Metoprolol Tartrate (metoprolol tartrate) - Drug Summary

Mylan Pharmaceuticals Inc.

Related Drug Information

Metoprolol (metoprolol tartrate)

BOXED WARNING

Do not abruptly d/c therapy in patients w/ coronary artery disease (CAD). Severe exacerbation of angina, MI, and ventricular arrhythmias reported in patients w/ CAD following abrupt discontinuation of therapy w/ β-blockers. When discontinuing chronically administered metoprolol, particularly in patients w/ CAD, gradually reduce dose over a period of 1-2 weeks w/ careful monitoring. If angina markedly worsens or acute CAD develops, promptly reinstate metoprolol administration, at least temporarily, and take other measures appropriate for management of unstable angina. CAD may be unrecognized; may be prudent not to d/c therapy abruptly even in patients treated only for HTN.

COMMON BRAND NAMES

Lopressor, Metoprolol

THERAPEUTIC CLASS

Selective beta$_1$ blocker

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Hypertension

Tab:
Initial: 100mg/day PO in single or divided doses, whether used alone or added to a diuretic
Titrate: May increase at weekly (or longer) intervals until optimum BP reduction is achieved
Effective Range: 100-450mg/day

Doses >450mg/day not studied

Angina Pectoris

Long-Term Treatment:
Tab:
Initial: 100mg/day PO in 2 divided doses
Titrate: Gradually increase at weekly intervals until optimum clinical response is achieved or there is pronounced slowing of HR
Effective Range: 100-400mg/day

Doses >400mg/day not studied

If treatment is to be discontinued, gradually decrease dose over 1-2 weeks

Myocardial Infarction

Treatment of hemodynamically stable patients w/ definite or suspected acute MI to reduce cardiovascular mortality

Early Phase:
5mg IV bolus every 2 min for 3 doses (monitor BP, HR, and ECG); initiate treatment as soon as possible after patient's arrival in the hospital
In Patients Who Tolerate Full IV Dose (15mg): Initiate tabs, 50mg q6h, 15 min after last IV dose and continue for 48 hrs; thereafter, maint dose is 100mg bid
In Patients Who Cannot Tolerate Full IV Dose: Initiate tabs, either 25mg or 50mg q6h (depending on the

degree of intolerance) 15 min after the last IV dose or as soon as clinical condition allows; d/c w/ severe intolerance

Late Phase:
Initiate tabs, 100mg bid, as soon as clinical condition allows, for ≥3 months; start in patients w/ contraindications to early phase treatment, patients intolerant to the full early treatment, and patients in whom the physician wishes to delay therapy for any other reason

DOSING CONSIDERATIONS

Hepatic Impairment
Initiate at low doses w/ cautious gradual dose titration according to clinical response

Elderly
>65 Years:
Start at lower end of dosing range

ADMINISTRATION

Oral/IV route

Tab
Swallow unchewed w/ a glass of water.
Always take in standardized relation w/ meals; continue taking w/ the same schedule during the course of therapy.

Inj
Parenteral administration should be done in a setting w/ intensive monitoring.

HOW SUPPLIED

Tab: 25mg*; (Lopressor) 50mg*, 100mg*; **Inj:** (Lopressor) 5mg/5mL *scored

CONTRAINDICATIONS

HR <45 beats/min, 2nd- and 3rd-degree heart block, significant 1st-degree heart block, systolic BP <100mmHg, moderate to severe cardiac failure. **Tab:** Sinus bradycardia, >1st-degree heart block, cardiogenic shock, overt cardiac failure, sick sinus syndrome, severe peripheral arterial circulatory disorders.

