DESCRIPTION: Metoprolol succinate, is a beta$_1$-selective (cardio selective) adrenoceptor blocking agent, for oral administration, available as extended release tablets. METOPROL-XL has been formulated to provide a controlled and predictable release of Metoprolol for once-daily administration. The tablets comprise a multiple unit system containing Metoprolol succinate in a multitude of controlled release pellets. Each pellet acts as a separate drug delivery unit and is designed to deliver Metoprolol continuously over the dosage interval**.**

INDICATIONS: METOPROL-XL is indicated for the treatment of hypertension, angina pectoris, heart failure and treatment of stable, symptomatic (NYHA Class II or III) heart failure of ischemic, hypertensive, or cardiomyopathic origin.

DOSAGE AND METHOD OF ADMINISTRAITON: METOPROL-XL is an extended release tablet intended for once daily administration. For treatment of hypertension and angina, when switching from immediate release Metoprolol, the same total daily dose of METOPROL-XL should be used. Dosages of METOPROL-XL should be individualized and titration may be needed in some patients. Hypertension: The usual initial dosage is 25 to 100 mg daily in a single dose, whether used alone or added to a diuretic. Dosages above 400 mg per day have not been studied. Pediatric Hypertensive Patients ≥ 6 Years of age: A pediatric clinical hypertension study in patients 6 to 16 years of age did not meet its primary endpoint (dose response for reduction in SBP), however some other endpoints demonstrated effectiveness If selected for treatment, the recommended starting dose of METOPROL-XL is 1.0 mg/kg once daily however, the maximum initial dose should not exceed 50 mg once daily. Doses above 2.0 mg/kg (or in excess of 200 mg) once daily have not been studied in pediatric patients. Angina Pectoris: The usual initial dosage is 100 mg daily, given in a single dose. Dosages above 400 mg per day have not been studied.

CONTRAINDICATIONS: METOPROL-XL is contraindicated in severe bradycardia, heart block greater than first degree, 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.

ADVERSE REACTIONS: Tiredness, dizziness, depression, diarrhea, itching or rash, shortness of breath, slow heart rate, mental confusion, headache, somnolence, nightmares, insomnia, dyspnea, Nausea, dry mouth, gastric pain, constipation, flatulence, digestive tract disorders, heartburn, pruritus, musculoskeletal pain, blurred vision, decreased libido, and tinnitus have also been reported, intensification of AV block.

WARNING: *Bronchospastic Diseases:* Because of its relative beta$_1$-selectivity, however, METOPROL-XL may be used with caution in patients with bronchospastic disease who do not respond to, or cannot tolerate, other antihypertensive treatment. *Major Surgery:* The necessity or desirability of withdrawing beta-blocking therapy prior to major surgery is controversial; the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures. *Diabetes and Hypoglycemia:* Beta-blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. *Peripheral Vascular Disease:* Beta-blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease. *Calcium Channel Blockers:* Because of significant inotropic and chronotropic effects in patients, caution should be exercised in patients treated with these agents concomitantly.

PRECAUTIONS: General: METOPROL-XL should be used with caution in patients with impaired hepatic function. HIGH RISK GROUP: 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. Nursing Mothers: Metoprolol is excreted in breast milk in very small quantities. Caution should be exercised when METOPROL-XL is administered to a nursing woman. Pediatric Use: No clinically relevant differences in the adverse event profile were observed for pediatric patients aged 6 to 16 years as compared with adult patients. Safety and effectiveness of METOPROL-XL have not been established in patients < 6 years of age. Geriatric Use: There were no notable differences in efficacy or the rate of adverse events between older and younger patients.

DRUG INTERACTION: Catecholamine-depleting drugs (e.g. Reserpine, Monoamine Oxidase (MAO) inhibitors) may have an additive effect when given with beta-blocking agents. Drugs that inhibit CYP2D6 such as quinidine, fluoxetine, paroxetine and propafenone are likely to increase Metoprolol concentration. These increases in plasma concentration would decrease the cardioselectivity of Metoprolol. Concomitant use of digitalis glycosides and beta-blockers can increase the risk of bradycardia. Beta-blockers may exacerbate the rebound hypertension which can follow the withdrawal of clonidine.

PHARMACEUTICAL PRECAUTIONS: Store in cool dry place & away from children.

PRESENTATION: Box containing 5 blister strips of 10's tablets. Metoprolol XL 50: Each tablet contains Metoprolol Succinate 50 mg Extended Release Tablet. Metoprolol XL 100: Each tablet contains Metoprolol Succinate 100 mg Extended Release Tablet.