

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use EPINEPHRINE INJECTION safely and effectively. See full prescribing information for EPINEPHRINE INJECTION.

**EPINEPHRINE injection, for intramuscular or subcutaneous use**  
Initial U.S. Approval: 1939

### INDICATIONS AND USAGE

Epinephrine Injection is a alpha and beta-adrenergic receptor agonist, indicated for the emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 15 kg or greater. (1)

### DOSAGE AND ADMINISTRATION

The recommended dosage of Epinephrine Injection is based on weight. (2.1) Administer Epinephrine Injection intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. (2.2)

#### Recommended Dosage

Patient's Weight	Dosage
30 kg or greater	0.3 mg
15 kg to less than 30 kg	0.15 mg

- In the absence of clinical improvement or if symptoms worsen after the initial treatment, a second dose of Epinephrine Injection may be administered with a second auto-injector starting 5 minutes after the first dose. (2.1)
- Advise patients when to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required. (2.1)
- It is recommended that patients are prescribed and have immediate access to two Epinephrine Injection devices at all times. (2.1)
- See full prescribing information for administration instructions. (2.2)

### DOSAGE FORMS AND STRENGTHS

Injection:

- 0.3 mg (0.3 mg/0.3 mL) single-dose pre-filled auto-injector (3)
- 0.15 mg (0.15 mg/0.15 mL) single-dose pre-filled auto-injector (3)

### CONTRAINDICATIONS

None. (4)

### WARNINGS AND PRECAUTIONS

- Do not inject intravenously, into buttock, or into digits, hands, or feet. (5.1)
- Hold the child's leg firmly in place and limit movement prior to and during injection when administering to young children or infants to minimize the risk of injection-related injury. (5.1)
- Rare cases of serious skin and soft tissue infections have been reported following epinephrine injection. Advise patients to seek medical care if they develop signs or symptoms of infection. (5.2)
- Administer with caution in patients with heart disease; may aggravate angina pectoris or produce ventricular arrhythmias. (5.3)
- May aggravate certain coexisting conditions. (5.3)
- The presence of a sulfite in this product should not deter use. (5.4)

### ADVERSE REACTIONS

Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### DRUG INTERACTIONS

- Cardiac glycosides, diuretics, or anti-arrhythmics: observe for development of cardiac arrhythmias. (7.1)
- Tricyclic antidepressants, monoamine oxidase inhibitors, levothyroxine sodium, certain antihistamines, and catechol-O-methyl transferase inhibitors: may potentiate effects of epinephrine. (7.2)
- Beta-adrenergic blocking drugs: antagonize cardiostimulating and bronchodilating effects of epinephrine. (7.3)
- Alpha-adrenergic blocking drugs: antagonize vasoconstricting and hypertensive effects of epinephrine. (7.3)
- Ergot alkaloids: may reverse the pressor effects of epinephrine. (7.3)

### USE IN SPECIFIC POPULATIONS

Elderly patients may be at greater risk of developing adverse reactions. (5.3, 8.5)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

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## FULL PRESCRIBING INFORMATION

### 1 INDICATIONS AND USAGE

Epinephrine Injection is indicated for the emergency treatment of type I allergic reactions, including anaphylaxis in adult and pediatric patients who weigh 15 kg or greater.

### 2 DOSAGE AND ADMINISTRATION

#### 2.1 Recommended Dosage

Recommended dosage for patients who weigh 15 kg or greater is based on weight and the dosage is provided in Table 1. Administer Epinephrine Injection intramuscularly or subcutaneously into the anterolateral aspect of the thigh.

**Table 1 Recommended Dosage of Epinephrine Injection Based on Patient's Weight**

Patient's Weight	Dosage
30 kg or greater	0.3 mg
15 kg to less than 30 kg	0.15 mg

- Since the doses of epinephrine delivered from Epinephrine Injection are fixed, use other forms of injectable epinephrine if doses lower than 0.15 mg are deemed necessary.
- In the absence of clinical improvement or if symptoms worsen after the initial treatment, a second dose of Epinephrine Injection may be administered with a second auto-injector starting 5 minutes after the first dose.
- Advise patients when to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required.
- It is recommended that patients are prescribed and have immediate access to two Epinephrine Injection devices at all times.

