Adrenalin® epinephrine injection

FULL PRESCRIBING INFORMATION

ADRENalin® (epinephrine injection) 0.1 mg/mL epinephrine injection, 1 mL solution in a single-use clear glass vial; 1 mg/mL epinephrine injection, 1 mL solution in a single-use clear glass vial; 1 mg/mL epinephrine injection, 30 mL solution in a multiple-dose amber glass vial.

Store vials at 15° to 30°C (59° to 86°F); do not refrigerate. Do not store in freezing temperatures. Do not use beyond the expiration date marked on the vial.

INFORMATION FOR PATIENTS

Adrenalin® injection is intended for use in emergency life-threatening situations, such as food-induced anaphylaxis, anaphylaxis or exercise-induced anaphylaxis. The signs and symptoms associated with these conditions may result from allergic reactions to insect stings, biting insects, foods, drugs, vaccinations, antibiotics, or intramuscular and subcutaneous use of Adrenalin®. Adrenalin® injection must be administered by health professionals. See full prescribing information for Adrenalin® injection.

FULL PRESCRIBING INFORMATION

ADRENalin® epinephrine injection

1 INDIICATIONS AND USES

Adrenalin® injection is available in a single-use 1 mL vial and a multiple-use 30 mL vial for the treatment of anaphylaxis or exercise-induced anaphylaxis. The signs and symptoms associated with anaphylaxis include skin reactions, urticaria, angioedema, bronchospasm, laryngeal edema, hypotension, tachycardia, or shock from histamine release. Epinephrine should be administered by health professionals if anaphylaxis or exercise-induced anaphylaxis is suspected. See full prescribing information for Adrenalin® injection.

2 DOSAGE AND ADMINISTRATION

Injection of Adrenalin® should be given intramuscularly or subcutaneously in the anterolateral aspect of the thigh, high on the anterolateral aspect of the thigh, up to a maximum of 0.3 mg (0.3 mL) per injection, repeated every 5 to 15 minutes as necessary. Most studies have shown that intravenous administration is not required due to possible differences in absorption associated with the use of the vials.

Dosage and Administration: Treatment of anaphylaxis or exercise-induced anaphylaxis associated with severe respiratory distress or life-threatening life-threatening situations should be given intramuscularly or subcutaneously at the site of injection. In such patients, or in patients who are on drugs that sensitize the heart to arrhythmias, epinephrine should be administered with caution. The cardiostimulating and bronchodilating effects of epinephrine are antagonized by beta adrenergic blocking agents. See full prescribing information for Adrenalin® injection.

3 DOSAGE FORMS AND STRENGTHS

Adrenalin® 1 mg/mL epinephrine injection, 1 mL solution in a single-use clear glass vial; 1 mg/mL epinephrine injection, 30 mL solution in a multiple-dose amber glass vial. Adrenalin® 1 mg/mL epinephrine injection, 1 mL solution in a single-use clear glass vial; 1 mg/mL epinephrine injection, 30 mL solution in a multiple-dose amber glass vial. Adrenalin® 1 mg/mL epinephrine injection, 1 mL solution in a single-use clear glass vial; 1 mg/mL epinephrine injection, 30 mL solution in a multiple-dose amber glass vial.

4 CONTRAINDICATIONS

Intramuscular or subcutaneous injection should not be administered to patients who are on drugs that sensitize the heart to arrhythmias, epinephrine should be administered with caution. The cardiostimulating and bronchodilating effects of epinephrine are antagonized by beta adrenergic blocking agents. See full prescribing information for Adrenalin® injection.

5 WARNINGS AND PRECAUTIONS

5.1 Adrenaline Injection: Injection into the anterolateral aspect of the thigh (vastus lateralis muscle) is the most appropriate location for administration because of its location, size, and vascularity. Injection into the anterolateral aspect of the thigh is not recommended due to possible differences in absorption associated with the use of the vials.

5.1.1 The injection site should be used as follows: Injection into the anterolateral aspect of the thigh (vastus lateralis muscle) is the most appropriate location for administration because of its location, size, and vascularity. Injection into the anterolateral aspect of the thigh is not recommended due to possible differences in absorption associated with the use of the vials.

5.2 Allergic Reactions Associated with Sulfite

5.2.1 Adrenalin® contains sodium bisulfite, which may cause mild or severe allergic reactions including anaphylaxis and asthma in susceptible individuals. However, the presence of sulfite in the product should not preclude its use for treatment of life-threatening situations, such as anaphylaxis.

5.3 Disease Interactions

5.3.1 Adrenalin® contains sodium bisulfite, which may cause mild or severe allergic reactions including anaphylaxis and asthma in susceptible individuals. However, the presence of sulfite in the product should not preclude its use for treatment of life-threatening situations, such as anaphylaxis.

5.4 Allergic Reactions Associated with Sulfite

5.4.1 Adrenalin® contains sodium bisulfite, which may cause mild or severe allergic reactions including anaphylaxis and asthma in susceptible individuals. However, the presence of sulfite in the product should not preclude its use for treatment of life-threatening situations, such as anaphylaxis.

