Nebivolol BSS [1]

Nebivolol Sandoz 5mg tablets. Each tablet contains 5 mg nebivolol. Indications. Treatment of essential hypertension. Treatment of stable mild and moderate chronic heart failure in addition to standard therapies in elderly patients ?70 years. Posology. Hypertension. Adults. 5 mg daily. Beta-blockers can be used alone or concomitantly with other antihypertensive agents. To date, an additional antihypertensive effect has been observed only when nebivolol 5 mg is combined with hydrochlorothiazide 12.5-25 mg. In patients with renal insufficiency, the recommended starting dose is 2.5 mg daily. If needed, the daily dose may be increased to 5 mg. In patients with renal insufficiency, the recommended starting dose is 2.5 mg daily. If needed, the daily dose may be increased to 5 mg. Data in patients with hepatic insufficiency or impaired liver function are limited. Therefore the use of nebivolol in these patients is contraindicated. In patients over 65 years, the recommended starting dose is 2.5mg daily. If needed, the daily dose may be increased to 5 mg. The safety and efficacy of nebivolol in children aged less than 18 years have not been established. The treatment of stable chronic heart failure has to be initiated with a gradual uptitration of dose until the optimal individual maintenance dose is reached. The initial uptitration should be done according to the following steps at 1-2 weekly intervals based on patient tolerability: 1.25 mg nebivolol, to be increased to 2.5 mg nebivolol once daily, then to 5 mg once daily and then to 10 mg once daily. The maximum recommended dose is 10 mg nebivolol once daily. No dose adjustment is required in mild to moderate renal insufficiency since uptitration to the maximum tolerated dose is individually adjusted. Contraindicated. Hypersensitivity to the active substance or to any of the excipients. Liver insufficiency or liver function impairment. Acute heart failure, cardiogenic shock or episodes of heart failure decompensation requiring i.v. inotropic therapy. Sick sinus syndrome, including sino-atrial block. Second and third degree heart block (without a pacemaker). History of bronchospasm and bronchial asthma. Untreated phaeochromocytoma. Metabolic acidosis. Bradycardia (heart rate <60 bpm prior to start therapy). Hypotension (systolic blood pressure <90 mmHg). Severe peripheral circulatory disturbances. Precautions for use. Caution should be observed with certain anaesthetics that cause myocardial depression. Beta-adrenergic antagonists should not be used in patients with untreated congestive heart failure (CHF), unless their condition has been stabilised. Beta-adrenergic antagonists may induce bradycardia.Beta-adrenergic antagonists should be used with caution: in patients with peripheral circulatory disorders (Raynaud's disease or syndrome, intermittent claudication), as aggravation of these disorders may occur, in patients with first degree heart block, because of the negative effect of beta-blockers on conduction time, in patients with Prinzmetal’s angina due to unopposed alphareceptor mediated coronary artery vasoconstriction: beta-adrenergic antagonists may increase the number and duration of anginal attacks. Care should be taken in diabetic patients however, as nebivolol may mask certain symptoms of hypoglycaemia. In patients with chronic obstructive pulmonary disorders, beta-adrenergic antagonists should be used with caution as airway constriction may be aggravated. Beta-adrenergic antagonists may increase the sensitivity to allergens and the severity of anaphylactic reactions. Nebivolol has pharmacological effects that may cause harmful effects on pregnancy and/or the foetus/newborn. Breastfeeding is not recommended during administration of nebivolol. Adverse Events. Headache, dizziness, paraesthesia. Dyspnoea. Constipation, nausea, diarrhoea. Tiredness, oedema. Aggravation of cardiac failure. **CDS Apr 2015**

Links
[1] https://www.sandozca.com/en/nebivolol-bss