#### 2.2 Administration Instructions

- Each Epinephrine Injection contains a single-dose of epinephrine for single use.
- Visually inspect the epinephrine solution in the clear window of the Epinephrine Injection for particulate matter and discoloration prior to administration. Replace Epinephrine Injection if the epinephrine solution appears discolored (pinkish or brown color), cloudy, or contains particles.
- Instruct caregivers of young children who are prescribed an Epinephrine Injection and who may be uncooperative and kick or move during an injection to hold the leg firmly in place and limit movement prior to and during an injection [*see Warnings and Precautions (5.1)*].
- Inject the single-dose Epinephrine Injection intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Do not inject intravenously, and do not inject into buttocks, into digits, hands or feet [*see Warnings and Precautions (5.2)*].
- If a second dose is needed, administer a new Epinephrine Injection starting 5 minutes after the first dose. More than two sequential doses of epinephrine should be administered only under direct medical

supervision [see *Warnings and Precautions (5.1)*]. Refer patients and caregivers to the *Instructions for Use* for detailed administration instructions.

- Discard Epinephrine Injection after use. The Epinephrine Injection contains 1.1 mL epinephrine solution. Approximately 0.8 mL remains in the auto-injector after activation but is not available for future use.

### 3 DOSAGE FORMS AND STRENGTHS

Injection:

- 0.3 mg (0.3 mg/0.3 mL) of clear and colorless solution in single-dose pre-filled auto-injector
- 0.15 mg (0.15 mg/0.15 mL) of clear and colorless solution in single-dose pre-filled auto-injector

### 4 CONTRAINDICATIONS

None.

### 5 WARNINGS AND PRECAUTIONS

#### 5.1 Injection-Related Complications

Epinephrine Injection should **only** be injected into the anterolateral aspect of the thigh [see *Dosage and Administration (2.2)*].

##### Do not inject intravenously

Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to a sharp rise in blood pressure. Rapidly acting vasodilators can counteract the marked pressor effects of epinephrine for this inadvertent administration.

##### Do not inject into buttock

Injection into the buttock may not provide effective treatment of anaphylaxis. If Epinephrine Injection is injected into the buttock, advise the patient to administer a second dose of Epinephrine Injection into the anterolateral aspect of the thigh if symptoms worsen or persist, and then go immediately to the nearest emergency room for further treatment of anaphylaxis. Additionally, injection into the buttock has been associated with the development of Clostridial infections (gas gangrene). Cleansing with alcohol does not kill bacterial spores, and therefore, does not lower the risk.

##### Do not inject into digits, hands or feet

Since epinephrine is a strong vasoconstrictor, accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area and may not provide effective treatment of anaphylaxis. Advise the patient to administer a second dose of Epinephrine Injection into the anterolateral aspect of the thigh if experiencing anaphylaxis, and then go immediately to the nearest emergency room and inform the healthcare provider in the emergency room of the location of the accidental injection. Treatment of such inadvertent administration should consist of vasodilation, in addition to further appropriate treatment of anaphylaxis [see *Adverse Reactions (6)*].

##### Hold leg firmly during injection

To minimize the risk of injection related injury when administering Epinephrine Injection to young children or infants, instruct caregivers to hold the child's leg firmly in place and limit movement prior to and during injection.

## 5.2 Serious Infections at the Injection Site

Rare cases of serious skin and soft tissue infections, including necrotizing fasciitis and myonecrosis caused by *Clostridia* (gas gangrene), have been reported at the injection site following epinephrine injection for anaphylaxis. *Clostridium* spores can be present on the skin and introduced into the deep tissue with subcutaneous or intramuscular injection. While cleansing with alcohol may reduce presence of bacteria on the skin, alcohol cleansing does not kill *Clostridium* spores. To decrease the risk of *Clostridium* infection, do not inject Epinephrine Injection into the buttock [see *Warnings and Precautions (5.1)*]. Advise patients to seek medical care if they develop signs or symptoms of infection, such as persistent redness, warmth, swelling, or tenderness, at the epinephrine injection site.

