**INDICATIONS AND USAGE**

Adrenalin® is a non-selective alpha and beta adrenergic agonist indicated for:

- Emergency treatment of allergic reactions (Type I), including anaphylaxis (Adrenalin® 1 mL single-use vial and 30 mL multiple-dose vials).
- Beta-adrenergic blocking drugs: antagonize the vasoconstricting and bronchodilating effects of epinephrine and may precipitate or aggravate angina pectoris.
- Tricyclic antidepressants, MAO inhibitors, and sympathomimetic amines: may precipitate or aggravate angina pectoris.

**Dosage Forms and Strengths**

- Adrenalin® 1 mL single-use vials and 30 mL multiple-dose vials
- Adrenalin® 1 mg/mL (1:1000) epinephrine injection, 1 mL solution in a single-use vial only

**DOSAGE FORMS AND STRENGTHS**

- Injection: 1 mL single-use vials and 30 mL multiple-dose vials

**CONTRAINdications**

- Do not use 30 mL vial for ophthalmic injection
- Undiluted ophthalmic solution before intraocular use. Epinephrine containing sodium bisulfite has been used to cause gas gangrene. Cleansing with alcohol does not kill bacterial spores, and therefore, the product should not deter use for anaphylaxis.

**ADVERSE REACTIONS**

Common adverse reactions to adrenalin® include:

- Palpitations
- Tachycardia
- Vasoconstriction
- Hypertension
- Angina pectoris
- Nausea
- Vomiting
- Cerebral hemorrhage
- Arrhythmias
- Reaction in the anterolateral aspect of the thigh every 5 to 10 minutes as necessary (2.1)
- Injection into the buttock has resulted in cases of gas gangrene. Accidental injection into the digits, hands, or feet may result in loss of blood flow to the affected area and has been associated with tissue necrosis.

**Adverse Reactions**

- Cardiac dysrhythmias, palpitations, epinephrine, injection, 1 mL solution in a single-use vial only
- Injection into the anterolateral aspect of the thigh every 5 to 10 minutes as necessary (2.1)
- Injection into the buttock has resulted in cases of gas gangrene. Accidental injection into the digits, hands, or feet may result in loss of blood flow to the affected area and has been associated with tissue necrosis.

**Dosage and Administration**

- Anaphylaxis (Adrenalin® 1 mL single-use vial and 30 mL multiple-dose vials)
- Induction and maintenance of mydriasis during Intraocular Surgery (Adrenalin® 1 mL single-use vial only)

**Use in Specific Populations**

- Elderly patients and pregnant women (8.3, 8.4, 8.5)

**Drug Interactions**

- Sympathomimetic amines: may precipitate or aggravate angina pectoris.
- Tricyclic antidepressants, MAO inhibitors, and sympathomimetic amines: may precipitate or aggravate angina pectoris.

**Warnings and Precautions**

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Epinephrine, also known as adrenaline, is a drug used to treat anaphylaxis, a medical emergency caused by an allergic reaction. It is often used as an intramuscular or subcutaneous injection. Here is a summary of its key uses, dosages, and side effects:

### 8.1 Pregnancy

- **Teratogenic Effects:** Pregnancy Category C.
- There are no adequate and well-controlled studies in pregnant women. Epinephrine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus (fetal anoxia, spontaneous abortion, or both).

### 8.2 Labor and Delivery

- Use with caution during labor and delivery. Although epinephrine improves maternal hypotension associated with anaphylaxis, it may result in uterine vasoconstriction, decreased uterine blood flow, and fetal anoxia.

### 8.3 Nursing Mothers

- Epinephrine should not be used to counteract circulatory collapse or hypotension caused by phenothiazines, as a reversal of the pressor effects of epinephrine may result in further lowering of blood pressure.

### 8.4 Pediatric Use

- Use with caution in patients aged 65 and over to determine whether they respond differently from younger subjects. However, other reported clinical experience with use of epinephrine for the treatment of anaphylaxis has not identified that geriatric patients may be particularly sensitive to the effects of epinephrine. Therefore, for the treatment of anaphylaxis, consider starting with a lower dose to take into account potential concomitant disease or other drug therapy.

