

Product Monograph
Including Patient Medication Information

ADRENALIN®

Epinephrine

Solution for injection

For Intramuscular (IM), Subcutaneous (SC), Intravenous (IV), Intraspinal, Intracardial or Ophthalmologic
use

1 mg/mL of epinephrine

30 mg/30 mL (1 mg/mL) of epinephrine

USP

Sympathomimetic

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Recent Major Label Changes

None at the time of most recent authorization.

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Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

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Part 1: Healthcare Professional Information

1. Indications

ADRENALIN® (Epinephrine Injection) is indicated:

- to relieve respiratory distress due to bronchospasm and bronchial asthmatic paroxysms;
- to restore cardiac rhythm in cardiac arrest due to various causes, cardiac resuscitation in cardiac arrest following anesthetic accidents, and in syncope due to complete heart block or carotid sinus hypersensitivity;
- to prolong the action of local and intraspinal anesthetics (see [2. Contraindications](#));
- in simple (open angle) glaucoma;
- to provide rapid relief of hypersensitivity reactions to drugs and other allergens;
- to treat mucosal congestion of hay fever, rhinitis, and acute sinusitis;
- for symptomatic relief of serum sickness, urticaria, angioneurotic edema;
- for relaxation of uterine musculature and to inhibit uterine contractions;
- as a hemostatic agent.

Epinephrine is not used in cardiac failure or in hemorrhagic traumatic, or cardiogenic shock (see [2. Contraindications](#)).

1.1. Pediatrics

Pediatrics (< 18 years): Since the pediatric data for clinical trials is not available, the safety and efficacy of ADRENALIN in pediatric patients cannot be determined. However, based on the available dosing information for bronchial asthma, ADRENALIN can be used for pediatric patients. See [4.2. Recommended Dose and Dosage Adjustment](#).

1.2. Geriatrics

Geriatrics (> 65 years): Evidence from clinical studies and experience suggests that use in the geriatric population is associated with differences in safety or effectiveness. See [7.1.4. Geriatrics](#).

2. Contraindications

ADRENALIN® is contraindicated:

- in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see [6 Dosage Forms, Strengths, Composition, and Packaging](#).
- in patients with narrow angle (congestive) glaucoma, shock during general anesthesia with halogenated hydrocarbons or cyclopropane and in individuals with organic brain damage.
- with use of local anesthesia of certain areas, e.g., fingers, toes, because of the danger of vasoconstriction producing sloughing of tissue;

- during labour because it may delay the second stage;
- in cardiac dilatation and coronary insufficiency.

4. Dosage and Administration

4.1. Dosing Considerations

Subcutaneous is the preferred route of administration. If given intramuscularly, injection into the buttocks should be avoided.

4.2. Recommended Dose and Dosage Adjustment

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

For bronchial asthma and certain allergic manifestations, e.g., 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 (0.1 to 0.4 mg) 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).

4.3. Reconstitution

Preparation for reconstitution:

Parenteral Products for Intramuscular (IM), Subcutaneous (SC) or Intravenous (IV) use:

	Volume of ADRENALIN® solution (mL)	Total epinephrine dose (mg)	Volume of Water for Injection (mL)	Total Volume (mL)	Final Concentration (mg/mL)
Min.	0.1	0.1	0.3 – 1.0	0.4 – 1.1	0.09 - 0.25

Max.	0.4	0.4	1.2 – 4.0	1.6 – 4.4	0.09 - 0.25
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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. See [11 Storage, Stability, and Disposal](#).

4.4. Administration

For Intramuscular (IM), Subcutaneous (SC), Intravenous (IV), Intracardial, Intraspinous or Ophthalmologic use.

4.5. Missed Dose

Since ADRENALIN® is administered under medical supervision, the healthcare professional will determine the dosing requirement.

5. Overdose

Overdosage or inadvertent intravenous injection of epinephrine may cause cerebrovascular hemorrhage resulting from the sharp rise in blood pressure. See [7. Warnings and Precautions, General](#).

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
Intramuscular (IM), Subcutaneous (SC), Intravenous (IV), Intracardial, Intraspinous or Ophthalmologic	Solution for Injection, 1 mg/mL; 30 mg/30 mL of Epinephrine as hydrochloride	Hydrochloric acid, sodium bisulfate or metabisulfite and sodium chloride. Vial: contains additional chlorobutanol and water for injection.

