METOCARD XL

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **METOCARD XL** (Metoprolol succinate extended release Tablet)

[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: The mechanism of the antihypertensive effects of beta-blocking agents has not been elucidated. However, several possible mechanisms have been proposed: competitive antagonism of 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.

INDICATIONS: For the treatment of essential hypertension in adults.

<u>DOSAGE AND ADMINISTRATION</u>: Metoprolol Succinate Extended Release tablet is intended for once daily administration.

For treatment of hypertension and angina, when switching from immediate-release metoprolol to Metoprolol Succinate, the same total daily dose of Metoprolol Succinate

Extended Release tablet should be used. Individualize the dosage of metoprolol succinate. Titration may be needed in some patients.

Metoprolol Succinate tablets are scored and can be divided; however, do not crush or chew the whole or half tablet.

CONTRAINDICATION: Contraindicated in severe bradycardia, second or third degree heart block, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), and in patients who are hypersensitive to any component of this product..

<u>WARNINGS & PRECAUTIONS</u>: Heart failure: worsening cardiac failure may occur during uptitration of metoprolol succinate. bronchospastic disease: patients with bronchospastic diseases should, in general, not receive beta-blockers. pheochromocytoma, major surgery, diabetes and hypoglycemia (beta-blockers may mask tachycardia occurring with hypoglycemia), hepatic impairment, thyrotoxicosis (beta-adrenergic blockade may mask certain clinical signs of hyperthyroidism, such as tachycardia), anaphylactic reaction, peripheral vascular disease (beta-blockers can precipitate or aggravate symptoms of arterial insufficiency) and caution should be exercised in patients treated with calcium channel blockers.

DRUG INTERACTIONS: The concomitant use of Catecholamine depleting drugs (eg, reserpine, monoamine oxidase (MAO) inhibitors) may have an additive effect when given with beta-blocking agents. Metoprolol may interact with CYP2D6 Inhibitors, Digitalis, Clonidine, and Calcium Channel Blockers.

ADVERSE REACTIONS: Worsening angina or myocardial infarction, worsening heart failure, worsening av block, hypertension, angina, tiredness, dizziness, depression, diarrhea, shortness of breath, bradycardia, rash, cold extremities, arterial insufficiency (usually of the raynaud type), palpitations, peripheral edema, syncope, chest pain, hypotension, wheezing (bronchospasm), dyspnea, confusion, short-term memory loss, headache, somnolence, nightmares, insomnia, anxiety/nervousness, hallucinations, paresthesia, nausea, dry mouth, constipation, flatulence, heartburn, hepatitis, vomiting, pruritus, musculoskeletal pain, arthralgia, blurred vision, decreased libido, male impotence, tinnitus, reversible alopecia, agranulocytosis, dry eyes, worsening of psoriasis, peyronie's disease, sweating, photosensitivity, taste disturbance, reversible mental depression progressing to catatonia, granulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura, laryngospasm and respiratory distress..

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(Additional information is available on request)