in www.notificaram.es