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

Betaloc 25mg, 50 mg and 100 mg tablet

Metoprolol tartrate

Abbreviated Prescribing Information

COMPOSITION

Each tablet contains metoprolol tartrate 25, 50 and 100 mg respectively.

INDICATION

- Hypertension: to reduce blood pressure and to reduce the risk of cardiovascular and coronary mortality (including
- sudden death), and morbidity.
- Angina pectoris.
- Disturbances of cardiac rhythm including especially supraventricular tachycardia.
- Maintenance treatment after myocardial infarction.
- Functional heart disorders with palpitations.
- Migraine prophylaxis.
- Hyperthyroidism.

DOSAGE AND METHOD OF ADMINISTRATION

The tablets should be taken on an empty stomach.

Hypertension: The recommended dosage in patients with hypertension is 100-200 mg daily, given as a single dose in the morning or in divided doses (morning and evening). If needed, the dose may be increased or other antihypertensive agents added. Long-term antihypertensive treatment with Betaloc in daily doses of 100-200 mg has been shown to reduce total mortality, including sudden cardiovascular death, stroke and coronary events in hypertensive patients.

Angina pectoris: The recommended dosage is 100-200 mg daily, given in divided doses (morning and evening). If needed, other antianginal agents may be added.

Cardiac arrhythmias: The recommended dosage is 100-200 mg daily given in divided doses (morning and evening). If needed, other antiarrhythmic agents may be added.

Maintenance treatment after myocardial infarction: Long-term oral treatment with Betaloc in doses of 200 mg daily, given in divided doses (morning and evening) 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, given as a single dose in the morning. If needed, the dose can be increased to 200 mg.

Migraine prophylaxis: The recommended dosage is 100-200 mg daily, given in divided doses morning and evening.

Hyperthyroidism: The recommended dosage is 150-200 mg daily, divided in 3-4 doses. If needed, the dose can be increased.

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. shunt-operated patients) a dose reduction should be considered.

Elderly: Dose adjustment is not needed in the elderly.

Children: There is limited experience with Betaloc 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 -receptor agonism; marked clinically relevant sinus bradycardia, sick-sinus syndrome, cardiogenic shock, severe peripheral arterial circulatory disorder.

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

Special warnings and precautions for use

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

Generally when treating patients with asthma, concomitant therapy with a beta2-agonist (tablet and/or inhalation) should be administered. The dosage of 2-agonists may require adjustment (increase) when treatment with Betaloc is started.

During treatment with Betaloc, the risk of interfering with carbohydrate metabolism or masking hypoglycaemia is less than with nonselective -blockers.

Patients suffering from heart failure should have their decompensation treated both before and during treatment with Betaloc.

Very rarely, a pre-existing A-V conduction disorder of moderate degree may become aggravated (possibly leading to A-V block).

If the patients develop increasing bradycardia, Betaloc should be given in lower doses or gradually withdrawn.

Betaloc may aggravate the symptoms of peripheral arterial circulatory disorders, mainly due to its blood pressure lowering effect.

Where Betaloc is prescribed for a patient known to be suffering from a phaeochromocytoma, an alpha-blocker should be given concomitantly.

Prior to surgery the anaesthetist should be informed that the patient is receiving Betaloc. It is not recommended to stop beta-blocker treatment in patients undergoing surgery.

Abrupt interruption of the medication is to be avoided. If treatment has to be withdrawn it should, when possible, be done gradually. Many patients can be withdrawn over a 14 day period. This can be done by cutting the daily dose in sequential steps, reaching a final dose of 25 mg once a day (half a 50 mg tablet). During this period especially

patients with known ischemic heart disease should be kept under close surveillance. The risk for coronary events, including sudden death, may increase during withdrawal of beta-blockade. In patients taking beta-blockers anaphylactic shock assumes a more severe form.

Interactions

Metoprolol is a metabolic substrate for the Cytochrome P450 isoenzyme CYP2D6. Drugs that act as enzymeinducing and enzyme-inhibiting substances may exert an influence on the plasma level of metoprolol. 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.

A watch should be kept for possible negative inotropic and chronotropic effects when metoprolol is given together with calcium antagonists of the verapamil and diltiazem type and/or antiarrhythmic agents. In patients treated with beta-blockers intravenous administration of calcium antagonists of the verapamil-type should not be given.

beta-blockers may enhance the negative inotropic and negative dromotropic effect of antiarrhythmic agents (of the quinidine type and amiodarone).

Digitalis glycosides in association with beta-blockers may increase atrioventricular conduction time and may induce bradycardia.

Pregnancy and lactation

As with most drugs, Betaloc should not be given during pregnancy and lactation unless its use is considered essential. As with all antihypertensive agents, -blockers may cause side-effects,e.g. bradycardia, in the fetus and in the newborn and breast-fed infant.

The amount of metoprolol ingested via breast-milk, however, seems to be negligible as regards beta-blocking effect in the infant if the mother is treated with metoprolol in doses within the normal therapeutic range.

Effects on ability to drive and use machines

Patients should know how they react to Betaloc before they drive or use machines because occasionally dizziness or fatigue may occur.

Undesirable effects

Betaloc is well tolerated and adverse reactions have generally been mild and reversible.

Cardiovascular system:

Common: Bradycardia, postural disorders (very rarely with syncope), cold hands and feet, Palpitations.

Uncommon: Transient deterioration of heart failure symptoms, AV-block I, oedema, pericordial pain. Cardiogenic shock in patients with acute myocardial infraction.

Rare: Disturbances of cardiac conduction, cardiac arrhythmias.

Very rare: Gangrene in patients with pre-existing severe peripheral circulatory disorders.

Betaloc is an applied trademark of AstraZeneca group of companies.

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For more information, refer full prescribing information year 2013.