Betaloc-XR

Metoprolol Succinate USP

Composition : Betaloc-XR-50 : Each extended release tablet contains Metoprolol Succinate USP 47.5mg (eqv. to Metoprolol Tartrate 50mg).
Betaloc-XR-100 : Each extended release tablet contains Metoprolol Succinate USP 95mg (eqv. to Metoprolol Tartrate 100mg).

Pharmacology : (Metoprolol Succinate) is a beta $_1$-selective (cardioselective) adrenoceptor blocking agent. For oral administration, available as extended release form provides a controlled and predictable release of Metoprolol for once-daily administration. Each tablet is designed to deliver Metoprolol continuously over the dosage interval. Absorption of Metoprolol is rapid and complete. Elimination is mainly by biotransformation in the liver, and the plasma half-life ranges from approximately 3 to 7 hours. Less than 5% of an oral dose of Metoprolol is recovered unchanged in the urine.

Indications : Hypertension : Extended release Metoprolol Succinate tablet is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

Angina Pectoris : Extended release Metoprolol Succinate tablet is indicated in the long-term treatment of angina pectoris.

Heart Failure : Betaloc-XR Tablet is indicated for the treatment of stable, symptomatic (NYHA Class II or III) heart failure of ischemic, hypertensive, or cardiomyopathic origin.

Dosage and administration : Hypertension : The usual initial dosage is 25 to 100mg daily in a single dose, whether used alone or added to a diuretic.

Angina Pectoris : The dosage of extended release Metoprolol Succinate should be individualized. The usual initial dosage is 100mg daily, in a single dose.

Heart Failure : The recommended starting dose of **Betaloc-XR** is 25mg once daily for two weeks in patients with NYHA class II heart failure and 12.5mg once daily in patients with more severe heart failure. The dosage may be increased at weekly (or longer) intervals until optimum blood pressure reduction is achieved. If treatment is to be discontinued, the dosage should be reduced gradually over a period of (1-2 weeks). Or, as directed by the registered physician.

Contraindications : Extended release Metoprolol Succinate is contraindicated in severe bradycardia, heart block greater than first degree, cardiogenic shock decompensated cardiac failure, sick sinus syndrome and in patients who are hypersensitive to any component of this product.

Precautions : Extended release Metoprolol Succinate should be used with caution in patients with impaired hepatic function.

Side effects : Most adverse effects have been mild and transient. The following adverse reactions have been reported for Metoprolol Succinate : tiredness, dizziness, depression, headache, somnolence, nightmares, insomnia, palpitations, dyspnea, nausea, dry mouth, constipation, psoriasis has also been reported.

Use in pregnancy and lactation : There are no adequate and well-controlled studies in pregnant women. Metoprolol is excreted in breast milk in a very small quantities. Caution should be exercised when extended release Metoprolol Succinate is administered to a nursing woman.

Use in Child : There is no data available.

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

Overdose : Overdose can induce an increased heart rate, dizziness and vomiting.

Storage : Store below 30 °C in a dry place.

Packing : Betaloc-XR-50 : Each box contains 10 x 10's tablets in blister pack.
Betaloc-XR-100 : Each box contains 5 x 10's tablets in blister pack.

Manufactured by
DRUG INTERNATIONAL LTD.
Tongi, Gazipur, Bangladesh

05/2023/Nil