5.5 Clinical Pharmacology

5.5.1 Adrenalin® contains sodium bisulfite, which may cause mild or severe allergic reactions including anaphylaxis and asthma in susceptible individuals. However, the presence of sulfite in the product should not preclude its use for treatment of life-threatening situations, such as anaphylaxis.

5.6 Adrenalin® contains sodium bisulfite, which may cause mild or severe allergic reactions including anaphylaxis and asthma in susceptible individuals. However, the presence of sulfite in the product should not preclude its use for treatment of life-threatening situations, such as anaphylaxis.

6 USE IN SPECIFIC POPULATIONS

6.1 Pregnancy

6.1.1 Adrenalin® contains sodium bisulfite, which may cause mild or severe allergic reactions including anaphylaxis and asthma in susceptible individuals. However, the presence of sulfite in the product should not preclude its use for treatment of life-threatening situations, such as anaphylaxis.

6.2 Lactation

6.2.1 Adrenalin® contains sodium bisulfite, which may cause mild or severe allergic reactions including anaphylaxis and asthma in susceptible individuals. However, the presence of sulfite in the product should not preclude its use for treatment of life-threatening situations, such as anaphylaxis.

6.3 Children

6.3.1 Adrenalin® contains sodium bisulfite, which may cause mild or severe allergic reactions including anaphylaxis and asthma in susceptible individuals. However, the presence of sulfite in the product should not preclude its use for treatment of life-threatening situations, such as anaphylaxis.

6.4 Geriatric Use

6.4.1 Adrenalin® contains sodium bisulfite, which may cause mild or severe allergic reactions including anaphylaxis and asthma in susceptible individuals. However, the presence of sulfite in the product should not preclude its use for treatment of life-threatening situations, such as anaphylaxis.

6.5 Other Populations

6.5.1 Adrenalin® contains sodium bisulfite, which may cause mild or severe allergic reactions including anaphylaxis and asthma in susceptible individuals. However, the presence of sulfite in the product should not preclude its use for treatment of life-threatening situations, such as anaphylaxis.
In vivo, therapeutic effects (including emphysema relief) were observed at approximately 3 to 4 times the maximum recommended intranasal or subcutaneous dose (0.1 mg/kg) at a maximum subcutaneous dose of 0.1 mg/kg for 16 days. These effects were not observed at approximately 4 times the maximum recommended subcutaneous dose (0.2 mg/kg) at a maximum subcutaneous dose of 0.05 mg/kg for 16 days.

In vitro, therapeutic effects were observed at approximately 2 times the maximum recommended intranasal or subcutaneous dose (0.1 mg/kg) at a maximum subcutaneous dose of 0.05 mg/kg for 4 days.

3.2 Labor and Delivery

Use with caution during labor and delivery. Although epinephrine improves uterine contractility associated with episiotomy, it may result in adverse vasoconstriction, decreased cerebral blood flow, and fetal access.

3.3 Nursing Mothers

It is not known whether epinephrine is secreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when epinephrine is administered to a nursing woman.

4.6 Pediatric Use

Clinical studies for the treatment of anaphylaxis have not been performed in pediatric patients, and other reported clinical experience with use of epinephrine for the treatment of anaphylaxis has identified that patients aged 65 and over respond differently from younger subjects. This information should be considered in designing a regimen for an idiopathic patient 65 years of age or older.

12.2 Pharmacodynamics

Epinephrine acts on both alpha and beta-adrenergic receptors.

12.1 Mechanism of Action

Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink in color. The active ingredients are as follows:

- USP epinephrine, 6.15 mg sodium chloride, 0.457 mg sodium metabisulfite, 0.920 mg
- USP sodium hydroxide, 2.25 mg tartaric acid, 0.20 mg disodium edetate dihydrate.

α-epinephrine is: 1,2-Benzenediol, 4-[(1R)-1-hydroxy-2-(methylamino)ethyl]-, or
- 1,2-Benzenediol, 4-[1R)-(1R,2S)-2-hydroxy-1-(methylamino)ethyl]-

The molecular weight of epinephrine is 188.3. Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink in color from oxidation to adrenaline and benzene through the formation of metamphetamine.

13. CLINICAL PHARMACOLOGY

13.1 Mechanisms of Action

Epinephrine acts on both alpha- and beta-adrenoreceptors.

13.2 Pharmacodynamics

Through its action on beta-adrenoreceptors, epinephrine causes bronchodilation, systemic muscle relaxation, and help alleviate bronchospasm, wheezing, and oppression that may occur during anaphylaxis.

Epinephrine also stimulates positive, autonomic, and angiotensin II and may elevate heart rate and heart rate variability. Beta-adrenergic antagonists are found in the pulmonary system associated with epinephrine because of its release effects on the muscle of the small airways, bronchial, and pulmonary blood vessels.

Epinephrine increases glycogenolysis, reduces glucose uptake by tissues, and inhibits muscle release in the release, resulting in hyperglycemia and increased blood lactate acid (see Therapeutics and Precautions (6.3)).