WARNINGS/PRECAUTIONS

May cause depression of myocardial contractility and may precipitate heart failure (HF) and cardiogenic shock. May be necessary to lower the dose or d/c if signs/symptoms of HF develop. Chronically administered therapy should not be routinely withdrawn prior to major surgery; however, may augment risks of general anesthesia and surgical procedures. Bradycardia, including sinus pause, heart block, and cardiac arrest reported; increased risk in patients w/ 1st degree atrioventricular block, sinus node dysfunction, or conduction disorders. Reduce dose or d/c if severe bradycardia develops. Avoid w/ bronchospastic diseases; may be used in patients w/ bronchospastic disease who do not respond to or cannot tolerate other antihypertensive treatment. May mask tachycardia occurring w/ hypoglycemia; other manifestations (eg, dizziness, sweating) may not be significantly affected. If used in the setting of pheochromocytoma, should be given in combination w/ an α-blocker, and only after the α-blocker has been initiated; may cause a paradoxical increase in BP if administered alone. May mask certain clinical signs (eg, tachycardia) of hyperthyroidism and may precipitate thyroid storm w/ abrupt withdrawal. Patients w/ a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge and may be unresponsive to usual doses of epinephrine.

ADVERSE REACTIONS

Bradycardia, tiredness, dizziness, depression, SOB, diarrhea, pruritus, rash, heart block, HF, hypotension.

DRUG INTERACTIONS

Additive effects w/ catecholamine-depleting drugs (eg, reserpine). May increase risk of bradycardia w/ digitalis glycosides; monitor HR and PR interval. May produce an additive reduction in myocardial contractility w/ calcium channel blockers. Potent CYP2D6 inhibitors (eg, fluvoxamine, chlorpromazine, quinidine) may increase levels. Hydralazine may inhibit presystemic metabolism, leading to increased levels. May potentiate antihypertensive effects of α-blockers (eg, guanethidine, betanidine, reserpine). May potentiate the postural hypotensive effect of 1st dose of prazosin. May potentiate hypertensive response to withdrawal of clonidine; when given concomitantly w/ clonidine, d/c several days before clonidine is withdrawn. May enhance vasoconstrictive action of ergot alkaloids. Withhold therapy before dipyridamole testing, w/ careful monitoring of HR following the dipyridamole inj. **Inj:** Some inhalational anesthetics may enhance cardiodepressant effect.

PREGNANCY AND LACTATION

Pregnancy: Category C.
Lactation: Excreted in breast milk in a very small quantity. An infant consuming 1L of breast milk daily would receive a dose of <1mg of the drug.

MECHANISM OF ACTION

Selective β_1-blocker; has not been established. Possible mechanisms proposed include competitive antagonism catecholamines at peripheral (especially cardiac) adrenergic neuron sites, leading to decreased cardiac output; a central effect leading to reduced sympathetic outflow to the periphery; and suppression of renin activity.

PHARMACOKINETICS

Absorption: Oral bioavailability (50%). **Distribution:** V_d=3.2-5.6L/kg. Plasma serum binding (10% to albumin); crosses placenta and blood brain barrier; found in breast milk. **Metabolism:** Liver via CYP2D6. **Elimination:** Urine (95%; [PO] <5% unchanged, [IV] <10% unchanged); $T_{1/2}$=3-4 hrs, 7-9 hrs (poor CYP2D6 metabolizers).

ASSESSMENT

Assess for hypersensitivity to the drug, sinus bradycardia, heart block, cardiogenic shock, HF, CAD, bronchospastic diseases, hypoglycemia, hyperthyroidism, hepatic impairment, any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions. Obtain baseline ECG.

MONITORING

Monitor for signs/symptoms of HF, cardiogenic shock, bradycardia, thyroid storm, hypersensitivity reactions, and other adverse reactions. Monitor BP, HR, ECG, and hemodynamic status.

PATIENT COUNSELING

Advise to take tabs regularly and continuously, ud, w/ or immediately following meals. Warn against interruption or discontinuation of therapy w/o physician's advice. Advise to avoid operating automobiles and machinery or engaging in other tasks requiring alertness until response to therapy has been determined. Instruct to contact physician if difficulty in breathing or other adverse reactions occur, and to inform physician/dentist of therapy before undergoing any type of surgery.

STORAGE

20-25°C (68-77°F). Protect from moisture. (Lopressor) 25°C (77°F); excursions permitted to 15-30°C (59-86°F). **Tab:** Protect from moisture and heat. **Inj:** Protect from light and heat.

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