## 5.3 Risks Associated with Use of Epinephrine in Certain Coexisting Conditions

Some patients may be at greater risk for developing adverse reactions after epinephrine administration. Despite these concerns, it should be recognized that the presence of these conditions is not a contraindication to epinephrine administration in an acute, life-threatening situation. Therefore, instruct patients with these conditions, and/or caregivers to the circumstances under which epinephrine should be used.

Administer epinephrine with caution to patients who have heart disease, including patients with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias [see *Adverse Reactions (6)* and *Drug Interactions (7)*].

Epinephrine can temporarily exacerbate the underlying condition or increase symptoms in patients with the following: hyperthyroidism, Parkinson's disease, diabetes, renal impairment. Administer epinephrine with caution in patients with these conditions, including elderly patients and pregnant women.

## 5.4 Allergic Reactions Associated with Sulfite

Epinephrine is the preferred treatment for serious allergic reactions or other emergency situations even though Epinephrine Injection 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 Epinephrine Injection should not deter administration of the drug for treatment of serious allergic or other emergency situations.

## 6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Injection-Related Complications [see *Warnings and Precautions (5.1)*]
- Serious Infections at the Injections [see *Warnings and Precautions (5.2)*]
- Risks Associated with Use of Epinephrine in Certain Coexisting Conditions [see *Warnings and Precautions (5.3)*]
- Allergic Reactions Associated with Sulfite [see *Warnings and Precautions (5.4)*]

The following adverse reactions associated with the use of epinephrine were identified in observational trials, case reports, studies, or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

*Cardiovascular:* angina, arrhythmias (including fatal ventricular fibrillation), cerebral hemorrhage, hypertension, pallor, palpitations, tachyarrhythmia, tachycardia, vasoconstriction, ventricular ectopy, and stress cardiomyopathy

*Gastrointestinal Disorders:* nausea and vomiting

*Infections:* Clostridial infections (gas gangrene)

*Metabolism and Nutrition Disorders:* transient hyperglycemia, sweating

*Neurological:* disorientation, impaired memory, panic, psychomotor agitation, sleepiness, tingling, weakness, tremor, hypoesthesia, dizziness, headache

*Psychiatric:* anxiety, apprehensiveness, restlessness

*Respiratory:* respiratory difficulties

*Skin and Subcutaneous Tissue Disorders:* bruising, bleeding, discoloration, erythema, necrotizing fasciitis, myonecrosis

## **7 DRUG INTERACTIONS**

### **7.1 Drugs Increasing Risk of Cardiac Arrhythmias**

Patients who receive epinephrine while concomitantly taking cardiac glycosides, diuretics, or anti-arrhythmics should be observed carefully for the development of cardiac arrhythmias [see *Warnings and Precautions (5.3) and Adverse Reactions (6)*].

### **7.2 Drugs Potentiating Effects of Epinephrine**

The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, levothyroxine sodium, and certain antihistamines, notably chlorpheniramine, tripeleminamine, and diphenhydramine, and catechol-O-methyl transferase (COMT) inhibitors such as entacapone.

### **7.3 Drugs Antagonizing Effects of Epinephrine**

The cardiostimulating and bronchodilating effects of epinephrine are antagonized by beta- adrenergic blocking drugs, such as propranolol.

The vasoconstricting and hypertensive effects of epinephrine are antagonized by alpha-adrenergic blocking drugs, such as phentolamine.

Ergot alkaloids may also reverse the pressor effects of epinephrine.

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

#### Risk Summary

Prolonged experience with epinephrine use in pregnant women over several decades, based on published literature, have not identified a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with anaphylaxis, and treatment with epinephrine should not be delayed (*see Clinical Considerations*). In animal reproduction studies, epinephrine administered by the subcutaneous route to pregnant rabbits, mice, and hamsters, during the period of organogenesis was teratogenic at doses 7 times and higher than the maximum recommended human intramuscular and subcutaneous dose on a mg/m<sup>2</sup> basis (*see Data*).

