

COMPOSITION

Anril™ SR Tablet: Each sustained release tablet contains Nitroglycerin USP 2.6 mg.

PHARMACOLOGY

The principal pharmacological action of Nitroglycerin is relaxation of vascular smooth muscle, and consequent dilatation of peripheral arteries and veins, especially the later. Dilatation of the veins promotes peripheral pooling of blood and decreases venous return to the heart, thereby reducing left ventricular end diastolic pressure and pulmonary capillary wedge pressure (preload). Arteriolar relaxation reduces systemic vascular resistance, systolic arterial pressure, and mean arterial pressure (afterload). Dilatation of the coronary arteries also occurs.

INDICATION

The prophylaxis of chronic stable angina pectoris.

DOSAGE AND ADMINISTRATION

Dosage should be adjusted to the requirements of the individual patient but will usually be 1 or 2 tablets taken three times daily. The lowest effective dose should be used.

CONTRAINDICATION AND PRECAUTION

Sublingual Nitroglycerin therapy is contraindicated in patients with early myocardial infarction, severe anemia, increased intracranial pressure and those with a known hypersensitivity to Nitroglycerin.

Nitroglycerin should not be used in patients with marked anaemia, head trauma, cerebral haemorrhage, closed angle glaucoma, known hypersensitivity to nitrates, hypotensive conditions, hypovolaemia, hypertrophic obstructive cardiomyopathy, aortic/mitral stenosis, cardiac tamponade, constrictive pericarditis & orthostatic dysfunction. Administration of Nitroglycerin is contraindicated in patients who are using sildenafil citrate since sildenafil citrate has been shown to potentiate the hypotensive effects of organic nitrates.

SIDE EFFECT

Side effects include facial flushing, headache, dizziness and postural hypotension which may be associated with reflex tachycardia or paradoxical bradycardia.

OVERDOSE

In the event of accidental or deliberate overdosage toxic effects of Nitroglycerin include vomiting, restlessness, hypotension, cyanosis, methaemoglobinaemia, tachycardia and syncope. Patients should receive gastric aspiration and lavage and be given respiratory and circulatory support.

PRECAUTION

Only the smallest dose required for effective control of the acute anginal attack should be used. Excessive use may lead to the development of tolerance. This drug should be used with caution in patients who may be volume-depleted or are already hypotensive.

DRUG INTERACTION

Patients receiving antihypertensive drugs, beta-adrenergic blockers or phenothiazines and nitrates should be observed for possible additive hypotensive effects. Marked orthostatic hypotension has been reported when calcium channel blockers and organic nitrates were used concomitantly. Concomitant use of nitrates and alcohol may cause hypotension. The vasodilatory and hemodynamic effects of Nitroglycerin may be enhanced by concomitant administration of aspirin. Patients receiving sublingual Nitroglycerin should avoid ergotamine and related drugs or be monitored for symptoms of ergotism if this is not possible.

USE IN PREGNANCY AND LACTATION

There is no evidence relating to the safety of nitrates in pregnancy and lactation. Nitrates should not be administered to pregnant women and nursing mothers unless considered essential by the physician. It is not known whether Nitroglycerin is excreted in human milk.

PEDIATRIC USE

Not recommended.

STORAGE CONDITION

Store below 30° C, protect from light and moisture. Keep out of reach of children.

HOW SUPPLIED

Anril™ SR Tablet: Box containing 50 Sustained Release tablets in blister pack.

Manufactured by

