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

Abridged Prescribing Information

METOPROLOL SUCCINATE PROLONGED RELEASE TABLETS IP
Metosan™ XR 12.5, 25, 50, 100mg

COMPOSITION
Metosan XR 12.5mg: Each tablet contains 11.875mg Metoprolol succinate IP equivalent to 12.5mg Metoprolol tartrate;
Metosan XR 25mg: Each tablet contains: 23.75mg Metoprolol succinate IP equivalent to 25mg Metoprolol tartrate;
Metosan XR 50mg : Each tablet contains: 47.5 mg Metoprolol succinate IP equivalent to 50mg Metoprolol tartrate;
Metosan XR 100mg: Each tablet: 95 mg Metoprolol succinate IP equivalent to 100mg Metoprolol tartrate

THERAPEUTIC INDICATION
For the treatment of hypertension alone or in combination. For the management of angina pectoris. For the treatment of stable, symptomatic (NYHA Class II or III) heart failure of ischemic, hypertensive or cardiomyopathic origin in patients receiving ACE inhibitors, diuretics and digitalis.

DOSAGE & ADMINISTRATION
Dosage & Administration: Administer once daily. Dosing should be individualized. For adult use.
Hypertension*:** Usual initial dosage is 25 to 100mg once daily. Dosage may be increased at weekly (or longer) intervals until optimum blood pressure reduction is achieved. Dosage above 400mg per day have not been studied. ***Angina Pectoris: The usual initial dosage is 100mg daily given in a single dose. ***Heart Failure:*** Recommended starting dose is 12.5mg or 25mg doubled every two weeks to the highest tolerated dose or upto 200mg.

SAFETY RELATED INFORMATION
Contraindications: 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 & 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 a high-dose regimen of prolonged 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. Patients with hepatic impairment. Thyrotoxicosis: Abrupt withdrawal in patients with thyrotoxicosis may precipitate a thyroid storm. Anaphylactic Reaction: Patients may be unresponsive to the usual doses of epinephrine used to treat allergic reaction. Peripheral Vascular Disease: Can aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease. Calcium Channel Blocker: 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.
Pregnancy*:* Should not be used during pregnancy only if clearly needed. **Lactation:** Consider possible infant exposure when Metosan XR is administered to a nursing woman.
Adverse Reactions: The most common adverse reactions are tiredness, dizziness, depression, shortness of breath, bradycardia, hypotension, diarrhoea, pruritus and rash.

For full prescribing information please contact: Sanofi India Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai 400072.

Source: Toprol (AstraZeneca) US Prescribing Information dated May 2014 and Seloken (AstraZeneca) India Prescribing Information dated July 2008. **Updated:** April 2016