

PRESCRIBING INFORMATION

Slow Trasicor Tablets 160mg (oxprenolol hydrochloride)

Presentation: Contains 160mg oxprenolol hydrochloride in a sustained-release tablet

Indication: Hypertension and angina pectoris (long-term prophylaxis)

Dosage and administration: Oral tablets to be swallowed whole.

Adults: Hypertension: 160mg once daily. If necessary, the dosage can be raised to 320mg. Angina pectoris: 160mg once daily. If necessary, the dosage can be raised to 320mg. *Elderly:* No special dosage regimen is necessary but concurrent hepatic insufficiency should be taken into account. *Children:* Not recommended.

Contraindications: Hypersensitivity to oxprenolol and related derivatives, cross-sensitivity to other beta-blockers or to any of the excipients, cardiogenic shock, second or third degree atrioventricular block, uncontrolled heart failure, sick-sinus syndrome, bradycardia, hypotension, untreated phaeochromocytoma, severe peripheral arterial circulatory disturbances, history of bronchospasm and bronchial asthma, Prinzmetal's angina, use of anaesthetics which are known to have a negative inotropic effect, and metabolic acidosis.

Precautions and warnings: Use with caution in patients with chronic obstructive lung disease, first degree AV block, peripheral circulatory disorders, liver cirrhosis, severe renal failure, diabetes, hyperthyroidism, and ischaemic heart disease. Beta-blockers should not be used in patients with untreated congestive heart failure. The dosage should be reduced or gradually withdrawn if the patient develops increasing bradycardia less than 50-55 beats per minute at rest and the patient experiences symptoms related to bradycardia. In patients with phaeochromocytoma a beta-blocker should only be given together with an alpha-blocker. Owing to the

danger of cardiac arrest, a calcium antagonist of the verapamil type must not be administered intravenously to patients already receiving treatment with a beta-blocker. Beta-blockers should be discontinued in patients who are at increased risk for anaphylaxis.

Interactions: Verapamil, diltiazem, disopyramide, quinidine, amiodarone, adrenaline, noradrenaline, isoprenaline, ephedrine, phenylephrine, clonidine, guanethidine, reserpine, oral antidiabetic drugs, NSAIDs, cimetidine, ergot alkaloids, anaesthetics, digitalis glycosides, lidocaine and alcohol.

Pregnancy and lactation: Use with caution during pregnancy especially in the first 3 months. Breast feeding is not recommended.

Undesirable effects: *Very Common:* Dry mouth, constipation. *Common:* Fatigue, dizziness, headache, mental depression, hypotension, heart failure, peripheral vascular disorders, nausea, dyspnoea, bronchoconstriction, disturbances of libido and potency.

(Please refer to the Summary of Product Characteristics for detailed information)

Overdose: Symptoms may include pronounced hypotension, bradycardia, hypoglycaemia, heart failure, cardiogenic shock, conduction abnormalities or even cardiac arrest. Patients who are seen soon after potentially life-threatening overdosage (within 4 hours) should be treated by gastric lavage and activated charcoal.

Legal category: POM

Basic NHS cost: £7.96 for pack size of 28 tablets

Marketing Authorisation Number: PL 20072/0017

Marketing Authorisation Holder: Amdipharm Mercury Company Limited (AMCo), 1st Floor, Capital House, 85 King William Street, London, EC4N 7BL.

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Adverse events should be reported to the local regulatory authority.

Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard**

Adverse events should also be reported to **Amdipharm Mercury Medical Information**

at **08700 70 30 33** or via e-mail to **medicalinformation@amcolimited.com**