

SITAXA E/EMPAZIO S/COSPFAQ S

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for SITAXA E/EMPAZIO S/COSPFAQ S [Empagliflozin and Sitagliptin Tablets 25 mg+100 mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Empagliflozin and Sitagliptin tablets combines two antihyperglycaemic medicinal products with complementary mechanisms of action to improve glycaemic control in patients with type 2 diabetes: empagliflozin, a sodium-glucose co-transporter (SGLT2) inhibitor, and sitagliptin, DPP-4 inhibitor.

INDICATIONS: It is indicated in patients with Type 2 Diabetes Mellitus inadequately controlled on Metformin monotherapy.

DOSAGE AND ADMINISTRATION: The recommended dose is one tablet daily. Each film coated tablet contains a fixed dose of Empagliflozin and Sitagliptin, the medication started as per the Physician's recommendation. It should be given orally once daily.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: *Ketoacidosis:* In patients where ketoacidosis is suspected or diagnosed, treatment with empagliflozin should be discontinued immediately. *Renal impairment:* In patients with an eGFR below 60 mL/min/1.73 m² the daily dose of empagliflozin is limited to 10 mg. Empagliflozin Sitagliptin is not recommended when eGFR is below 30 mL/min/1.73 m². Empagliflozin/Sitagliptin should not be used in patients with ESRD or in patients on dialysis. There are insufficient data to support use in these patients. *Hepatic injury:* Cases of hepatic injury have been reported with empagliflozin in clinical trials. A causal relationship between empagliflozin and hepatic injury has not been established. *Elevated haematocrit:* Haematocrit increase was observed with empagliflozin treatment. *Chronic kidney disease:* Patients with albuminuria may benefit more from treatment with empagliflozin. *Risk for volume depletion:* Based on the mode of action of SGLT2 inhibitors, osmotic diuresis accompanying glucosuria may lead to a modest decrease in blood pressure. *Elderly:* The effect of empagliflozin on urinary glucose excretion is associated with osmotic diuresis, which could affect the hydration status.

DRUG INTERACTIONS: Diuretics, Insulin, and insulin secretagogues, *Effects of empagliflozin on other medicinal products:* lithium, metformin, glimepiride, pioglitazone, sitagliptin, linagliptin, simvastatin, warfarin, ramipril, digoxin, diuretics and oral contraceptives. *Effects of other medicinal products on sitagliptin:* Potent CYP3A4 inhibitors (i.e. ketoconazole, itraconazole, ritonavir, clarithromycin), Metformin, Ciclosporin. *Effects of sitagliptin on other medicinal products:* Digoxin.

ADVERSE REACTIONS: *Empagliflozin:* Hypoglycaemia (when used with sulphonylurea or insulin), volume depletion, vaginal moniliasis, vulvovaginitis, balanitis and other genital infectiona urinary tract infection (including pyelonephritis and urosepsis), thirst, constipation, pruritus (generalised) rash, increased urinationa, serum lipids increased, ketoacidosis, urticaria, angioedema, dysuria, blood creatinine increased/ glomerular filtration rate decrease, haematocrit increased, necrotising fasciitis of the perineum (fournier's gangrene) and tubulo-interstitial nephritis. *Sitagliptin:* headache, dizziness, thrombocytopenia, constipation, and pruritus.

MARKETED BY:

TORRENT
PHARMA

Torrent Pharmaceuticals Limited.

IN/SITAXA E/EMPAZIO S/COSPIAQ S (25 mg +100 mg)/MAY 2026/01/ABPI

(Additional information is available on request)