GTN 2.6® SR

Nitroglycerin Sustained Release Tablet

DESCRIPTION

GTN 2.6®SR is a sustained release tablet preparation of nitroglycerin 2.6 mg. It is a potent coronary vasodilator. 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 relaxations reduce 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.

INDICATIONS

1. The prophylaxis of chronic stable angina pectoris.
2. Supplementary treatment of heart failure refractory to digitalis and diuretic treatment.

DOSAGE AND ADMINISTRATION

For adults and elderly patients: 1 tablet twice a day before meal (e.g. at 8 AM & 2 PM, with a daily nitrate-free interval of 10-12 hours). If necessary, the dosage may be raised gradually to 2 or 3 tablets twice daily. But dosage should be individualized depending on the nitroglycerin sensitivity of the patient, the severity of the illness and the occurrence of side effects. **GTN 2.6®SR** tablets are recommended for oral administration. For children: Not recommended.

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 temponade, 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 registered physician.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

GTN 2.6®SR Tablet :

Box containing 5 strips of 10 tablets each. Each sustained release tablet contains diluted Nitroglycerin USP equivalent to Nitroglycerin 2.6 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH

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