Drug Interactions:
Cyclopropane and halothane anesthetics increase cardiac autonomic irritability and therefore seem to sensitize the myocardium to the action of intravenously administered epinephrine or norepinephrine. NORADRENALINE should be used with extreme caution in patients receiving monoamine oxidase inhibitors (MAOI) or antidepressants of the triptyline or imipramine types, because severe, prolonged hypertension may result.

Carcinogenesis, Mutagenesis, Impairment of Fertility:
Studies have not been performed.

Pregnancy Category C:
Animal reproduction studies have not been conducted with NORADRENALINE. It is also not known whether NORADRENALINE can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. NORADRENALINE should be given to a pregnant woman only if clearly needed.

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

Pediatric Use:
Safety and effectiveness in pediatric patients has not been established.

Geriatric Use:
NORADRENALINE infusions should not be administered into the veins in the leg in elderly patients

ADVERSE REACTIONS: The following reactions can occur:
Body as a Whole: Ischemic Injury due to potent vasoconstrictor action tissue hypoxia.

Cardiovascular System : Bradycardia, probably as a reflex result of a rise in blood pressure.arrhythmias.
Nervous SystemAnxiety. transient headache.
Respiratory System: Respiratory difficulty.
Skin and Appendages: Extravasations necrosis at injection site.

Overdosage : NORADRENALINE may result in headache, severe hypertension, reflex bradycardia, marked increase in peripheral resistance, and decreased cardiac output. In case of accidental overdosage, as evidenced by excessive blood pressure elevation, discontinue NORADRENALINE until the condition of the patient stabilizes.

DOSAGE AND ADMINISTATION: Noradrenaline Bitartrate Injection is a concentrated. potent drug which must be diluted in dextrose containing solutions prior to infusion. An infusion of NORADRENALINE should be given into a large vein (see PRECAUTIONS)
Restoration of Blood Pressure in Acute Hypotensive States: Blood volume depletion should always be corrected as fully as possible before any vasopressor is administered. When, as an emergency measure, intraaortic pressure must be maintained to prevent cerebral or coronary artery ischemia, NORADRENALINE can be administered before and concurrently with blood volume replacement.

Diluent: Norodom should be diluted in 5 percent dextrose injection or 5 percent dextrose and sodium chloride injections. These dextrose containing fluids are protection against significant loss of potency due to oxidation. Administration in saline solution alone is not recommended. Whole blood or plasma. if indicated to increase blood volume, should be administered separately (for example. by use of a Y-tube and individual containers if given simultaneously).

Fluid Intake: The degree of dilution depends on clinical fluid volume requirements. If large volumes of fluids (dextrose) are needed at a flow rate that would involve an excessive dose of the pressoragent per unit of time, a solution more dilute that 4 mcg per ml should be used. On the other hand. when large volumes of fluid are clinically undesirable. a concentration greater than 4 mg per ml may be necessary.

Duration of Therapy : The infusion should be continued until adequate blood pressure and tissue perfusion are maintained without therapy. Infusion of NORADRENALINE should be reduced gradually, avoiding abrupt withdrawal. In some of the reported cases of vascular collapse due to acutemyocardial infarction, treatment was required for up to six days.

Adjunctive Treatment in Cardiac arrest : Infusion of NORADRENALINE are usually administered intravenously during cardiac resuscitation to restore and maintain an adequate blood pressure after an effective heartbeat and ventilation have been established by other means (NORADRENALINE's powerful beta-adrenergic stimulating actions is also through to increase the strength and effectiveness of systolic contractions once they occur).

Average Dosage : To maintain systemic blood pressure during the management of cardiac arrest. NORADRENALINE is used in the same manner as described under Restoration of Blood Pressure in Acute hypotensive states.

STORAGE: Store in dry and dark place, temperature not exceeding 25°C. Do not freeze.
Improper storage may deteriorate the product.

PRESENTATION : NORADRENALINE injection I.P. 2mg/ml. is a clear colourless solution filled in amber colour glass ampoule.

Manufactured by:
AMERICAN REMEDIES©
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
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℞ Sterile Noradrenaline Concentrate IP

NOR-ADR 2 mg / ml

FOR INTRAVENOUS INFUSION AFTER DILUTION

COMPOSITION:

Each ml. contains:

Noradrenaline Bitartrate (equivalent to Noradrenaline 1 mg)	I.P	2 mg
Water for injection	I.P	q.s.

