PRESCRIBING INFORMATION

EPINEPHRINE INJECTION

1 mg / mL
Sterile Solution
For Intramuscular (IM), Intravenous (IV), or Subcutaneous (SC) Use

Manufacturer's Standard
(Epinephrine base)
1 mg base/mL

SYMPATHOMIMETIC

Acala Pharmaceuticals Inc. (a division of
Fernbank Management Corporation)
224 King Street W, Suite 1702
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Canada

DATE OF PREPARATION: May 17, 2021

Control no.: 246228

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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.

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 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, tripelennamine, 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.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

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/m^2 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).

Composition

Each mL of aqueous solution 1:1000 contains: epinephrine 1 mg dissolved in isotonic sodium chloride solution with hydrochloric acid as dissolution agent and pH adjuster. Nonmedicinal ingredients: hydrochloric acid, and sodium chloride. Supplied as 1 mL fill in 2 mL ampoule.

Stability and Storage Recommendations

Protect from light and freezing. Store at room temperature between 15 and 25°C.

AVAILABILITY OF DOSAGE FORMS

Epinephrine Injection:

Ampoules: Each 1 mL ampoule contains 1 mg epinephrine.

If you want more information about Epinephrine Injection:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (http://hc-sc.gc.ca/index-eng.php); or by e-mailing medinfo@acalapharma.com.

PHARMACEUTICAL INFORMATION

Drug Substance

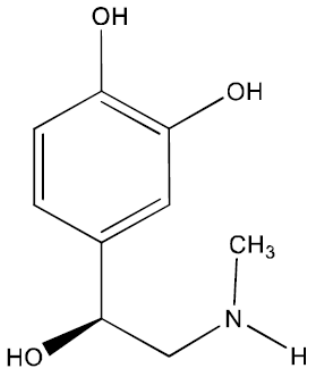
Proper Name: Epinephrine

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

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

Molecular Weight: 183.20

Structural Formula:



REFERENCES

1. Adrenaline* Chloride Injection (Epinephrine Injection U.S.P.), Solution, 1 mg/mL, Control No. 100467, Prescribing Information, Erfa Canada 2012 Inc. January 10, 2001.