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

### Clinical Considerations

#### *Disease-Associated Maternal and Embryo/Fetal Risk:*

During pregnancy, anaphylaxis can be catastrophic and can lead to hypoxic-ischemic encephalopathy and permanent central nervous system damage or death in the mother and, more commonly, in the fetus or neonate. Treatment of anaphylaxis during pregnancy should not be delayed.

### Data

#### *Animal Data*

In an embryofetal development study with rabbits dosed during the period of organogenesis, epinephrine was shown to be teratogenic (including gastroschisis and embryonic lethality) at doses approximately 40 times the maximum recommended intramuscular or subcutaneous dose (on a mg/m<sup>2</sup> basis at a maternal subcutaneous dose of 1.2 mg/kg/day for two to three days).

In an embryofetal development study with mice dosed during the period of organogenesis, epinephrine was shown to be teratogenic (including embryonic lethality) at doses approximately 8 times the maximum recommended intramuscular or subcutaneous dose (on a mg/m<sup>2</sup> basis at maternal subcutaneous dose of 1 mg/kg/day for 10 days). These effects were not seen in mice at approximately 4 times the maximum recommended daily intramuscular or subcutaneous dose (on a mg/m<sup>2</sup> basis at a subcutaneous maternal dose of 0.5 mg/kg/day for 10 days).

In an embryofetal development study with hamsters dosed during the period of organogenesis from gestation days 7 to 10, epinephrine was shown to be teratogenic at doses approximately 7 times the maximum recommended intramuscular or subcutaneous dose (on a mg/m<sup>2</sup> basis at a maternal subcutaneous dose of 0.5 mg/kg/day).

## **8.2 Lactation**

### Risk Summary

There is no information on the presence of epinephrine in human milk, the effects on the breastfed infants, or the effects on milk production. However, due to its poor oral bioavailability and short half-life, transfer of epinephrine into breastmilk is expected to be low. Treatment of anaphylaxis in breastfeeding patients should not be delayed.

## **8.4 Pediatric Use**

The safety and effectiveness of Epinephrine Injection for the emergency treatment of type I allergic reactions, including anaphylaxis have been established in pediatric patients who weigh 15 kg or greater. The use of Epinephrine Injection for this indication is supported by clinical experience. Clinical experience with the use of epinephrine suggests that the adverse reactions seen in pediatric patients are similar in nature and extent to those both expected and reported in adults. Since the doses of epinephrine delivered from Epinephrine Injection are fixed, use other forms of injectable epinephrine if doses lower than 0.15 mg are deemed necessary.

The safety and effectiveness of Epinephrine Injection have not been established in pediatric patients who weigh less than 15 kg.

## 8.5 Geriatric Use

Clinical studies of Epinephrine Injection for emergency treatment of type I allergic reactions, including anaphylaxis, were not conducted in geriatric patients aged 65 and over to determine whether they respond differently from younger adult patients. However, other reported clinical experience with use of epinephrine for the treatment of anaphylaxis has identified that geriatric patients may be particularly sensitive to the effects of epinephrine. Therefore, these patients may be at greater risk for developing adverse reactions after epinephrine administration.

## 10 OVERDOSAGE

Overdosage of epinephrine has been reported to produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients. Overdosage may also result in pulmonary edema because of peripheral vascular constriction together with cardiac stimulation.

Epinephrine overdosage can also cause transient bradycardia followed by tachycardia which may be accompanied by fatal cardiac arrhythmias; premature ventricular contractions followed by multifocal ventricular tachycardia; atrial tachycardia and occasionally by atrioventricular block; extreme pallor and coldness of the skin; metabolic acidosis; kidney failure.

