

Epinephrine Injection USP

Therapeutic Category: sympathomimetic

PHARMACOLOGY: Epinephrine is a sympathomimetic drug. It activates adrenergic receptive mechanism on effector cells and imitates all actions of the sympathetic nervous system, except those on the arteries of the face and sweat glands. Epinephrine acts on both alpha and beta receptors and is the most potent alpha receptor activator.

INDICATIONS: In general, the most common uses of epinephrine are to relieve respiratory distress due to bronchospasm, to provide rapid relief of hypersensitivity reactions to drugs and other allergens, and to prolong the action of infiltration anesthetics. Its cardiac effects may be of use in restoring cardiac rhythm in cardiac arrest due to various causes, but it is not used in cardiac failure or in hemorrhagic, traumatic, or cardiogenic shock.

Epinephrine is used as a hemostatic agent. It is also used in treating mucosal congestion of hay fever, rhinitis, and acute sinusitis, to relieve bronchial asthmatic paroxysms, in syncope due to complete heart block or carotid sinus hypersensitivity, for symptomatic relief of serum sickness, urticaria, angio-neurotic edema, for resuscitation in cardiac arrest following anesthetic accidents, in simple (open angle) glaucoma, for relaxation of uterine musculature and to inhibit uterine contractions. Epinephrine Injection can be utilized to prolong the action of intraspinal and local anesthetics (see Contraindications).

CONTRAINDICATIONS: Epinephrine is contraindicated in narrow angle (congestive) glaucoma, shock, during general anesthesia with halogenated hydrocarbons or cyclopropane and in individuals with organic brain damage. Epinephrine is also contraindicated with local anesthesia of certain areas, e.g.; fingers, toes, because of the danger of vasoconstriction producing sloughing of the tissues in labor because it may delay the second stage; in cardiac dilation and coronary insufficiency.

WARNINGS: Administer with caution to elderly people, to those with cardiovascular disease, hypertension, diabetes or hyperthyroidism, in psychoneurotic individuals, and in pregnancy. Patients with long-standing bronchial asthma and emphysema who have developed degenerative heart disease should be administered the drug with extreme caution.

Overdose of inadvertent intravenous injection of epinephrine may cause cerebrovascular hemorrhage resulting from sharp rise in blood pressure.

Fatalities may also result from pulmonary edema because of the peripheral constriction and cardiac stimulation produced. Rapidly acting vasodilators such as nitrites or alpha blocking agents may counteract the marked pressor effects of epinephrine.

Epinephrine is the preferred treatment for serious allergic or other emergency situations even though this product contains sodium metabisulfite, a sulfite that may in other products because allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons. The alternatives to using epinephrine in a life-threatening situation may not be satisfactory. The presence of the sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations.

Use of epinephrine with excessive doses of digitalis, mercurial diuretics, or other drugs that sensitize the heart to arrhythmias is not recommended. Anginal pain may be induced when coronary insufficiency is present.

PRECAUTIONS: Epinephrine Injection should be protected from exposure to light. Do not use if solution is pinkish or darker than slight yellow or contains precipitate.

Epinephrine is readily destroyed by alkalies and oxidizing agents. In the latter category are oxygen, chlorine, bromine, iodine, permanganates, chromates, nitrites and salts of easily reducible metals, especially iron.

The effects of epinephrine may be potentiated by tricyclic antidepressants, certain antihistamines, e.g. diphenhydramine, tripeleminamine, d-chlorpheniramine, and sodium l-thyroxine.

Pregnancy: Epinephrine has been shown to be teratogenic in rats when given in doses about 25 times the human dose. There are no adequate and well controlled studies in pregnant women. Epinephrine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

ADVERSE EFFECTS: Transient and minor side effects of anxiety, headache, fear and palpitations often occur with therapeutic doses, especially in hyperthyroid individuals. Repeated local injections can result in necrosis at sites of injection from vascular constriction. "Epinephrine-fastness" can occur with prolonged use.

OVERDOSAGE; SYMPTOMS AND TREATMENT: Erroneous administration of large doses of epinephrine may lead to precordial distress, vomiting, headache, dyspnea, as well as unusually elevated blood pressure.

Toxic effects of overdosage can be counteracted by injection of an alpha-adrenergic blocker and a beta-adrenergic blocker. In the event of a sharp rise in blood pressure, rapid-acting vasodilators such as the nitrites or alpha-adrenergic blocking agents can be given to counteract the marked pressor effect of large doses of epinephrine.