DESCRIPTION: Noradrenaline is a sympathomimetic amine which differs from adrenaline by the absence of a methyl group on the nitrogen atom. NORADRENALINE is supplied in sterile aqueous solution in the form of the bilartrate salt to be administered by intravenous infusion following dilution.

CLINICAL PHARMACOLOGY: NORADRENALINE functions as a peripheral vasoconstrictor (alpha-adrenergic action) and as an isotropic stimulator of the heart and dilator of coronary arteries (beta-adrenergic action)

INDICATIONS AND USAGE: For blood pressure control in certain acute hypotensive states (e.g. pheochromocytomectomy. sympathectomy, poliomyelitis. spinal anaesthesia. myocardial infraction, septicemia, blood transfusion and drug reactions). As an adjunct in the treatment &cardiac arrest and profound hypotension.

CONTRAINDICATIONS & DRUG INTERACTIONS: NORADRENALINE should not be given to patients who are hypotensive from blood volume deficits excepts as an emergency measure to maintain coronary and cerebral artery perfusion until blood volume replacement therapy can be completed. II NORADRENALINE is continuously administered to maintain blood pressure in the absence of blood volume replacement, the following may occur: severe peripheral and visceral vasoconstriction. decreased renal perfusion and urine output. poor systemic blood flow despite "normal" blood pressure, tissue hypoxia. and lactate acidosis.

NORADRENALINE should also not be given to patients with mesenteric or peripheral vascular thrombosis (because of the risk of increasing ischemia and extending the area of infarction) unless, in the opinion of the attending physician, the administration of NORADRENALINE is necessary as a life-saving procedure.

Cyclopropane and halothane anesthetics increase cardiac autonomic irritability and therefore seem to sensitize the myocardium to the action of intravenously administered adrenaline or noradrenaline. Hence, the use of NORADRENALINE during cyclopropane and halothane anesthesia is generally considered contraindicated because of the risk of producing ventricular tachycardia or fibrillation.

The same type of cardiac arrhythmias may result the use of NORADRENALINE in patients with profound hypoxia or hypercarbia.

WARNINGS: NORADRENALINE should be used with extreme caution in patients receiving monoamine oxidase inhibitors (MAGI) or antidepressants of the triptyline or imipramine types, because severe. prolonged hypertension may result.

PRECAUTION: Avoid Hypertension Because of the potency of NORADRENALINE and because of varying response to pressor substances, the possibility always exists that dangerously high blood pressure may be produced with overdose of this pressor agent. It is desirable, therefore. to record the blood pressure every five minutes from the time administration is started until the desired blood pressure is obtained, then every five minutes if administration is to be continued.

Site of Infusion: Whenever possible, infusions of NORADRENALINE should be given into a large vein, particularly an antecubital vein because, when administered into this vein, the risk of necrosis of the overlying skin from prolonged vasoconstriction is apparently very slight. Some authors have indicated that the femoral vein is also an acceptable route of administration. A catheter tie-in technique should be avoided, if possible, since the obstruction to blood flow around the tubing may cause stasis and increased local concentration of the drug. Occlusive vascular diseases (for example, atherosclerosis, arteriosclerosis, diabetic endarteritis, Buerger's disease) are more likely to occur in the lower than in the upper extremity. Therefore, one should avoid the veins of the leg in elderly patients or in those suffering from such disorders. Gangrene has been reported in a lower extremity when infusions of NORADRENALINE were given in an ankle vein.

Extravasation: The infusion site should be checked frequently for free flow. Care should be taken to avoid extravasation of NNORADRENALINE into the tissues, as local necrosis might ensue due to the vasoconstrictive action of the drug. Blanching along the course of the infused vein, sometimes without obvious extravasation, has been attributed to vasa vasorum constriction with increased permeability of the vein wall, permitting some leakage.

IMPORTANT - **Antidote for Extravasation Ischemia:** To prevent sloughing and necrosis in areas in which extravasation has taken place, the area should be infiltrated as soon as possible with 10 mL to 15 mL of saline solution containing from 5 mg to 10 mg **(phentolamine**), an adrenergic blocking agent.. Therefore, phentolamine should be given as soon as possible after the extravasation is noted.