AMERICAN

METOFOX 5 Injection

For Intravenous Injection Only

Metoprolol injection IP

Composition :
Each ml contains :

Metoprolol Tartrate	IP	1mg
Sodium Chloride	IP	9mg
Water for Injection	IP	q.s.

Indications and Usage for Metoprolol Tartrate Injection

Metoprolol tartrate Injection is indicated in the treatment of definite or suspected acute myocardial infarction in hemodynamically stable patients to reduce cardiovascular mortality when used in conjunction with metoprolol maintenance therapy.

Metoprolol Tartrate Injection Dosage and Administration

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
Initiate treatment in a coronary care or similar unit immediately after the patient's hemodynamic condition has stabilized.
Begin treatment in this early phase with the administration of three bolus injections of 1 mg of Metoprolol tartrate each; give the injections at approximately 2-minute intervals. During the administration of Metoprolol tartrate, monitor blood pressure, heart rate, and electrocardiogram.
Transition to Metoprolol:
Following administration of Metoprolol tartrate Injection, transition patients to an intravenous formulation of metoprolol. See prescribing information for metoprolol for dose selection.

Dosage Forms and Strengths

Injection: 5 mg metoprolol tartrate supplied in 5 mL Single-dose Ampoule

Contraindications

Hypersensitivity to Metoprolol tartrate and related derivatives, or to any of the excipients; hypersensitivity to other beta-blockers (cross sensitivity between beta-blockers can occur).
Metoprolol tartrate is contraindicated in patients with a heart rate <45 beats/min; second- and third-degree heart block (unless a functioning pacemaker is present); significant first-degree heart block (P-R interval ≥0.24 sec); systolic blood pressure <100 mmHg; or decompensated cardiac failure.

Warnings and Precautions

Bradycardia

Bradycardia, including sinus pause, heart block, and cardiac arrest have occurred with the use of Metoprolol tartrate. Patients with first-degree atrioventricular block, sinus node dysfunction, or conduction disorders may be at increased risk. Monitor heart rate and rhythm in patients receiving Metoprolol tartrate. If severe bradycardia develops, reduce or stop Metoprolol tartrate.

Heart Failure

Worsening cardiac failure may occur during metoprolol use. If such symptoms occur, increase diuretics and restore clinical stability before administering the next dose of metoprolol Such episodes do not preclude subsequent successful titration of metoprolol.

Bronchospastic Disease

PATIENTS WITH BRONCHOSPASTIC DISEASES, IN GENERAL, SHOULD NOT RECEIVE BETA-BLOCKERS because they can exacerbate bronchospasm. Because of its relative beta1 cardio-selectivity, however, metoprolol may be used in patients with bronchospastic disease for initial treatment of myocardial infarction. Bronchodilators, including beta2-agonists, should be readily available or administered concomitantly

Pheochromocytoma

If metoprolol tartrate is used in the setting of pheochromocytoma, it should be given in combination with an alpha blocker, and only after the alpha blocker has been initiated. Administration of beta-blockers alone in the setting of pheochromocytoma has been associated with a paradoxical increase in blood pressure due to the attenuation of beta-mediated vasodilatation in skeletal muscle.

Peripheral Vascular Disease

Beta-blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease.

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