CORBIS 1.25/2.5/5/10

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only. Abbreviated Prescribing information for CORBIS 1.25/2.5/5/10 mg (Bisoprolol Fumarate Tablets)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: 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.

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

CONTRAINDICATION:

Bisoprolol is contraindicated in chronic heart failure patients with: Acute heart failure or during episodes of heart failure decompensation requiring i.v. inotropic therapy, Cardiogenic shock, Second or third degree AV block, Sick sinus syndrome, Sinoatrial block, Symptomatic bradycardia, Symptomatic hypotension, Severe bronchial asthma, Severe forms of peripheral arterial occlusive disease or severe forms of raynaud's syndrome, Untreated phaeochromocytoma, Metabolic acidosis, Hypersensitivity to bisoprolol or to any of the excipients.

WARNINGS & PRECAUTIONS: Insulin dependent diabetes mellitus (type I), severely impaired renal function and hepatic function, restrictive cardiomyopathy, congenital heart disease, haemodynamically significant organic valvular disease, myocardial infarction. Bisoprolol must be used with caution in: Bronchospasm (bronchial asthma, obstructive airways diseases), diabetes mellitus with large fluctuations in blood glucose values; Symptoms of hypoglycaemia can be masked, strict fasting, ongoing desensitisation therapy. As with other beta-blockers, bisoprolol may increase both the sensitivity towards allergens and the severity of anaphylactic reactions. Epinephrine treatment does not always yield the expected therapeutic effect, First-degree AV block, Prinzmetal's angina, Peripheral arterial occlusive disease, General anaesthesia.

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), Topical beta-blockers, Parasympathomimetic drugs, Insulin and oral antidiabetic drugs, Anaesthetic agents, Digitalis glycosides, Non-steroidal anti-inflammatory drugs (NSAIDs), β-Sympathomimetic agents (e.g. isoprenaline, dobutamine), antihypertensive agents as well as with other drugs with blood pressure lowering potential (e.g. tricyclic antidepressants, barbiturates, phenothiazines) may increase the risk of hypotension. *Combinations to be considered:* Mefloquine, monoamine oxidase inhibitors (except MAO-B inhibitors).

ADVERSE REACTIONS: Bradycardia, worsening of pre-existing heart failure, AV-conduction disturbances, sleep disorders, depression, nightmares, hallucinations, dizziness, headache, syncope, dry eyes, impaired vision, conjunctivitis, hearing disorders, feeling of coldness or numbness in the extremities, hypotension, orthostatic hypotension, Cyanosis of

extremities, paraesthesia bronchospasm in patients with bronchial asthma or a history of obstructive airways disease, allergic rhinitis, as nausea, vomiting, diarrhoea, constipation, hepatitis, erectile dysfunction, hypersensitivity reactions (itching, rash), alopecia, muscular weakness and cramps, asthenia, increased liver enzymes, Perspiration, Oedema, lassitude fatigue, Increased triglycerides, angioedema.

Marketed by:



TORRENT PHARMACEUTICALS LTD.

IN/CORBIS®-1.25, 2.5, 5 and 10 mg/Mar-2021/04/ABPI

(Additional information is available on request)