For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Metoprolol Succinate Extended Release Tablets USP

Seloken® XL 25, 50, 100 & 200mg*

Abbreviated Prescribing Information

Indications:

Hypertension: to reduce blood pressure and to reduce the risk of cardiovascular and coronary mortality (including sudden death), and morbidity.

Angina pectoris: Stable symptomatic chronic heart failure with impaired systolic left ventricular function as an adjunct to existing heart failure therapy. Prevention of cardiac death and reinfarction after the acute phase of myocardial infarction. Cardiac arrhythmias especially including supraventricular tachycardia, reduction of ventricular rate in atrial fibrillation and in ventricular extrasystoles. Functional heart disorders with palpitations. Migraine prophylaxis.

Dosage and method of administration

Seloken XL is intended for once daily treatment and is preferably taken in the morning. The Seloken XL tablet should be swallowed with liquid. The tablets and the divided halves should not be chewed or crushed. Concomitant intake of food does not influence the bioavailability.

Dosage should be adjusted to avoid bradycardia.

Hypertension: The recommended dosage in patients with mild to moderate hypertension is 50 mg Seloken XL given once daily. In patients not responding to 50 mg the dose could be increased to 100-200 mg once daily and/or combined with other antihypertensive agents.

Angina pectoris: The recommended dosage is 100-200 mg Seloken XL given once daily. If needed, Seloken XL can be combined with other antianginal agents.

Stable symptomatic chronic heart failure with impaired systolic left ventricular function as an adjunct to existing heart failure therapy The patients should have a stable chronic heart failure, without acute failure for the latest 6 weeks and an essentially unchanged basal therapy for the latest 2 weeks.

Cardiac arrhythmias: The recommended dosage is 100-200 mg Seloken XL given once daily.

Prophylactic treatment after myocardial infarction: Long-term oral treatment with metoprolol in doses of 200 mg given once daily has been shown to reduce the risk of death (including sudden death), and to reduce the risk of reinfarction (also in patients with diabetes mellitus).

Functional heart disorders with palpitations: The recommended dosage is 100 mg once daily. If needed, the dose can be increased to 200 mg.

Migraine prophylaxis: The recommended dosage is 100-200 mg once daily.

Impaired renal function: Dose adjustment is not needed in patients with impaired renal function.

Impaired hepatic function: Dose adjustment is normally not needed in patients suffering from liver cirrhosis because metoprolol has a low protein binding (5-10 %). When there are signs of serious impairment of liver function (e.g. shuntoperated patients) a dose reduction should be considered.

Elderly: Dose adjustment is not needed in the elderly.

Children: There is limited experience with Seloken XL treatment in children.

Contraindications

Atrioventricular block of second or third degree, patients with unstable decompensated cardiac heart failure (pulmonary oedema, hypoperfusion or hypotension), and patients with continuous or intermittent inotropic therapy acting through beta-receptor agonism; marked clinically relevant sinus bradycardia, sick-sinus syndrome, cardiogenic shock, severe peripheral arterial circulatory disorder.

Metoprolol should not be given to patients with suspected acute myocardial infarction as long as the heart rate is <45 beats/min, the PQ interval is > 0.24 sec or the systolic blood pressure is <100 mm Hg. Seloken XL is contra-indicated in patients who have shown hypersensitivity to any component of the product or to other β-blockers.

Special warnings and precautions for use

Intravenous administration of calcium antagonists of the verapamil-type should not be given to patients treated with β-blockers.

Patients suffering from heart failure should have their decompensation treated both before and during treatment with Seloken XL. Very rarely, a pre-existing A–V conduction disorder of moderate degree may become aggravated (possibly leading to A–V block).

Where Seloken XL is prescribed for a patient known to be suffering from a phaeochromocytoma, an alphablocker should be given concomitantly.

Abrupt interruption of the medication is to be avoided. Sudden withdrawal of beta-blockade is hazardous, especially in high-risk patients, and may aggravate chronic heart failure as well as increase the risk of myocardial infarction and sudden death. Any withdrawal of Seloken XL should therefore, if possible, be made gradually over at least two weeks when the dose is reduced by half in each step, down to the final dose when a 25mg tablet is reduced to half a tablet. The final dose should be given for at least four days before discontinuation. If symptoms occur, a slower withdrawal rate is recommended.

In patients taking β-blockers anaphylactic shock assumes a more severe form.

Interactions

Plasma levels of metoprolol may be raised by co-administration of compounds metabolised by CYP2D6, e.g. antiarrhythmics, antihistamines, histamine-2- receptor antagonists,

antidepressants, antipsychotics, and COX-2-inhibitors. The plasma concentration of metoprolol is lowered by rifampicin and may be raised by alcohol and hydralazine.

If concomitant treatment with clonidine is to be discontinued. Concomitant treatment with indomethacin or other prostaglandin synthetase inhibiting drugs may decrease the antihypertensive effect of β-blockers.

Digitalis glycosides in association with β-blocker, may increase artioventricular conduction time may induce bradycardia.

Use in pregnancy and lactation: As with most drugs, Seloken XL should not be given during pregnancy and lactation unless its use is considered essential.

Undesirable effects: Bradycardia, postural disorders (very rarely with syncope), cold hands and feet, palpitations, Transient deterioration of heart failure symptoms, AV-block I, oedema, precordial pain. Cardiogenic shock in patients with acute myocardial infraction. Gangrene in patients with pre-existing severe peripheral circulatory disorders. Fatigue, Dizziness, headache, Paraesthesia, muscle cramps. Nausea, abdominal pain, diarrhoea, constipation, Thrombocytopenia, Depression, concentration impaired, somnolence or insomnia, nightmares. Disturbances of vision, dry and/or irritated eyes, conjuctivities, Tinnitus, taste disturbances. Rash (in the form of urticaria psoriasiform and dystrophic skin lesions), increased sweating, Loss of hair, Photosensitivity reactions, aggravated psoriasis.

Presentation: Seloken XL 25mg, 50mg, 100mg

please refer to outer carton for pack size.

*Seloken XL 200mg currently not available.

Special precautions for storage: Do not store above 30^0C. Protect from light.

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For more information, refer full prescribing information July 2008.