

**PRESCRIBING INFORMATION
PRODUCT MONOGRAPH**

ADRENALIN*

**Adrenalin* Chloride Solution
(Epinephrine Injection U.S.P.)
(1 mg/mL)**

**Adrenalin* Chloride Injection
(Epinephrine Injection U.S.P.)
30 mg/30 mL (1 mg/mL)**

**Adrenalin* Chloride Topical Solution
(Epinephrine Nasal Solution U.S.P.)
30 mg/30 mL (1 mg/mL)**

SYMPATHOMIMETIC



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THERAPEUTIC CLASSIFICATION

Sympathomimetic

ACTION AND CLINICAL PHARMACOLOGY

Epinephrine is a sympathomimetic drug. It activates an 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 AND USAGE

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, angioneurotic 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, eg, fingers, toes, because of the danger of vasoconstriction producing sloughing of tissue; in labour because it may delay the second stage; in cardiac dilatation 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.

Overdosage or inadvertent intravenous injection of epinephrine may cause cerebrovascular hemorrhage resulting from the 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 nitrates, 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 bisulfite, a sulfite that may in other products **cause 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 a 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

ADRENALIN (epinephrine injection) should be protected from exposure to light. Do not remove from carton until ready to use. Do not use if solution is pinkish or darker than slightly yellow or contains a 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, eg. diphenhydramine, tripeleminamine, d-chlorpheniramine; and sodium L-thyroxine.

ADVERSE REACTIONS

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.

DOSAGE AND ADMINISTRATION

Intramuscularly or subcutaneously – 0.2 to 1 mL. Start with small dose and increase if required.

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

For bronchial asthma and certain allergic manifestations, eg. angioedema, urticaria, serum sickness, anaphylactic shock, use epinephrine subcutaneously. For bronchial asthma in pediatric patients, administer 0.01 mL/kg or 0.3 mL/m² to a maximum of 0.5 mL subcutaneously, repeated every four hours if required.

For cardiac resuscitation – A dose of 0.5 mL diluted to 10 mL with sodium chloride injection can be administered intravenously or intracardially to restore myocardial contractility and stimulate the heart in cases of apparent death. External cardiac massage should follow intracardial administration to permit the drug to enter coronary circulation. The drug should be used secondarily to unsuccessful attempts with physical or electromechanical methods.

Intravenously 0.1 to 0.4 mL diluted with 3 to 10 parts of Water for Injection, injected slowly.

Intraspinal use – Usual dose is 0.2 to 0.4 mL added to anesthetic spinal fluid mixture (may prolong anesthetic action by limiting absorption). For use with local anesthetic – Epinephrine

1:100,000 (0.01 mg/mL) to 1:20,000 (0.05 mg/mL) is the usual concentration employed with local anesthetics.

Ophthalmologic use (for producing conjunctival decongestion, to control hemorrhage, produce mydriasis and reduce intraocular pressure) – use concentration of 1:10,000 (0.1 mg/mL) to 1:1,000 (1 mg/mL).

Topical Nasal Solution: For topical application only as a nasal decongestant. Do not inject. Sterile until opened. Apply locally as drops or spray or with a sterile swab, as required.

Composition

C32501- Ampoules Injection: Each mL of aqueous solution 1:1000 contains: epinephrine 1 mg as the hydrochloride dissolved in isotonic sodium chloride solution with sulfites as antioxidant. Nonmedicinal ingredients: hydrochloric acid, sodium bisulfate or metabisulfite and sodium chloride. Supplied in 1mL ampoule.

C32521 -Vials: Each mL of aqueous solution 1:1000 contains: epinephrine 1 mg as the hydrochloride dissolved in isotonic sodium chloride solution with sulfites as an antioxidant and 0.5% chlorobutanol as a preservative. Nonmedicinal ingredients: chlorobutanol, hydrochloric acid, sodium bisulfite or metabisulfite and sodium chloride. (latex-free rubber stopper)

C32511-Topical: Each mL of aqueous solution 1:1000 contains: epinephrine 1 mg as the hydrochloride dissolved in isotonic sodium chloride solution. Nonmedicinal ingredients: chlorobutanol, hydrochloric acid, sodium bisulfite of metabisulfite and sodium chloride. (latex-free rubber stopper)

Stability and Storage Recommendations

Protect from light and freezing. Store at room temperature between 15 and 30°C.

AVAILABILITY OF DOSAGE FORMS

Epinephrine Injection:

Ampoules: Each 1 mL ampoule contains 1 mg epinephrine as the hydrochloride.

Vials: Each 30 mL vial contains 30 mg epinephrine as the hydrochloride (Rubber Diaphragm Capped).

Epinephrine Topical: For Topical Application Only. Do Not Inject.

Bottle: Each 30 mL bottle contains 30 mg epinephrine as the hydrochloride.

PHARMACEUTICAL INFORMATION

Drug Substance

Proper Name: Epinephrine

Chemical Name: (-)-3,4-Dihydroxy- α - [(methylamino)methyl] benzylalcohol

Empirical Formula: (Levorotatory isomer) $C_9H_{13}NO_3$

Molecular Weight: 183.20 in USP

Structural Formula:

