CORBIS-H 5

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for CORBIS-H 5 (Bisoprolol Fumarate and Hydrochlorothiazide Tablets I.P.)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:
Mechanism of action: Bisoprolol is a highly $beta_1$-selective-adrenoceptor blocking agent, lacking intrinsic stimulating and relevant membrane stabilising activity. It only shows low affinity to the $beta_2$-receptor of the smooth muscles of bronchi and vessels as well as to the $beta_2$-receptors concerned with metabolic regulation and Hydrochlorothiazide blocks the reabsorption of sodium and chloride ions, and it thereby increases the quantity of sodium traversing the distal tubule and the volume of water excreted. A portion of the additional sodium presented to the distal tubule is exchanged there for potassium and hydrogen ions. With continued use of hydrochlorothiazide and depletion of sodium, compensatory mechanisms tend to increase this exchange and may produce excessive loss of potassium, hydrogen and chloride ions. Hydrochlorothiazide also decreases the excretion of calcium and uric acid, may increase the excretion of iodide and may reduce glomerular filtration rate.

DOSAGE AND ADMINISTRATION: As directed by physician.
CONTRAINDICATION Hypersensitivity to hydrochlorothiazide and other thiazides, Sulphonamides, bisoprolol or any of the other ingredients are Acute cardiac failure or during decompensation cardiac failure, where i. v.- inotropic therapy is warranted, Cardiogenic shock, AV block Grade II Or III (without pacemaker), Sick sinus syndrome, SA block, Bradycardia less than 60 beats / minute before the start of treatment, Late stages of peripheral arterial disease and Raynaud's syndrome, Severe bronchial asthma or severe chronic obstructive pulmonary disease, Metabolic acidosis, Therapy resistant hypokalemia, Severe hyponatremia, Hypercalcemia, Severe renal impairment with oliguria or anuria (creatinine clearance < 30 ml / min and / or serum creatinine > 1.8 mg / 100 ml), Acute glomerulonephritis, Severe hepatic impairment including hepatic precoma and coma, Untreated pheochromocytoma, Pregnancy, lactation, concomitant use of floctafenine and sultopride.

WARNINGS & PRECAUTIONS: Careful monitoring is required in case of :Cardiac failure, Bronchospasm, Simultaneous treatment with inhalation anesthetics, Diabetes mellitus with strongly fluctuating blood sugar levels, Strict fasting, Simultaneous desensitization therapy, AV block I. degree, Prinzmetal's angina, Peripheral arterial occlusive diseases, Hypovolemia, Impaired hepatic function, Patients with hyperuricemia; here the risk of a gout attack is increased, General anesthesia, Photosensitivity reactions associated with thiazide diuretics may occur**,** respiratory distress (including pneumonitis and pulmonary oedema) Non-melanocytic skin cancer, Acute cholecystitis has been reported in patients with cholelithiasis., Pregnancy.

DRUG INTERACTION:

Combinations not recommended

Calcium antagonists of the verapamil type and to a lesser extent of the diltiazem type, Class I antiarrhythmic drugs (e.g. quinidine, disopyramide; lidocaine, phenytoin; flecainide, propafenone), Centrally acting antihypertensive drugs such as clonidine and others (e.g. methyldopa, moxonodine, rilmenidine. **Combinations to be used with caution:** Calcium antagonists of the dihydropyridine type such as felodipine and amlodipine, Class-III antiarrhythmic drugs (e.g. amiodarone): Effect on atrio-ventricular conduction time may be

potentiated, Topical beta-blockers (e.g. eye drops for glaucoma treatment) may add to the systemic effects of bisoprolol, Para sympathomimetic drugs: Concomitant use may increase atrio-ventricular conduction time and the risk of bradycardia, Insulin and oral antidiabetic drugs Anaesthetic agents, Digitalis glycosides, Non-steroidal anti-inflammatory drugs (NSAIDs): NSAIDs may reduce the hypotensive effect of bisoprolol, β-Sympathomimetic agents (e.g. isoprenaline, dobutamine. **Combinations to be considered:** Mefloquine, Monoamine oxidase inhibitors (except MAO-B inhibitors)**, Hydrochlorthiazide:** Alcohol, Barbiturates or Narcotics, Antidiabetic Drugs (Oral Agents and Insulin), Other Antihypertensive Drugs, Cholestyramine and Colestipol Resins, Corticosteroids, ACTH , Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity, Non-Steroidal Anti-Inflammatory Drugs.

DVERSE REACTIONS: Increased triglyceride and cholesterol, hyperglycemia and glucosuria, hyperuricemia, Disorders of fluid and electrolyte imbalance (especially hypokalemia and hyponatremia, and additionally hypomagnesemia and hypochloremia as well hypercalcemia), metabolic alkalosis, Tiredness, feeling weak, dizziness, headache, Feeling of coldness or numbness in hands or feel, Low blood pressure, Stomach or intestine problems such as nausea, vomiting, diarrhoea, or constipation, Slow heart rate, Worsening of heart failure, Loss of appetite, Stomach ache, increase in the amylase (enzyme), pancreatitis, sleep disturbances, Depression, breathing problems in patients with asthma or chronic lung disease, Muscle weakness, muscle cramps, Leukocytopenia, thrombocytopenia, Temporary loss of consciousness caused by a fall in blood pressure, Reduced tear flow (to be considered if the patient uses lenses), blurred vision, Hearing problems, Allergic runny nose, Inflammation of the liver which can cause yellowing of the skin or whites of the eyes, Certain blood test results for liver function or fat levels differing from normal, Allergy-like reactions such as itching, flush, rash, Impaired erection, Nightmares, hallucinations, Fainting, Chest pain, Agranulocytosis, Irritation and redness of the eye (conjunctivitis), Hair loss, Appearance or worsening of scaly skin rash (psoriasis); psoriasis-like rash.

Manufactured by:

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(Additional information is available on request)