Description

Ampoule - Each 1 mL ampoule contains 1 mg epinephrine provided as a sterile single dose solution.

Each carton contains five single dose vials containing 1 mg/mL of ADRENALIN® (epinephrine injection).
Supplied as 2 cartons for a total of 10 ampoules.

Vial - Each vial of 30 mL contains 30 mg of epinephrine (1 mg/mL) provided as a sterile multidose solution in an amber glass vial. The vial stopper is made with latex-free rubber. ADRENALIN® 30 mg/mL vial contains chlorobutanol as a preservative.

7. Warnings and Precautions

General

Overdosage or inadvertent intravenous injection of epinephrine may cause cerebrovascular hemorrhage resulting from the sharp rise in blood pressure. See [5. Overdose](#).

Cardiovascular

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.

Immune

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.

Respiratory

Patients with long-standing bronchial asthma and emphysema who have developed degenerative heart disease should be administered the drug with extreme caution.

7.1. Special Populations

7.1.1. Pregnancy

Administer with caution in pregnancy.

7.1.2. Breastfeeding

This information is not available for this drug product.

7.1.3. Pediatrics

Since the pediatric data for clinical trials is not available, the safety and efficacy of ADRENALIN in pediatric patients cannot be determined. However, based on the available dosing information for bronchial asthma, ADRENALIN can be used for pediatric patients. See [1.1. Pediatrics](#), [4.2. Recommended Dose and Dosage Adjustment](#).

7.1.4. Geriatrics

Administer with caution to elderly people. See [1.2. Geriatrics](#).

8. Adverse Reactions

8.1. Adverse Reaction Overview

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.

9. Drug Interactions

9.4. Drug-Drug Interactions

The drugs listed in this table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

Table 4 – Established or Potential Drug-Drug Interactions

Non-proprietary name of the drug product	Source of evidence	Effect	Clinical comment
Tricyclic antidepressants and antihistamines, e.g., diphenhydramine, triprolidine, d-chlorpheniramine; and sodium L-thyroxine.	T	The effects of epinephrine may be potentiated	Because TCAs inhibit norepinephrine reuptake which increase synaptic NE which leads exogenous epinephrine increase leading to the adrenergic response. Patients must tell dentists, anesthesiologists, emergency staff, and surgeons that they are taking TCAs or thyroxine because these drugs potentiate epinephrine's cardiovascular effects, producing severe hypertension and arrhythmias. If local anesthesia is needed (e.g., dental procedures), physicians should recommend reducing or avoiding epinephrine in anesthetic solutions because TCAs can cause 2–4× increased pressor response, leading to dangerous BP elevation. Because TCAs enhance epinephrine's vasopressor effect, physicians should monitor BP, heart rate, and ECG for signs of severe hypertension or arrhythmias.

Legend: T = Theoretical

9.5. Drug-Food Interactions

Interactions with food have not been established.

9.6. Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7. Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10. Clinical Pharmacology

10.1. Mechanism of Action

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.

10.2. Pharmacodynamics

This information is not available for this drug product.

10.3. Pharmacokinetics

This information is not available for this drug product.

11. Storage, Stability, and Disposal

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

Part 2: Scientific Information

13. Pharmaceutical Information

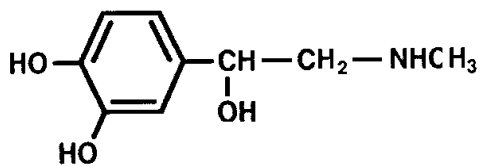
Drug Substance

Non-proprietary name of the drug substance: Epinephrine

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

Molecular formula and molecular mass: (Levorotatory isomer) $C_9H_{13}NO_3$ and 183.20 g/mol

Structural formula:



Physicochemical properties: Epinephrine is a white to practically white, odourless, microcrystalline powder or granules, gradually darkening on exposure to light and air. Soluble in aqueous solutions of mineral acids. Very slightly soluble in ethanol (96%) and methanol. Practically insoluble in acetone, chloroform, methylene chloride and in ether. Melting range according to Merck Index is ab. 215°C, with decomposition.

