

# Anril<sup>®</sup> SR

Nitroglycerin USP

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## COMPOSITION

Anril<sup>®</sup> 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 latter. 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. The relative importance of preload reduction, afterload reduction, and coronary dilatation remains undefined. Dosing regimens for most chronically used drugs are designed to provide plasma concentrations that are continuously greater than a minimally effective concentration. This strategy is inappropriate for organic nitrates. Several well-controlled clinical trials have used exercise testing to assess the antianginal efficacy of continuously-delivered nitrates. In the large majority of these trials, active agents were indistinguishable from placebo after 24 hours (or less) of continuous therapy. Attempts to overcome nitrate tolerance by dose escalation, even to doses far in excess of those used acutely, have consistently failed. Only after nitrates had been absent from the body for several hours was their antianginal efficacy restored.

## INDICATION

The prophylaxis of chronic stable angina pectoris.

## DOSAGE AND ADMINISTRATION

Adults and Elderly Patients: 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.

## CONTRAINDICATIONS AND PRECAUTION

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.

Sildenafil has been shown to potentiate the hypotensive effects of nitrates, and its co-administration with nitrates or nitric oxide donors is therefore contraindicated.

### **SIDE EFFECTS**

Side-effects include facial flushing, headache, dizziness and postural hypotension which may be associated with reflex tachycardia or paradoxical bradycardia. Toxic effects of Nitroglycerin include vomiting, restlessness, cyanosis, methaemoglobinaemia and syncope.

### **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.

### **DRUG INTERACTIONS**

Nitroglycerin may enhance the effects of peripheral vasodilators. The hypotensive effects of nitrates are potentiated by concurrent administration of sildenafil.

### **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.

### **PEDIATRIC USE**

Not recommended.

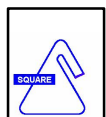
### **STORAGE CONDITION**

Store in a cool and dry place. Protect from light and moisture.

### **HOW SUPPLIED**

Anril® SR Tablet: Box containing 3X10 Sustained Release tablets in Alu-Alu blister pack.

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PHARMACEUTICALS LTD.  
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