

Nitrosco[®] SR

Capsules* نائٹروسکات ایس آر کپسولز

COMPOSITION: *Each capsule contains:*

Nitroglycerine SR Pellets eq. to Nitroglycerine USP.....2.6 & 6.4 mg, respectively.

DESCRIPTION: Nitroglycerine an organic nitrate is a potent coronary vasodilator. The chemical name of Nitroglycerine is propane-1, 2, 3-triol trinitrate and the chemical formula is $C_3H_5(NO_3)_3$. Nitroglycerine has a molecular weight of 227.10.

PHARMACOLOGY: *Pharmacodynamics:* The principal pharmacological action of Nitroglycerine 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 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 (after load). Dilatation of the coronary arteries also occurs. *Pharmacokinetics:* Following oral administration Nitroglycerine is rapidly metabolized to glyceryl 1, 2 dinitrate and glyceryl 1, 3 dinitrate. Although less potent the metabolites probably provide the predominant pharmacological effect. Studies with Nitroglycerine 2.6mg and 6.4mg demonstrate a t_{max} for both metabolites of approximately 1 hour and an apparent $t_{1/2}$ of approximately 2 hours. There is evidence of activity extending over 6 hours or more.

INDICATIONS: NITROSCOT SR is indicated for:

- The prophylaxis of angina pectoris.
- Prevention and treatment of effort and vasospastic angina.
- Supplementary treatment of heart failure refractory to digitalis and diuretic treatment.

CONTRAINDICATIONS: Nitroglycerine should not be used in patients with marked anaemia, head trauma, cerebral haemorrhage or incipient glaucoma. Sildenafil has been shown to potentiate the hypotensive effects of nitrates, and its co-administration with nitrates or nitric oxide donors is therefore contraindicated.

POSSIBLE ADVERSE EFFECTS: Adverse effects include facial flushing and headache. Toxic effects of Nitroglycerine include vomiting, restlessness, cyanosis, methaemoglobinaemia and syncope. They disappear on dosage reduction and usually do not necessitate the discontinuation of the treatment. Regular use of Nitroglycerine (3 times a day) should be avoided because of the development of tolerance. 2 times daily administration and withdrawal for a short period may reestablish the original sensitivity.

DRUG INTERACTIONS: Nitroglycerine may enhance the effects of peripheral vasodilators. The hypotensive effects of nitrates are potentiated by concurrent administration of sildenafil.

WARNINGS: Withdrawal: As with other drugs for the treatment of angina pectoris, abrupt discontinuation of therapy may lead to exacerbation of symptoms. When discontinuing long term treatment, the dosage should be reduced gradually over several days, and the patient carefully monitored. **Pregnancy & 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:** Nitroglycerine is not recommended for use in children.

DOSAGE & ADMINISTRATION: NITROSCOT SR Capsules are not for sublingual administration. **Usual Dosage:** 1 capsule of NITROSCOT SR 2 times a day before meals (in the morning and evening). If necessary the doses may be raised gradually to 2 or 3 capsules 2 times daily. After a 1 or 2 week period of NITROSCOT SR administration a nitrate-free interval (few days) should be inserted in the treatment of cardiac insufficiency. **Children:** Not recommended.

SPECIAL INSTRUCTIONS TO THE PHYSICIAN: Overdosage: In the event of accidental or deliberate overdosage toxic effects of glyceryl trinitrate includes vomiting, restlessness, cyanosis, methaemoglobinaemia, tachycardia and syncope. Patients should receive gastric aspiration and lavage and be given respiratory and circulatory support. The physician should be aware that capsules in the intestine will release their content over several hours.

STORAGE/PRECAUTIONS: Store in a cool, dry and dark place between 15-30 °C. Keep all medicines out of the children's reach.

PRESENTATION: NITROSCOT SR 2.6 & 6.4 mg capsules are available in packing containing 30 capsules, respectively.

*Scotmann Specs.

عمومی خوراک: نائٹروسکاٹ ایس آر (نائٹروگلیسرین 2.6 اور 6.4 ملی گرام) کپسولز مریض کی ضرورت اور اثر کے مطابق کم سے کم موثر مقدار میں استعمال کروانے چاہئیں۔ نائٹروسکاٹ ایس آر (نائٹروگلیسرین 2.6 اور 6.4 ملی گرام) 1 کپسول دن میں 2 مرتبہ (صبح اور شام) جسے ضرورت پڑنے پر بتدریج 2 یا 3 کپسولز دن میں 2 مرتبہ تک بڑھایا جاسکتا ہے یا ڈاکٹر کی ہدایت کے مطابق۔

احتیاط: روشنی، نمی اور گرمی سے بچائیں۔ 15 سے 30 ڈگری سینٹی گریڈ کے درمیان محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Complete Medical Information available only for doctors on request.



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