Epinephrine is rapidly inactivated in the body and treatment following overdosage with epinephrine is primarily supportive. Treatment of epinephrine associated pulmonary edema consists of a rapidly acting alpha-adrenergic blocking drug (such as phentolamine mesylate) and respiratory support. Treatment of epinephrine associated arrhythmias consists of administration of a beta-adrenergic blocking drug (such as propranolol). If necessary, pressor effects may be counteracted by rapidly acting vasodilators or  $\alpha$ -adrenergic blocking drugs. If prolonged hypotension follows such measures, it may be necessary to administer another pressor drug.

Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdosage management recommendations.

## 11 DESCRIPTION

Epinephrine Injection, USP 0.3 mg and 0.15 mg, are single-dose auto-injectors and combination products containing drug and device components.

Each Epinephrine Injection, USP 0.3 mg, delivers a single dose of 0.3 mg epinephrine from Epinephrine Injection, USP (0.3 mL) in a sterile solution.

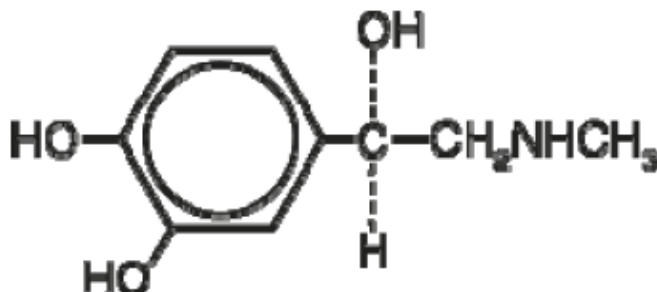
Each Epinephrine Injection, USP 0.15 mg, delivers a single dose of 0.15 mg epinephrine from Epinephrine Injection, USP (0.15 mL) in a sterile solution.

Epinephrine Injection, USP 0.3 mg and Epinephrine Injection, USP 0.15 mg each contain 1.1 mL of epinephrine solution. 0.3 mL and 0.15 mL epinephrine solution are dispensed for Epinephrine Injection, USP 0.3 mg and Epinephrine Injection, USP 0.15 mg, respectively, when activated. The solution remaining after activation is not available for future use and should be discarded.

Each 0.3 mL in Epinephrine Injection, USP 0.3 mg, contains 0.3 mg epinephrine, 2.6 mg sodium chloride, not more than 1.5 mg chlorobutanol, 0.45 mg sodium bisulfite, hydrochloric acid and sodium hydroxide to adjust pH, and water for injection. The pH range is 2.2-5.0.

Each 0.15 mL in Epinephrine Injection, USP 0.15 mg, contains 0.15 mg epinephrine, 1.3 mg sodium chloride, not more than 0.75 mg chlorobutanol, 0.225 mg sodium bisulfite, hydrochloric acid and sodium hydroxide to adjust pH, and water for injection. The pH range is 2.2-5.0.

Epinephrine is a sympathomimetic catecholamine. Chemically, epinephrine is (-)-3,4-Dihydroxy- $\alpha$ -[(methylamino)methyl]benzyl alcohol with the following structure:



Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin. Replace Epinephrine Injection, USP if the epinephrine solution appears discolored (pinkish or brown color), cloudy, or contains particles.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

Epinephrine acts on both alpha- and beta-adrenergic receptors.

Through its action on alpha-adrenergic receptors, epinephrine lessens the vasodilation and increased vascular permeability that occurs during anaphylaxis, which can lead to loss of intravascular fluid volume and hypotension.

Through its action on beta-adrenergic receptors, epinephrine causes bronchial smooth muscle relaxation and helps alleviate bronchospasm, wheezing, and dyspnea that may occur during anaphylaxis.

Epinephrine also alleviates pruritus, urticaria, and angioedema, and may relieve gastrointestinal and genitourinary symptoms associated with anaphylaxis because of its relaxer effects on the smooth muscle of the stomach, intestine, uterus and urinary bladder.

### 12.2 Pharmacodynamics

When given subcutaneously or intramuscularly, epinephrine has a rapid onset and short duration of action.

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies to evaluate the carcinogenic potential of epinephrine have not been conducted.