### 8.5 Geriatric Use

- Clinical studies for the treatment of anaphylaxis have not been performed in subjects aged 65 and over to determine whether they respond differently from younger subjects. However, other reported clinical experience with use of epinephrine for the treatment of anaphylaxis has not identified that geriatric patients may be particularly sensitive to the effects of epinephrine. Therefore, for the treatment of anaphylaxis, consider starting with a lower dose to take into account potential concomitant disease or other drug therapy.

### 10 OVERDOSAGE

Overdose of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients. Bradycardia may also result in pulmonary vascular constriction together with cardiac stimulation. Treatment consists of a rapidly acting α-adrenergic blocking drug and respiratory support.

Epinephrine is rapidly inactivated in the body and treatment following overdose with epinephrine is primarily supportive. If necessary, pressor effects may be countered by rapidly acting vasodilators or α-adrenergic blocking drugs. If prolonged hypotension follows such measures, it may be necessary to administer another pressor drug.

Epinephrine overdose can also cause transient bradycardia followed by tachycardia and these may be accompanied by potentially fatal cardiac arrhythmias. Premature ventricular contractions may appear within one minute after injection and may be followed by multifocal ventricular tachycardia (pre fibrillation rhythm). Subsidence of the ventricular effects may be followed by atrial tachycardia and occasionally by atrioventricular block. Treatment of arrhythmias consists of administration of a β-adrenergic blocking drug such as propranolol. Overdose sometimes results in extreme paleness and coldness of the skin, metabolic acidosis due to elevated blood lactate acid levels, and kidney failure. Suitable corrective measures must be taken in such situations.

### 14.1 Induction and Maintenance of Mydriasis during Intraocular Surgery

In randomized, controlled studies, patients undergoing routine cataract extraction were evaluated after receiving intraocular injection of epinephrine diluted to 1:1,666,666 (0.6 mcg/mL). Patients have also been evaluated after receiving bolus intracamerale injections of epinephrine diluted between 1:250,000 and 1:250,000 (5.0 mcg/mL).

In patients with similar pupil diameters at baseline, with or without the use of preoperative mydriatic agents, mydriasis was maintained better in the eyes receiving epinephrine by an average of one to two millimeters in pupil diameter. Pupil constriction to 5mm or less occurred more often in the patients not receiving epinephrine.

### 16 HOW SUPPLIED/STORAGE AND HANDLING

- **Adrenalin® 1 mL Single-Use Vials:** Each carton contains 25 single-use vials containing 1 mL Adrenalin® (epinephrine injection, USP) solution 1 mg/mL (1:1000) in a 3 mL clear glass vial.
  - NDC 42023-159-25 1 mL vial

- **Adrenalin® 30 mL Multi-Dose Vials:** Each carton contains either 1 multi-dose vial or 10 multi-dose vials containing 30 mL Adrenalin® (epinephrine injection, USP) solution 1 mg/mL (1:1000) in a 36 mL amber glass vial.
  - NDC 42023-168-01 30 mL vial, pack of 1
  - NDC 42023-168-10 30 mL vial, pack of 10

**Vial and contents must be discarded 30 days after initial use.**

Store between 20° to 25°C (68° to 77°F). (See USP Controlled Room Temperature.)

Epinephrine is light sensitive. Protect from light and freezing.

Inspect visually for particulate matter and discoloration prior to administration. Do not use the solution if it is colored or cloudy, or if it contains particulate matter.

### 17 PATIENT COUNSELING INFORMATION

Advise patients or their caregivers about common adverse reactions associated with the use of epinephrine including an increase in heart rate, the sensation of a more forceful heartbeat, palpitations, swelling, nausea and vomiting, difficulty breathing, pallor, dizziness, weakness or shakiness, headache, apprehension, nervousness, or anxiety. These symptoms and signs usually subside rapidly, especially with rest, quiet and recumbent positioning.

Warn patients with a good response to initial treatment about the possibility of recurrence of symptoms and instruct patients to obtain proper medical attention if symptoms return.

Warn patients with diabetes that they may develop increased blood glucose levels following epinephrine administration.

Distributed by:

Par Pharmaceutical Companies, Inc.

Chestrut Ridge, NY 10977

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