Prescribing Information For Use by Registered Medical Practitioner or Hospital or Laboratory Only

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Nitroglycerin Sublingual Tablets USP 0.5 mg.

COMPOSITION:
Each uncoated tablet contains:
Diluted nitroglycerin USP
equivalent to Nitroglycerin 0.5 mg

ATC Code: C01DA02

PHARMACEUTICAL FORM:
Oral Sublingual Tablets

DESCRIPTION:
White round shaped flat uncoated tablets with bevelled edges.

Pharmacodynamics:
Nitroglycerin is one of a group of medicines called nitrate vasodilators. These medicines work by relaxing the muscle layer in the blood vessel wall of the heart. This reduces the strain on the heart by making it easier to pump blood.
Nitroglycerin has a double action in the treatment of angina pectoris, by reducing cardiac output and dilation of the coronary arteries.

Pharmacokinetics:
Nitroglycerin is readily absorbed from the oral mucosa, but rapidly metabolised so that it only has a fleeting duration of action.
Nitroglycerin is also readily absorbed from the gastrointestinal tract, but owing to the extensive first-pass metabolism in the liver, its bioavailability is reduced (short plasma half-life).
Nitroglycerin is metabolised by hydrolysis to dinitrates and the mononitrate, which is the main urinary metabolite.
The effects of Nitroglycerin occur in approximately 2-3 minutes and its action lasts for about 30-60 minutes.

INDICATION:
As a short-acting vasodilator in the prophylaxis and continued treatment of:
1) Angina pectoris
2) Congestive heart failure

RECOMMENDED DOSAGE:
1-2 tablets (0.5-1.0mg) should be placed under the tongue and allowed to dissolve slowly; this dose should be repeated as required. Local burning or tingling sensation may occur.
Dosage should be adjusted according to the response obtained by the individual patient and the severity of the anginal pain.

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Tolerance may develop with daily use, but withdrawal for a week re-establishes the original sensitivity.
Discard remaining tablets after 8 weeks of opening of bottle, if unused.

ROUTE OF ADMINISTRATION:
Oral-Sublingual

CONTRAINDICATIONS:
Nitroglycerin should not be used in patients with marked anaemia, head trauma, cerebral haemorrhage or closed angle glaucoma.
Nitroglycerin is also contraindicated in patients with coronary thrombosis or in those who are sensitive to nitrates.
Sildenafil has been shown to potentiate the hypotensive effects of nitrates, and its co-administration with nitrates or nitric oxide donors is therefore contraindicated.

WARNINGS AND PRECAUTIONS:
Development of tolerance may occur with all forms of nitrate therapy particularly with the long acting preparations that maintain continuously high plasma nitrate concentration.
Not recommended for phenyketonuric due to the substance aspartame.

INTERACTIONS WITH OTHER MEDICAMENTS:
Some effects of Nitroglycerin are enhanced by

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alcohol. The hypotensive effects of nitrates are potentiated by concurrent administration of sildenafil.

Pregnancy and Lactation:
There is no, or inadequate, evidence of safety of nitrates in human pregnancy or lactation; nitrates should not be administered in pregnancy or lactation unless considered essential.

Side Effects:
Side-effects are predominantly headache and facial flushing. Other side-effects include dizziness, weakness and tachycardia.

Symptoms and Treatment of Overdose:
Toxic effects of Nitroglycerin include vomiting, restlessness, hypotension, syncope, cyanosis and methaemoglobinaemia; coldness of the skin, impairment of respiration, bradycardia and psychosis may ensue.
Overdosage should be treated with gastric aspiration and lavage, plus attention to any respiratory and circulatory symptoms. Oxygen may prove additionally useful.
Effects of hypotension may be minimized by treating the patient in the recumbent position with the head lowered. Methaemoglobinaemia may be treated with methylene blue intravenously 1-4mg/kg body-weight.
The circulation may be maintained with infusions of plasma or suitable electrolyte solutions.

Effects on Ability to Drive and Use Machine:
As nitroglycerin can cause dizziness patients should make sure they are not affected before driving or operating machinery. This effect appears to be accentuated by alcohol.

STORAGE CONDITIONS:
Store below 30°C, protected from light and moisture. Tablets should be stored in the original container which should be kept tightly closed.

SHELF LIFE: 3 years
Tablets should be stored in the original container which should be kept tightly closed and using tablets within 8 weeks after opening of a bottle and discard remaining tablets after 8 weeks of opening of bottle if unused.

PACK SIZE:
30 Tablets are packed in 3mL Fiolax amber colored glass bottle closed with Screw Cap. 5 Bottles are placed in Tray in a carton along with package insert (30s x 5), or 10 such cartons placed in outer carton (30s x 5 x 10s).

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