

# R METPROL ER

## Metoprolol Succinate Extended-Release Tablets USP 47.5mg

### WARNING : ISCHEMIC HEART DISEASE

Following abrupt cessation of therapy with certain beta-blocking agents, exacerbations of angina pectoris and, in some cases, myocardial infarction have occurred. When discontinuing chronically administered metoprolol succinate extended release, particularly in patients with ischemic heart disease, the dosage should be gradually reduced over a period of 1 to 2 weeks and the patient should be carefully monitored. If angina markedly worsens or acute coronary insufficiency develops, metoprolol succinate extended-release administration should be reinstated promptly, at least temporarily, and other measures appropriate for the management of unstable angina should be taken. Warn patients against interruption or discontinuation of therapy without the physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue metoprolol succinate extended-release therapy abruptly even in patients treated only for hypertension.

### Composition:

Each film coated extended release tablet contains :  
Metoprolol Succinate USP 47.5mg  
Eqvt. to Metoprolol Tartrate 50 mg  
Excipients q.s.  
Approved colour used

### Pharmaceutical Form:

Extended Release Tablet

### Therapeutic indications:

METPROL ER is indicated for the treatment of:

- **Hypertension** : To lower blood pressure. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions.
- **Angina Pectoris** : To reduce angina attacks and to improve exercise tolerance.
- **Heart Failure** : Stable, symptomatic (NYHA Class II or III) heart failure of ischemic, hypertensive, or cardiomyopathic origin.

### Dosage and method of administration:

#### Dosage:

Administer once daily. Dosing of METPROL ER should be individualized.

- **Hypertension**: Usual initial dosage is 25 to 100 mg once daily. The dosage may be increased at weekly (or longer) intervals until optimum blood pressure reduction is achieved.
- **Angina Pectoris**: Usual initial dosage is 100 mg once daily. Gradually increase the dosage at

weekly intervals until optimum clinical response has been obtained or there is an unacceptable bradycardia.

- **Heart Failure**: Recommended starting dose is 12.5 mg or 25 mg doubled every two weeks to the highest dose tolerated or up to 200 mg.

Switching from immediate release metoprolol to metoprolol succinate extended-release tablets: use the same total daily dose of metoprolol succinate extended-release tablets.

**Method of administration:** For Oral administration.

### Contraindications:

- METPROL ER is contraindicated in patients with,
- Known hypersensitivity to product components.
  - Severe bradycardia.
  - Heart block greater than first degree.
  - Cardiogenic shock.
  - Decompensated cardiac failure.
  - Sick sinus syndrome without a pacemaker.

### Warnings and Precautions:

Heart Failure: Worsening cardiac failure may occur.

Bronchospastic Disease: Avoid beta-blockers.

Pheochromocytoma: If required, first initiate therapy with an alpha blocker.

Major Surgery: Avoid initiation of high-dose extended-release metoprolol in patients undergoing non cardiac surgery because it has been associated with bradycardia, hypotension,

stroke and death. Do not routinely withdraw chronic beta-blocker therapy prior to surgery.

Diabetes and Hypoglycemia: May mask tachycardia occurring with hypoglycemia.

Thyrototoxicosis: Abrupt withdrawal in patients with thyrototoxicosis might precipitate a thyroid storm.

Anaphylactic Reactions: Patients may be unresponsive to the usual doses of epinephrine used to treat allergic reaction.

Peripheral Vascular Disease: Can aggravate symptoms of arterial insufficiency.

Calcium Channel Blockers: Because of significant inotropic and chronotropic effects in patients treated with beta-blockers and calcium channel blockers of the verapamil and diltiazem type, caution should be exercised in patients treated with these agents concomitantly.

### Drug interactions:

Catecholamine-depleting drugs may have an additive effect when given with beta-blocking agents CYP2D6 Inhibitors are likely to increase metoprolol concentration. Concomitant use of glycosides, clonidine, and diltiazem and verapamil with beta-blockers can increase the risk of bradycardia. Beta-blockers including metoprolol, may exacerbate the rebound hypertension that can follow the withdrawal of clonidine.

### Pregnancy and Lactation:

#### Pregnancy:

Use METPROL ER during pregnancy if clearly needed, after consultation with the physician.

#### Lactation:

Metoprolol is excreted in breast milk in very small quantities. Consider possible infant exposure when metoprolol succinate extended-release is administered to a nursing woman.

### Undesirable effects:

Most common adverse reactions: tiredness, dizziness, depression, shortness of breath, bradycardia, hypotension, diarrhea, pruritus, rash.

### Overdose:

#### Signs and Symptoms:

Overdosage of METPROL ER lead to severe bradycardia, hypotension, and cardiogenic

shock. It may also include, atrioventricular 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. Seek consultation with a regional poison control center and a medical toxicologist as needed. 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. There is very limited experience with the use of hemodialysis to remove metoprolol, however metoprolol is not highly protein bound.

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 a receptor agonistic drugs added in presence of vasodilation.

Bronchospasm: Can usually be reversed by bronchodilators.

### Storage:

Store below 30°C in dry place. Protect from light. Keep the medicine out of reach of children.

### Presentation:

A pack of 100 tablets

MOH, Kuwait

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