

GLUCRETA

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for GLUCRETA (Dapagliflozin Tablets)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Dapagliflozin is a highly potent (Ki: 0.55 nM), selective and reversible inhibitor of SGLT2, which is a predominant transporter, responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. The SGLT2 is selectively expressed in the kidney with no expression detected in more than 70 other tissues including liver, skeletal muscle, adipose tissue, breast, bladder and brain. Dapagliflozin improves both fasting and post-prandial plasma glucose levels by reducing renal glucose reabsorption leading to urinary glucose excretion.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician.

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

WARNINGS & PRECAUTIONS: Renal impairment, hepatic impairment, diabetic ketoacidosis, necrotising fasciitis of the perineum (fournier's gangrene), urinary tract infections, cardiac failure, lower limb amputations, urine laboratory assessments tests positive for glucose in urine, also tablets contain lactose, patients with hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

DRUG INTERACTION: *Pharmacodynamic interaction:* It can interact with diuretics and insulin and insulin secretagogues. *Pharmacokinetic interaction:* Dapagliflozin neither inhibited cytochrome P450 (CYP) 1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP3A4, nor induced CYP1A2, CYP2B6 or CYP3A4 so, it doesn't alter medicinal products altered by these enzymes. Also, Dapagliflozin are not altered by metformin, pioglitazone, sitagliptin, glimepiride, voglibose, hydrochlorothiazide, bumetanide, valsartan, or simvastatin, digoxin or warfarin.

ADVERSE REACTIONS: Vulvovaginitis, balanitis and related genital infections, urinary tract infection, fungal infection, necrotising fasciitis of the perineum (fournier's gangrene), hypoglycaemia, volume depletion, thirst, diabetic ketoacidosis, dizziness, constipation, dry mouth, angioedema, rash, back pain, dysuria, polyuria, nocturia, vulvovaginal pruritus, and pruritus genital.

Marketed BY:

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IN/ GLUCRETA 5mg, 10 mg/JUL-20/01/ABPI
(Additional information is available on request)