DOSAGE AND ADMINISTRATION: Epinephrine injection is administered by the following routes: Intravenous, intracardiac (left ventricular chamber), subcutaneous or intramuscular and via endotracheal tube in the bronchial tree. Dosage is provided for Epinephrine Injection USP 1 mg/mL, with dilutions stated where appropriate.

Note: The subcutaneous is the preferred route of administration. If given intramuscularly, injection into the buttocks should be avoided, due to the possibility of poor absorption.

Hypersensitivity Reactions:

Adults: For bronchial asthma and certain allergic manifestations, e.g. angioedema, urticarias, serum sickness, anaphylactic shock, use epinephrine 0.2 to 1 mg (0.2 to 1 mL) S.C. or I.M. Subcutaneous doses may be repeated at 10 to 15 minute intervals in patients with anaphylactic shock. In patients with asthma, S.C. doses may be given at 20 minute to 4 hour intervals depending on the severity of the condition and the response of the patient. In severe anaphylactic shock, I.V. administration may be necessary since absorption of the drug may be impaired with S.C. or I.M. administration. If necessary, 0.1 to 0.25 mg of epinephrine (1 to 2.5 mL of 1:10,000 solution prepared by diluting 1 mL of 1 mg/mL solution (1:1000) with 10 mL of 0.9% sodium chloride injection) may be administered I.V. slowly (over 5 to 10 minutes) and repeated every 5 to 15 minutes as necessary. Start with small doses and increase if required.

Children: For bronchial asthma and other allergic manifestations in pediatric patients, administer 0.01 mg/kg (0.01 mL/kg) or 0.3 mg/m² (0.3 mL/m²) to a maximum of 0.5 mg (0.5 mL) S.C. Doses may be repeated at 20 minute to 4 hour intervals, depending on the severity of the condition and the response of the patient. In severe anaphylactic shock, I.V. administration may be necessary since absorption of the drug may be impaired with S.C. administration. If necessary, some clinicians recommend an initial I.V. epinephrine dose of 0.1 mg (10 mL of a 1:100,000 solution prepared by diluting 0.1 mL of a 1 mg/mL solution (1:1,000) with 10 mL of 0.9% sodium chloride injection) given over 5 to 10 minutes (the initial dose may have to be reduced in young children), followed by a continuous infusion at an initial rate of 0.1 µg/kg per minute, (to a maximum of 1.5 µg/kg per minute).

Cardiac Resuscitation: Epinephrine should be used secondary to unsuccessful attempts with physical or electromechanical methods.

Adults: A dose of 0.5 mg I.V. (range 0.1 to 1 mg, usually as 1 to 10 mL of a 1:10,000 solution), repeated every 5 minutes if needed. Adult intracardiac doses of 0.1 to 1 mg (usually as 1 to 10 mL of a 1:10,000 solution) have been recommended. External cardiac massage should follow intracardiac administration to permit the drug to enter coronary circulation.

Children: The usual pediatric I.V. dose is 0.01 mg/kg (0.1 mL/kg of 1:10,000 solution). I.V. doses may be repeated every 5 minutes if needed.

The usual neonatal I.V. dose is 0.01 to 0.03 mg/kg (0.1 to 0.3 mL/kg of a 1:10,000 solution). I.V. doses may be repeated every 5 minutes if necessary.

Endotracheal Dosage: Alternatively, as a means for advanced cardiac life support, when vascular access is hampered and patients intubated, epinephrine can be administered via the endotracheal tube directly into the bronchial tree. To aid delivery of the drug via an endotracheal tube, the dose may be diluted with 0.9% sodium chloride.

Adults: 1 mg (10 mL of a 1:10,000 solution).

Children: 0.01 mg/kg (0.1 mL/kg of a 1:10,000 solution).

Neonates: 0.01 to 0.03 mg/kg (0.1 to 0.3 mL/kg of a 1:10,000 solution).

Regional Anesthesia: A final concentration of 1:100,000 to 1:200,000 of epinephrine injection is recommended for infiltration injection, nerve block, caudal or other epidural blocks. From 0.2 to 0.4 mg of epinephrine (0.2 to 0.4 mL) may be mixed with spinal anesthetic agents (may prolong anesthetic action by limiting absorption).

AVAILABILITY: Each mL of sterile solution contains 1 mg epinephrine, 1 mg sodium metabisulfite (as antioxidant), sodium chloride (for isotonicity) and hydrochloric acid (to adjust pH). Ampoules of 1 mL boxes of 10.

STORAGE: Store at room temperature (15° to 30° C). Protect from light.

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Manufactured for :

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