Topress® 50

Metoprolol Tartrate USP Film Coated Tablet

DESCRIPTION

Topress® is a preparation of Metoprolol tartrate. It is a selective beta-1 adrenoreceptor blocking agent. By blocking beta-receptors, chiefly located in cardiac muscle, metoprolol reduces the heart rate and cardiac output at rest and upon exercise, reduces systolic blood pressure upon exercise, inhibits isoproterenol induced tachycardia and reduces reflex orthostatic tachycardia. By reducing the heart rate and the force of muscle contraction, metoprolol also reduces heart muscle oxygen demand.

INDICATIONS

Topress® is indicated for the treatment of:

- Hypertension
- Angina Pectoris
- Cardiac Arrhythmia
- Myocardial Infarction
- Migraine Prophylaxis
- Hyperthyroidism

DOSAGE AND ADMINISTRATION

The dosage of **Topress®** should be individualized. It should be taken with or immediately following meals.

Hypertension: The usual initial dosage is 100 mg daily in single or divided doses, whether used alone or added to a diuretic. The dosage may be increased at weekly (or longer) intervals until optimum blood pressure reduction is achieved. In general, the maximum effect of any given dosage level will be apparent after 1 week of therapy. The effective dosage range is 100-450 mg per day. A usual maintenance dose is 100-200 mg daily in 1-2 doses.

Angina Pectoris: The usual initial dosage is 50-100 mg daily, given in two or three divided doses. The dosage may be gradually increased at weekly intervals until optimum clinical response has been obtained or there is pronounced slowing of the heart rate. The effective dosage range is 100-400 mg per day. If treatment is to be discontinued, the dosage should be reduced gradually over a period of 1-2 weeks.

Myocardial Infarction: **Topress®** is also used as an adjunct in the early management of acute myocardial infarction. **Topress®**, 50 mg every 6 hours should be initiated 15 minutes after the last metoprolol tartrate IV dose and continued for 48 hours, in patients who have received the full IV dose. Patients who appear not to tolerate the full IV dose should be given half the suggested oral dose. Thereafter, patients should receive a maintenance dosage of 100 mg twice daily. In patients who did not receive metoprolol by IV injection as part of the early management of acute myocardial infarction, metoprolol 100 mg twice daily may be started once the clinical condition of the patient stabilizes.

Cardiac Arrhythmias: Usually 50 mg 2-3 daily. If necessary the dose can be increased up to 300 mg per day in divided doses.

Hyperthyroidism: (adjunct), 50 mg 4 times daily.

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

CONTRAINDICATIONS

Hypertension and angina: Metoprolol is contraindicated in sinus bradycardia, heart block greater than first-degree, cardiogenic shock, overt cardiac failure, Sick-sinus syndrome, severe peripheral arterial circulatory disorders, and pheochromocytoma.

It is also contraindicated in hypersensitivity to metoprolol and related derivatives, or to any of the excipients; hypersensitivity to other beta-blockers (cross sensitivity between beta-blockers can occur).

Myocardial Infarction: Metoprolol is contraindicated in patients with a heart rate <45 beats/min; second- and third-degree heart block; significant first-degree heart block (P-R interval ≥0.24 sec); systolic blood pressure <100 mm Hg; or moderate -to-severe cardiac failure.

PRECAUTIONS

General: Metoprolol should be used with caution in patients with impaired hepatic function. Patients should be advised to avoid operating automobiles and machinery or engaging in other tasks requiring alertness until the patient's response to therapy with metoprolol has been determined and should be advised to inform the physician or dentist before any type of surgery.

In patients with Cardiac failure: In hypertensive and angina patients who have congestive heart failure controlled by digitalis and diuretics, metoprolol should be administered cautiously. Both digitalis and metoprolol slow AV conduction.

In patients without a history of cardiac failure: Continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of impending cardiac failure, patients should be fully digitalized and/or given a diuretic. The response should be observed closely. If cardiac failure continues, despite adequate digitalization and diuretic therapy, metoprolol should be withdrawn.

Diabetes and Hypoglycemia: Metoprolol should be used with caution in diabetic patients if a beta-blocking agent is required.

Thyrotoxicosis: Patients suspected of developing thyrotoxicosis should be managed carefully to avoid abrupt withdrawal of beta blockade, which might precipitate a thyroid storm.

SIDE-EFFECTS

Most adverse effects have been mild and transient. Side effects include fatigue, dizziness, headache, nausea and vomiting, abdominal pain, diarrhea or constipation, dryness of the mouth, bradycardia, exertional dyspnoea, bronchospasm, disturbances of vision.

DRUG INTERACTION

Catecholamine-depleting drugs: (e.g., reserpine) may have an additive effect when given with beta-blocking agents. Patients treated with metoprolol plus a catecholamine depletory should therefore be closely observed for evidence of hypotension or marked bradycardia, which may produce vertigo, syncope or postural hypotension.

Risk of anaphylactic reaction: while taking beta blockers, patients with a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge, either accidental, diagnostic, or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reaction.

General anesthetics: Some inhalation anesthetics may enhance the cardio-depressant effect of beta-blockers.

CYP2D6 Inhibitors: Potent inhibitors of the CYP2D6 enzyme like fluoxetine, paroxetine or bupropion, thioridazine, quinidine or propafenone, ritonavir, diphenhydramine, terbinafine cimetidine may increase the plasma concentration of metoprolol. Caution should therefore be exercised when co-administering potent CYP2D6 inhibitors with metoprolol.

Clonidine: If combination treatment with clonidine is to be discontinued metoprolol should be withdrawn several days before clonidine. Rebound hypertension that can follow withdrawal of clonidine may be increased in patients receiving concurrent beta-blocker treatment.

USE IN PREGNANCY AND LACTATION

Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Metoprolol is excreted in breast milk in a very small quantity. An infant consuming 1-liter of breast milk daily would receive a dose of less than 1 mg of the drug. Caution should be exercised when metoprolol is administered to a nursing woman.

PHARMACEUTICAL PRECAUTION

Store in a cool and dry place, away from light. Keep out of reach of children.

PACKAGING

Topress® 50 tablet : Box containing 10 strips of 10 tablets each. Each film coated tablet contains metoprolol tartrate USP 50 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

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