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

Searchlight Pharma Inc. 1600 Notre-Dame West, suite 312 Montreal, QC H3J 1M1

Submission Control No: 267097

Date of Preparation: OCT 6, 2022

PRESCRIBING INFORMATION

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.

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

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

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:

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) C₉H₁₃NO₃ HCl

Molecular Weight: 219.66 g/mol

Structural Formula: