XILINGIO 25 mg/5 mg, 10mg/5mg

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

Abbreviated Prescribing information for Empagliflozin and Linagliptin Tablets [25 mg/5 mg, 10mg/5mg]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: XILINGIO 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 linagliptin, DPP-4 inhibitor.

INDICATIONS: It is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION: *Dosage:* As directed by the physician. *Method of administration:* XILINGIO tablets are for oral use and can be taken with or without a meal at any time of the day at regular intervals. The tablets should be swallowed whole with water.

CONTRAINDICATION: Hypersensitivity to the active substances, to any other Sodium-Glucose-Co-Transporter-2 (SGLT2) inhibitor, to any other Dipeptidyl-Peptidase-4 (DPP-4) inhibitor, or to any of the excipients.

WARNINGS & PRECAUTIONS: *Diabetic ketoacidosis:* XILINGIO should not be used in patients with type 1 diabetes. Data from a clinical trial program in patients with type 1 diabetes showed increased DKA occurrence with common frequency in patients treated with empagliflozin 10 mg and 25 mg as an adjunct to insulin compared to placebo. *Renal impairment:* In patients with an eGFR below 60 mL/min/1.73 m2 or CrCl <60 mL/min, the daily dose of empagliflozin/linagliptin is limited to 10 mg/5 mg. Empagliflozin/linagliptin is not recommended when eGFR is below 30 mL/min/1.73 m2 or CrCl is below 30 mL/min. Empagliflozin/linagliptin 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. *Elevated haematocrit:* Patients with pronounced elevations in haematocrit should be monitored and investigated for underlying haematological disease. *Chronic kidney disease:* Patients with albuminuria may benefit more from treatment with empagliflozin. *Risk for volume depletion:* Caution should be exercised in patients for whom an empagliflozin-induced drop in blood pressure could pose a risk, such as patients with known cardiovascular disease. Temporary interruption of treatment with XILINGIO should be considered until the fluid loss is corrected. *Elderly:* Special attention should be given to their volume intake in case of co-administered medicinal products which may lead to volume depletion. *Urinary tract infections:* Temporary interruption of XILINGIO should be considered in patients with complicated urinary tract infections. *Necrotising fasciitis of the perineum (Fournier's gangrene):* Patients should be advised to seek medical attention if they experience a combination of symptoms of pain, tenderness, erythema, or swelling in the genital or perineal area, with fever or malaise. Be aware that either uro-genital infection or perineal abscess may precede necrotising fasciitis. If Fournier´s gangrene is suspected, XILINGIO should be discontinued and prompt treatment (including antibiotics and surgical debridement) should be instituted. *Lower limb amputations*: it is important to counsel patients on routine preventative foot-care. Urine laboratory assessments: Due to the mechanism of action of empagliflozin, patients taking XILINGIO will test positive for glucose in their urine. *Interference with 1,5-anhydroglucitol (1,5-AG) assay:* Monitoring glycaemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycaemic control in patients taking SGLT2 inhibitors. *Acute pancreatitis:* If pancreatitis is suspected, XILINGIO should be discontinued; if acute pancreatitis is confirmed, XILINGIO should not be restarted. Caution should be exercised in patients with a history of pancreatitis. *Bullous pemphigoid:* If bullous pemphigoid is

suspected, XILINGIO should be discontinued. *Use with medicinal products known to cause hypoglycaemia*: Caution is advised when XILINGIO is used in combination with antidiabetics. A dose reduction of the sulphonylurea or insulin may be

DRUG INTERACTIONS: UGT enzyme inducers, UGT enzyme and OAT3 inhibitors (Probenecid), OAT3 and OATP1B1/1B3 inhibitors (Gemfibrozil), OATP1B1/1B3 inhibitor (Rifampicin, Strong P-gp and CYP3A4 inducers (e.g., Rifampicin, Carbamazepine, Phenobarbital, Phenytoin, Strong P-gp and CYP3A4 inhibitors (Ritonavir), Drugs potentially affected by empagliflozin: (Lithium), No clinically relevant interactions observed with: (Metformin, Glimepiride, Pioglitazone, Sitagliptin, Linagliptin, Warfarin, Verapamil, Ramipril, Simvastatin, Torasemide, Hydrochlorothiazide, Glibenclamide, Digoxin, Oral contraceptives).

ADVERSE REACTIONS: ***Common:*** Urinary tract infection (including pyelonephritis and urosepsis), Vaginal moniliasis, Vulvovaginitis, Balanitis and Other genital infections, Nasopharyngitis, Hypoglycaemia (when used with sulphonylurea or insulin), Thirst, Cough, Constipation, Pruritus, Rash, Increased urination, Amylase increased, Lipase increased. ***Uncommon:*** Hypersensitivity, Angioedema, urticaria, Volume depletion, Pancreatitis, Dysuria, Haematocrit increased, Serum lipids increased, Blood creatinine increased/Glomerular filtration rate decreased, ***Not known:*** Bullous pemphigoid. **Rare**: Necrotising fasciitis of the perineum (Fournier´s gangrene), Diabetic ketoacidosis, Mouth ulceration. **Very rare**: Tubulointerstitial nephritis.

MARKETED BY:

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)