

## CORBIS D

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

Abbreviated Prescribing information for **CORBIS D** (Dapagliflozin 10 mg and Bisoprolol Fumarate 5 mg Tablets)

[Please refer the complete prescribing information for details].

### **PHARMACOLOGICAL PROPERTIES:**

**MECHANISM OF ACTION:** *Dapagliflozin:* Dapagliflozin is a highly potent ( $K_i$  : 0.55 nM), selective and reversible inhibitor of SGLT2. Inhibition of SGLT2 by Dapagliflozin reduces sodium and glucose reabsorption. Reduction in sodium and glucose reabsorption leads to an osmotic diuresis and urinary excretion of glucose. Dapagliflozin therefore increases the delivery of sodium to the distal tubule which increases tubuloglomerular feedback and reduces intraglomerular pressure. This combined with osmotic diuresis leads to a reduction in volume overload, reduced blood pressure, and lower preload and afterload, which may have beneficial effects on cardiac remodelling and preserve renal function. *Bisoprolol fumarate:* Bisoprolol is a highly beta1-selective-adrenoceptor blocking agent, lacking intrinsic stimulating and relevant membrane stabilising activity. It only shows low affinity to the beta2-receptor of the smooth muscles of bronchi and vessels as well as to the beta2-receptors concerned with metabolic regulation.

**INDICATIONS:** It is indicated in patients with heart Failure with Reduced Ejection Fraction (HFrEF).

**DOSAGE AND ADMINISTRATION:** The treatment of heart failure with Dapagliflozin & Bisoprolol FDC is initiated according to the following titration scheme, individual adaptation may be necessary depending on how well the patient tolerates each dose, i.e. the dose is to be increased only, if the previous dose is well tolerated. The recommended starting dose is Dapagliflozin 10 mg + Bisoprolol fumarate 5 mg once daily for 1-2 weeks and if well tolerated increase to Dapagliflozin 10 mg + Bisoprolol fumarate 10 mg once daily and continue long term.

**CONTRAINDICATION:** This combination is contra-indicated in the case of, history of serious hypersensitivity reaction to dapagliflozin, bisoprolol or any of the excipients, severe bradycardia, second- or third-degree heart block, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), patients on dialysis.

**WARNINGS & PRECAUTIONS.** Combination should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Hepatic impairment, Renal Impairment, Use in patients at risk for volume depletion and/or hypotension, Diabetic ketoacidosis, Necrotising fasciitis of the perineum (Fournier's gangrene), Urinary tract infections, Hypertension or angina pectoris and accompanying heart failure, Diabetes mellitus showing large fluctuations in blood glucose values. Symptoms of hypoglycaemia can be masked, Strict fasting, Ongoing desensitisation therapy, AV block of first degree.

**DRUG INTERACTIONS:** *Dapagliflozin* Diuretics, Insulin and insulin secretagogues, Effect of dapagliflozin on other medicinal products:, Interference with 1,5-anhydroglucitol (1,5-AG) assay, *Bisoprolol fumarate:* Combinations not recommended: Calcium antagonists of the verapamil type and to a lesser extent of the diltiazem type, Centrally acting antihypertensive drugs such as clonidine and others:(e.g., methyl dopa, moxonidine, rilmenidine), Combinations to be used with caution, Class-III antiarrhythmic drugs (e.g., amiodarone), Parasympathomimetic drugs, Insulin and oral antidiabetic drugs, Anaesthetic agents, Digitalis glycosides, Non-steroidal anti-inflammatory drugs (NSAIDs),  $\beta$ -Sympathomimetic agents (e.g. isoprenaline, dobutamine), Sympathomimetics that activate both  $\beta$ - and  $\alpha$ -adrenoceptors (e.g. noradrenaline, adrenaline), Concomitant use with antihypertensive agents.

**ADVERSE REACTIONS:** *Dapagliflozin:* Hypoglycaemia, vulvovaginitis, balanitis, genital related infections, urinary tract infection, dizziness, rash, back pain, dysuria, polyuria, haematocrit, increased, creatinine renal clearance decreased during initial treatment. *Bisoprolol fumarate:* Dizziness, headache,

gastrointestinal complaints such as nausea, vomiting, diarrhoea, constipation, feeling of coldness or numbness in the extremities, hypotension, fatigue.

**MARKETED BY:**



TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)