

PRESCRIBING INFORMATION

Pr

ADRENALIN® TOPICAL SOLUTION

**Epinephrine Topical Solution (as epinephrine hydrochloride)
30 mg / 30 mL (1 mg/mL)**

HEMOSTATIC AGENT

For Topical Application Only

DO NOT INJECT

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PRESCRIBING INFORMATION**Pr****ADRENALIN® TOPICAL SOLUTION**

**Epinephrine Topical Solution (as epinephrine hydrochloride)
30 mg / 30 mL (1 mg/mL)**

THERAPEUTIC CLASSIFICATION

HEMOSTATIC AGENT

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.

Epinephrine when used topically can improve hemostasis and thereby improve the surgical field.

INDICATIONS AND USAGE

Epinephrine topical solution is used as a hemostatic agent in mucosal and sinus surgery. It is applied topically during procedures such as: endonasal surgeries, endodontic mini-surgeries when a reduction of local hemorrhage is indicated.

CONTRAINDICATIONS

Epinephrine topical solution is contraindicated in narrow angle (congestive) glaucoma, shock during general anesthesia with halogenated hydrocarbons or cyclopropane and in individuals with organic brain damage. Epinephrine topical solution 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

- Medication errors have been reported regarding inadvertent injection of epinephrine intended for topical use resulting in serious adverse events, including cardiac arrest and death.
- ADRENALIN® TOPICAL SOLUTION contains concentrated epinephrine 1mg/mL (1:1000).
- Care should be taken as the ADRENALIN® TOPICAL SOLUTION may be mistaken for an injectable use vial.
- To minimize the risk of inadvertent injection of a concentrated epinephrine solution, NEVER use a syringe to withdraw ADRENALIN® TOPICAL SOLUTION from the vial.
- To access the ADRENALIN® TOPICAL SOLUTION, remove the tear-off metal ferrule and rubber stopper to pour out the solution from the vial.

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® TOPICAL SOLUTION 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 alkalis 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

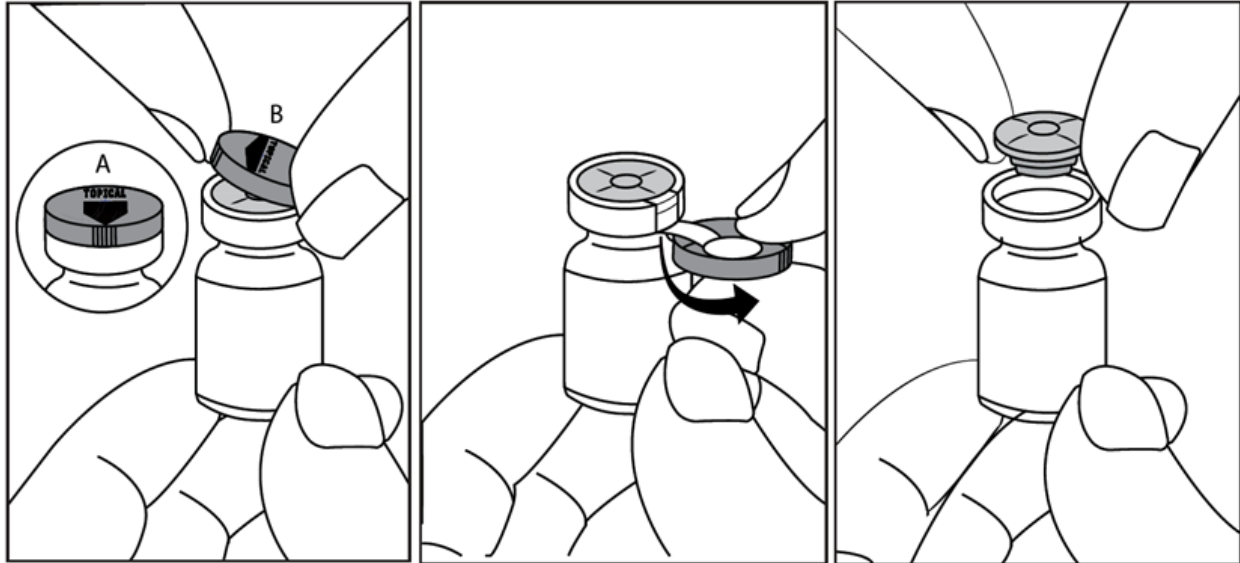
Adverse events depend on the systemic absorption of epinephrine following topical use. Systemic pressure can increase as more concentrated solution is used.

Transient and minor side effects of anxiety, headache, fear and palpitations often occur with therapeutic doses, especially in hyperthyroid individuals. “Epinephrine-fastness” can occur with prolonged use.

DOSAGE AND ADMINISTRATION

Vial opening instructions

ADRENALIN® TOPICAL SOLUTION is intended for topical use only. In order to obtain the solution, the cap of the vial should be removed completely by following the steps below:



Step 1: Lift the cap following the arrow that says “LIFT HERE”.

Step 2: Holding the cap, pull the metal ferrule back and all the way around the vial before tearing off.

Note: This is an important step and will help ensure that the rubber stopper can be removed in Step 3.

Step 3: Remove the rubber stopper to pour out the solution.

Topical administration: Apply the 1 mg / mL solution locally with a sterile swab, as required. Do not inject. Sterile until opened.

COMPOSITION

Vial: Each mL of ADRENALIN® TOPICAL SOLUTION 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. Non-medicinal ingredients: chlorobutanol, hydrochloric acid, sodium metabisulfite and sodium chloride.

STABILITY AND STORAGE RECOMMENDATIONS

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

AVAILABILITY OF DOSAGE FORMS

ADRENALIN® TOPICAL SOLUTION is for topical application only. **Do not inject.**

ADRENALIN® TOPICAL SOLUTION is available in vials of 30 mL, each containing 30 mg epinephrine as the hydrochloride. Each vial consists of a removable tear-off metal ferrule and rubber stopper, which allows for the solution to be poured out.

PHARMACEUTICAL INFORMATION**Drug Substance**

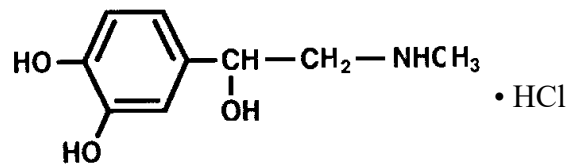
Proper Name: L-Epinephrine Hydrochloride

Chemical Name: 4-[(1L)-1-hydroxy-2-(methylamino)ethyl]benzene-1,2-diol hydrochloride

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

Molecular Weight: 219.66 g/mol

Structural Formula:



In-house revision date: OCT 6, 2022