

BETALOC

Metoprolol Tartrate USP

Composition : Betaloc : Each tablet contains Metoprolol Tartrate USP 50mg.

Betaloc-25 : Each film coated tablet contains Metoprolol Tartrate USP 25mg.

Pharmacology : Metoprolol is a selective beta1-blocker. Metoprolol reduces or inhibits the agonistic effect on the heart of catecholamines (which are released during physical and mental stress). This means that the usual increase in heart rate, cardiac output, cardiac contractility and blood pressure, produced by the acute increase in catecholamines, is reduced by Metoprolol. Metoprolol interferes less with Insulin release and carbohydrate metabolism than do non-selective beta-blockers. Metoprolol interferes much less with the cardiovascular response to hypoglycaemia than do non-selective beta-blockers. The estimated oral bioavailability of Metoprolol is about 50%. Metoprolol is extensively distributed with a reported volume of distribution of 3.2 L/kg to 5.6 L/kg. About 10% of Metoprolol in plasma is bound to serum albumin. Metoprolol is primarily metabolized by CYP2D6. Elimination of Metoprolol is mainly by biotransformation in the liver. The mean elimination half-life of Metoprolol is 3 to 4 hours; in poor CYP2D6 metabolizers the half-life may be 7 to 9 hours. Approximately 95% of the dose can be recovered in urine.

Indications : Betaloc is indicated for hypertension, angina, arrhythmia (including arrhythmias during anaesthesia), early intervention in acute myocardial infarction, heart failure, migraine prophylaxis and thyrotoxicosis.

Dosage and administration : Hypertension : Initially 100mg tablets daily, for maintenance therapy 100-200mg tablets daily in 1-2 doses for adults and 25mg tablet once daily for elderly.

Angina : 50-100mg tablet 2-3 times daily.

Arrhythmias : Usually 50mg tablet 2-3 times daily upto 300mg tablets daily in divided doses, if necessary.

Myocardial Infarction : If patient can not tolerate IV doses then he/she should be switched to oral treatment. Starting dose for such patient is 25mg tablets 6 hourly for 48 hours.

Heart Failure : 12-5-25mg once daily. Dose is increased at intervals of 2 weeks, to a maximum of 200mg once daily.

Migraine Prophylaxis : 100-200mg tablets daily in divided doses.

Thyrotoxicosis : 50mg tablet 4 times daily. Or, as directed by the registered physician.

Contraindications : Asthma, heart failure, second or third degree heart block, Prinzmetal's angina, hypotension, marked bradycardia, sick-sinus syndrome, cardiogenic shock, severe peripheral vascular disease.

Precaution : Cautions should be exercised during late pregnancy and breast feeding. Avoid abrupt withdrawal in angina. Reduce initial dose in renal impairment and reduce oral dose in liver disease.

Side-effects : Bradycardia, heart failure, bronchospasm, peripheral vasoconstriction, gastro-intestinal disturbances etc.

Use in Pregnancy & Lactation : Metoprolol should not be used in pregnancy or lactating mothers unless the physician considers that the benefit outweighs the possible hazard to the fetus or infant.

Use in Child : No data available.

Drug Interaction : Plasma level of Metoprolol may be raised by co-administration of compounds metabolised by CYP2D6 e.g. Antiarrhythmics, antihistamines, H2 receptor antagonists, antidepressants, antipsychotics and COX-2 inhibitors. The plasma concentration of Metoprolol is lowered by Rifampicin.

Overdose : Poisoning due to an overdose of metoprolol may lead to severe hypotension, sinus bradycardia, atrioventricular block, heart failure, cardiogenic shock, cardiac arrest, bronchospasm, impairment of consciousness, coma, nausea, vomiting, cyanosis, hypoglycaemia and, occasionally, hyperkalaemia. The first manifestations usually appear 20 minutes to 2 hours after drug ingestion.

Treatment: Treatment should include close monitoring of cardiovascular, respiratory and renal function, and blood glucose and electrolytes.

Storage : Store Below 30° C in a cool, dry place protected from light. Keep out of reach of children.

Packing : Betaloc : Each box contains 7 x 14's tablets in blister pack.

Betaloc-25 : Each box contains 7 x 14's tablets in blister pack.



DRUG INTERNATIONAL LTD.

UNIT-3

31/1, SATRONG, TONGI IIA, GAZIPUR

05/2023/NIH