Pharmaceutical standard: USP

14. Clinical Trials

The clinical trial data on which the original indication was authorized is not available.

16. Non-Clinical Toxicology

The non-clinical toxicology data on which the original indication was authorized is not available.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ADRENALIN®

epinephrine solution for injection

This Patient Medication Information is written for the person who will be taking **ADRENALIN**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **ADRENALIN**, talk to a healthcare professional.

What ADRENALIN is used for:

ADRENALIN is used to:

- start the heart again in cardiac arrest.
- provide rapid relief of severe allergic reactions and respiratory distress due to asthma.
- help local and spinal anaesthetics (used to block pain and feeling) last longer.
- to treat simple (open-angle) glaucoma, a condition that causes increased pressure in the eye.
- treat congestion caused by hay fever and inflammation of the tissues inside the nose and sinuses.
- relieve the symptoms of allergic reactions such as; serum sickness (rash, joint pain, fever), urticaria (skin reaction causing welts) and angioedema (swelling of the skin and mucous membranes).
- relax the uterus and stop it from contracting.
- stop bleeding.

How ADRENALIN works:

ADRENALIN contains the medicinal ingredient epinephrine. It works by acting on certain receptors in the body to narrow blood vessels, relax the muscles in the lungs and airways and stop severe allergic reactions.

The ingredients in ADRENALIN are:

Medicinal ingredient: epinephrine (as epinephrine hydrochloride)

Non-medicinal ingredients: Hydrochloric acid, sodium bisulfate or metabisulfite, sodium chloride and water for injection. The vials also contain chlorobutanol as a preservative.

ADRENALIN comes in the following dosage form:

Solution for injection: 1 mg / mL, 30 mg /30 mL

Do not use ADRENALIN if:

- you are allergic to epinephrine or to any of the non-medicinal ingredients in ADRENALIN (see [The ingredients in ADRENALIN are:](#)).
- you have narrow-angle glaucoma, a condition that causes increased pressure in the eye.
- you have organic brain damage.
- you are using local anesthetics in certain parts of the body like the fingers or toes, due to the risk of cutting off blood flow and damaging tissue.
- you are in labor, as it may slow down the birthing process.
- you have a history of certain heart problems, such as an enlarged heart or poor blood flow to your heart muscle.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ADRENALIN. Talk about any health conditions or problems you may have, including if you:

- have heart disease or poor blood flow to the heart as ADRENALIN may cause chest pain (angina).
- have heart disease cause by long-term breathing problems such as; asthma or emphysema.
- are pregnant or breastfeeding.

Other warnings you should know about:

- If too much ADRENALIN is given, or if it is accidentally injected into a vein, it can cause a sudden increase in blood pressure, which may lead to bleeding in the brain.
- ADRENALIN contains sodium bisulfite as a non-medicinal ingredient which can cause allergy-like reactions. Epinephrine, the medicinal ingredient in ADRENALIN, is still the best treatment for a severe allergic reaction.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**The following may interact with ADRENALIN:**

- Antihistamines, used to treat allergies, such as diphenhydramine, tripelemnamine, d-chlorpheniramine.
- Sodium L-thyroxine, used to treat thyroid problems.
- Tricyclic antidepressants, used to treat depression.

How to take ADRENALIN:

- ADRENALIN will be given to you by a healthcare professional in a hospital or a clinic setting.
- It will be injected either into a muscle, vein, the heart or around the spine; or under the skin.

Usual dose:

Your healthcare professional will determine the dose that is right for you based on your condition.

Overdose:

If you think you, or a person you are caring for, have taken too much ADRENALIN, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Possible side effects from using ADRENALIN:

These are not all the possible side effects you may have when taking ADRENALIN. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- headache
- fear, anxiety

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Unknown			
Heart Palpitations (fast-beating, fluttering or pounding heart): skipping beats, beating too fast, pounding, fluttering rapidly	√		
Injection Site Reactions: loss of sensation, swelling, discolored skin (pale, blue or black)			√
Epinephrine-Fatness: your body stops responding to ADRENALIN so it may not work as well as before (in patients repeatedly treating with epinephrine)			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

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

Keep out of reach and sight of children.

If you want more information about ADRENALIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database>); the manufacturer's website www.searchlightpharma.com; or by calling 1-800-667-4708.

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