

Anril®

Nitroglycerin injection

COMPOSITION

Anril® Injection: Each ampoule contains 10 ml injection having Nitroglycerin USP 5 mg/ml.

PHARMACOLOGY

The principal pharmacological action of nitroglycerin is relaxation of vascular smooth muscle and consequent dilatation of peripheral arteries and veins. 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 (after load). Dilatation of the coronary arteries also occurs.

INDICATION AND USAGE

Nitroglycerin Injection is indicated for the treatment of peri-operative hypertension; for controlling of congestive heart failure in the setting of acute myocardial infarction; for treatment of angina pectoris in patients who have not responded to sublingual nitroglycerin and beta blockers and for induction of Intraoperative hypotension.

DOSAGE AND ADMINISTRATION

NOT FOR DIRECT INTRAVENOUS INJECTION

Nitroglycerin injection is a concentrated, potent drug which must be diluted in dextrose (5%) injection or sodium chloride (0.9%) injection prior to its infusion. Nitroglycerin injection should not be mixed with other drugs.

1. **Initial Dilution:** Aseptically transfer the contents of one nitroglycerin ampoule (containing 50 mg of nitroglycerin) into a 500 ml glass bottle of either Dextrose (5%) Injection or Sodium Chloride Injection (0.9%). This yields a final concentration of 100mcg/ml.

2. **Maintenance Dilution:** It is important to consider the fluid requirements of the patient as well as the expected duration of infusion in selecting the appropriate dilution of Nitroglycerin Injection. After the initial dosage titration, the concentration of the solution may be increased, if necessary, to limit fluids given to the patient. The nitroglycerin concentration should not exceed 400 mcg / ml.

CONTRA-INDICATIONS

Allergic reactions to organic nitrates are extremely rare, but they do occur. Nitroglycerin Injection is contraindicated in patients who are allergic to it. In patients with pericardial tamponade, restrictive cardiomyopathy, or constrictive pericarditis, cardiac output is dependent upon venous return. Intravenous nitroglycerin is contraindicated in patients with these conditions.

USE IN PREGNANCY AND LACTATION

Pregnancy category C. 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 injection is administered to a nursing mother.

PEDIATRIC USE

Safety and effectiveness in children have not been established.

ADVERSE EFFECTS

Adverse reactions to nitroglycerin are generally dose-related and almost all of these reactions are the result of nitroglycerin's activity as a vasodilator. Headache, which may be severe, is the most commonly reported side effect. Headache may be recurrent with each daily dose, especially at higher doses. Transient episodes of lightheadedness, occasionally related to blood pressure changes, may also occur. Hypotension occurs infrequently, but in some patients it may be severe enough to warrant discontinuation of therapy. Syncope, crescendo angina, and rebound hypertension have been reported but are uncommon. Extremely rarely, ordinary doses of organic nitrates have caused methemoglobinemia in normal-seeming patients. Methemoglobinemia is so infrequent at these doses that further discussion of its diagnosis and treatment is deferred.

PRECAUTIONS

General: Severe hypotension and shock may occur with even small doses of nitroglycerin. This drug should therefore be used with caution in patients who may be volume depleted or who, for whatever reason, are already hypotensive. Hypotension induced by nitroglycerin may be accompanied by paradoxical bradycardia and increased angina pectoris. Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy. As tolerance to other forms of nitroglycerin develops, the effect of sublingual nitroglycerin on exercise tolerance, although still observable, is somewhat blunted. In industrial workers who have had long-term exposure to unknown (presumably high) doses of organic nitrates, tolerance clearly occurs. Chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitrates from these workers, demonstrating the existence of true physical dependence.

DRUG INTERACTIONS

The vasodilating effects of nitroglycerin may be additive with those of other vasodilators. Administration of nitroglycerin infusions through the same infusion set as blood can result in pseudoagglutination and hemolysis. More generally, nitroglycerin in 5% dextrose or sodium chloride 0.9% should not be mixed with any other medication of any kind. Intravenous nitroglycerin interferes, at least in some patients, with the anticoagulant effect of heparin. In patients receiving intravenous nitroglycerin, concomitant heparin therapy should be guided by frequent measurement of the activated partial thromboplastin time.

OVERDOSAGE

Homodynamic Effects: The ill effects of nitroglycerin overdose are generally the results of nitroglycerin's capacity to induce vasodilatation, venous pooling, reduced cardiac output, and hypotension. These hemodynamic changes may have protean manifestations, including increased intracranial pressure, with any or all of persistent throbbing headache, confusion, and moderate fever; vertigo; palpitation; visual disturbances; nausea and vomiting (possibly with colic and even bloody diarrhea); syncope (especially in the upright posture); air hunger and dyspnea, later followed by reduced ventilatory effort; diaphoresis, with the skin either flushed or cold and clammy; heart block and bradycardia; paralysis; coma; seizures; and death.

STORAGE CONDITION

Protect from light. Store below 25^o C. Keep out of the reach of the children.

HOW SUPPLIED

Anril® injection: Each pack contains 4 ampoules in blister pack.

Manufactured by :



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