

Now Available

Metoprolol Tartrate Tablets

12.5 mg



Not an actual product

NDC	Description	Strength	Package Size
72888-197-03	Metoprolol Tartrate Tablets	12.5 mg	60 ct

Metoprolol Tartrate Tablets 12.5 mg for oral use (Advagen Pharma Limited)

DESCRIPTION

Metoprolol Tartrate Tablets contain metoprolol tartrate, a beta-adrenergic blocker. Metoprolol tartrate is (±)-1-(Isopropylamino)-3-[p-(2-methoxyethyl) phenoxy]-2-propanol L-(+)-tartrate (2:1) salt.

Metoprolol tartrate USP is a white, practically odorless, crystalline powder with a molecular weight of 684.82 g/mol. It is very soluble in water; freely soluble in methylene chloride, in chloroform, and in alcohol; slightly soluble in acetone; and insoluble in ether.

Metoprolol Tartrate Tablets is available as 12.5 mg tablets for oral administration containing 12.5 mg metoprolol tartrate (equivalent to 9.76 mg of metoprolol).

Inactive Ingredients: Tablets contain colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate. Film coating contains D&C Red 30, hypromellose, polyethylene glycol, talc, and titanium dioxide.

INDICATIONS AND USAGE

Myocardial Infarction

Metoprolol Tartrate Tablets is a beta adrenergic blocker indicated in the treatment of hemodynamically stable adult patients with myocardial infarction, to reduce the risk of cardiovascular mortality.

DOSAGE FORMS AND STRENGTHS

Metoprolol Tartrate Tablets is supplied as a 12.5 mg tablet that is pink-colored, film coated, round, biconvex, debossed with "E" on one side, and plain on the other side.

DOSAGE AND ADMINISTRATION

Myocardial Infarction

The recommended starting dose in hemodynamically stable patients is 50 mg orally every 6 hours. In case of intolerance, reduce the starting dose to 25 mg orally every 6 hours and administer for 48 hours. Titrate dosage based on tolerability and hemodynamic parameters (i.e., heart rate, blood pressure). Metoprolol Tartrate Tablets should preferably be administered with or following meals. The maximum daily maintenance dosage is 100 mg orally twice daily.

OVERDOSAGE

Signs and Symptoms - Overdosage of Metoprolol Tartrate Tablets may lead to severe bradycardia, hypotension, and cardiogenic shock. Clinical presentation can also include AV block, heart failure, bronchospasm, hypoxia, impairment of consciousness/coma, nausea, and vomiting.

Treatment - Consider treating the patient with intensive care. Patients with myocardial infarction or heart failure may be prone to significant hemodynamic instability. Beta-blocker overdose may result in significant resistance to resuscitation with adrenergic agents, including beta-agonists. On the basis of the pharmacologic actions of metoprolol, employ the following measures.

Hemodialysis is unlikely to make a useful contribution to metoprolol elimination [see Clinical Pharmacology.

Bradycardia: Evaluate the need for atropine, adrenergic-stimulating drugs or pacemaker to treat bradycardia and conduction disorders.

Hypotension: Treat underlying bradycardia. Consider intravenous vasopressor infusion, such as dopamine or norepinephrine.

Heart failure and shock: May be treated when appropriate with suitable volume expansion, injection of glucagon (if necessary, followed by an intravenous infusion of glucagon), intravenous administration of adrenergic drugs such as dobutamine, with α_1 receptor agonistic drugs added in presence of vasodilation.

Bronchospasm: Can usually be reversed by bronchodilators.

Manufactured by:

Rubicon Research Ltd.,
Thane 421506, India.

Distributed by:

Advagen Pharma Ltd.,
East Windsor, NJ 08520, USA

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