Anril® Spray

Nitroglycerin

Antianginal

PRESENTATION

Anril® Spray: Each metered dose sublingual spray contains 400 micrograms of Nitroglycerin USP.

DESCRIPTION

Nitroglycerin, an organic nitrate, is a vasodilator which has effects on both arteries and veins. **Anril® Spray** is a metered dose spray containing nitroglycerin. This product delivers nitroglycerin (400 mcg per spray, 200 metered sprays) in the form of spray droplets under the tongue.

CLINICAL PHARMACOLOGY

The principal pharmacological action of nitroglycerin is relaxation of vascular smooth muscle, producing a vasodilator effect on both peripheral arteries and veins with more prominent effects on the latter. Dilation of the post-capillary vessels, including large veins, promotes peripheral pooling of blood and decreases venous return to the heart, thereby reducing left ventricular end-diastolic pressure (pre-load). Arteriolar relaxation reduces systemic vascular resistance and arterial pressure (after-load).

INDICATIONS AND USES

Anril® Spray is indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease.

DOSAGE & ADMINISTRATION

At the onset of an attack, 1 or 2 metered sprays should be administered under the tongue. No more than 3 metered sprays are recommended within a 15-minute period. If the chest pain persists, prompt medical attention is recommended. **Anril® Spray** may be used prophylactically 5 to 10 minutes prior to engaging in activities which might precipitate an acute attack.

CONTRAINDICATIONS

Hypersensitivity to nitrates or any constituents of the formulation. Hypotension, hypovolaemia, severe anaemia, cerebral haemorrhage and brain trauma, mitral stenosis and angina caused by hypertrophic obstructive cardiomyopathy. Concomitant administration of phosphodiesterase inhibitors used for the treatment of erectile dysfunction.

SIDE EFFECTS

A number of nitrate related adverse effects may occur including headache, facial flushing, dizziness, nausea, vomiting, feelings of weakness, postural hypotension and reflex tachycardia .

PRECAUTION & WARNING

The use of Nitroglycerin during the early days of acute myocardial infarction requires particular attention to monitoring hemodynamics and clinical status. Nitroglycerin should be used with caution in patients with severely impaired renal or hepatic function, hypothyroidism, malnutrition or hypothermia.

USE IN PREGNANCY AND LACTATION

Pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Nitroglycerin should be given to pregnant women only if clearly needed.

Nursing Mothers: It is not known whether nitroglycerin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Nitroglycerin spray is administered to a nursing woman.

PEDIATRIC USE

Safety and effectiveness of nitroglycerin in pediatric patients have not been established.

DRUG INTERACTION

Use of alcohol with Nitroglycerin may produce severe hypotension and collapse. Oral Nitroglycerin may enhance the bioavailability of dihydroergotamine. Orthostatic hypotension may occur with the combined use of calcium channel blocker, phenothiazines and tricyclic antidepressants.

OVERDOSAGE

Nitrate overdosage may result in: severe hypotension, persistent throbbing headache, vertigo, palpitation, visual disturbance, flushing and perspiring skin (later becoming cold and cyanotic), nausea and vomiting (possibly with colic and even bloody diarrhea), syncope (especially in the upright posture), methemoglobinemia with cyanosis and anorexia, initial hyperpnea, dyspnea and slow breathing, slow pulse, heart block, increased intracranial pressure with cerebral symptoms of confusion and moderate fever, paralysis and coma followed by clonic convulsions and possibly death due to circulatory collapse.

Methemoglobinemia: Case reports of clinically significant methemoglobinemia are rare at conventional doses of organic nitrates. The formation of methemoglobin is dose-related and in the case of genetic abnormalities of hemoglobin that favor methemoglobin formation, even conventional doses of organic nitrates could produce harmful concentrations of methemoglobin.

Treatment of Overdosage: Keep the patient recumbent in a shock position and comfortably warm. Passive movement of the extremities may aid venous return. Administer oxygen and artificial ventilation, if necessary. If methemoglobinemia is present, administration of methylene blue (1% solution), 1-2 mg per kilogram of body weight intravenously, may be required. If an excessive quantity of Nitroglycerin spray has been recently swallowed, gastric lavage may be of use.

STORAGE CONDITION

Store below 25^0C. Protect from light and moisture. Keep away from the reach of children.

HOW SUPPLIED

Anril® Spray: Each box contains one can of nitroglycerin sublingual spray, which will deliver 200 metered sprays containing 400 micrograms of nitroglycerin per spray after priming.

SPECIAL INSTRUCTIONS

1. It is important to carry **Anril® Spray** (Nitroglycerin) at all times
   (We recommend keeping a second supply at home on bedside table or wherever it can be reached easily)
2. This drug is not for routine use. It is only to be used at the onset of chest pain
3. Do not drink alcoholic beverages after taking this medication
4. Keep in a safe place away from children
5. DO NOT take sildenafil, vardenafil or tadalafil while using any nitroglycerin product. Using these drugs together can result in severe lowering of blood pressure, loss of consciousness, heart attack or death

HOW TO USE ANRIL® SPRAY

1. Sit down if possible as soon as an attack of angina coming on
2. Remove the plastic cap, do not shake the container
3. Hold the container upright with forefinger on top of the white button
4. Open the mouth and bring the container as close to it as possible, aiming it under the tongue
5. Press the button firmly with the forefinger to release the spray under the tongue
6. Release button and close mouth. Avoid swallowing immediately after administering the spray. The medication should not be expectorated or the mouth rinsed for 5 to 10 minutes following administration
7. If require a second administration to obtain relief, repeat steps 4, 5, and 6
8. Replace the plastic cap

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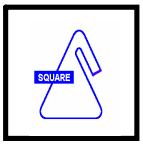

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