Epinephrine and other catecholamines have been shown to have mutagenic potential *in vitro*. Epinephrine was positive in the *Salmonella* bacterial reverse mutation assay, positive in the mouse lymphoma assay, and negative in the *in vivo* micronucleus assay. Epinephrine is an oxidative mutagen based on the *E. coli* WP2

Mutoxitest bacterial reverse mutation assay. This should not prevent the use of epinephrine where indicated [*see Indications and Usage (1)*].

The potential for epinephrine to impair reproductive performance has not been evaluated, but epinephrine has been shown to decrease implantation in female rabbits dosed subcutaneously with 1.2 mg/kg/day (40-fold the highest human intramuscular or subcutaneous daily dose) during gestation days 3 to 9.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

### How Supplied

Epinephrine Injection is a clear and colorless solution for intramuscular or subcutaneous use. Epinephrine Injection is available as an auto-injector as described in Table 2.

**Table 2 Epinephrine Injection Auto-injector Package Configurations and Strengths**

<b>Strength</b>	<b>Package Configuration</b>	<b>NDC</b>
0.3 mg/0.3 mL	Each carton contains 2 single-dose prefilled auto-injectors in individual carrier tubes	NDC 0115-1694-49
	Auto-injector in carrier tube	NDC 0115-1694-30
0.15 mg/0.15 mL	Each carton contains 2 single-dose prefilled auto-injectors in individual carrier tubes	NDC 0115-1695-49
	Auto-injector in carrier tube	NDC 0115-1695-30

### Storage and Handling

- Protect from light. Epinephrine Injection is light sensitive and should be stored in the individual carrier tube provided.
- Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
- Do not refrigerate or freeze.
- Before using, check to make sure the solution in the auto-injector is clear and colorless.
- Replace the auto-injector if the solution is discolored (pinkish or brown color), cloudy, or contains particles.
- Properly dispose of all used, unwanted, or expired Epinephrine Injection, USP.

## 17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

### Administration

- Each Epinephrine Injection contains a single dose of epinephrine for single use.
- Instruct patients and/or caregivers to inspect the epinephrine solution visually through the viewing window periodically. Epinephrine Injection should be replaced if the epinephrine solution appears discolored, cloudy, or contains particles.
- Instruct patients and/or caregivers on proper intramuscular or subcutaneous injection technique using the Epinephrine Injection Trainer. A Trainer device is not provided with epinephrine injection. Patients and/or caregivers may obtain a Trainer device at [www.epinephrineautoinject.com](http://www.epinephrineautoinject.com). Instructions for use of the Trainer

device are provided on the Trainer label. Instruct patients and/or caregivers to use the Trainer to familiarize themselves with the use of epinephrine injection in an allergic emergency. The Trainer device may be used multiple times.

For additional video instructions on the use of epinephrine injection, go to [www.epinephrineautoinject.com](http://www.epinephrineautoinject.com).

- Instruct caregivers to hold the leg of young children or infants firmly in place and limit movement prior to and during injection. *[see Warnings and Precautions (5.2)]*.
- Instruct patients and/or caregivers in the appropriate use of Epinephrine Injection. Epinephrine Injection should be injected into the middle of the outer thigh (through clothing if necessary).
- Instruct patients and/or caregivers when a second dose of Epinephrine Injection is needed. Administer a new Epinephrine Injection into the middle of the outer thigh starting 5 minutes after the first dose.
- Advise patients and/or caregivers when to seek emergency medical care for close monitoring of the type I allergic emergency and in the event that further treatment is required.

### Injection-Related Complications

Advise patients to seek immediate medical care in the case of accidental injection into the digits, hands or feet because such an accidental injection to these areas may cause loss of blood flow to the affected area *[see Warnings and Precautions (5.1)]*.

### Serious Infections at the Injection Site

Advise patients that rare cases of serious skin and soft tissue infections, including necrotizing fasciitis and myonecrosis caused by Clostridia (gas gangrene), have been reported at the injection site following injection of epinephrine for anaphylaxis. Instruct patients to seek medical care if they develop signs or symptoms of infection, such as persistent redness, warmth, swelling, or tenderness, at the Epinephrine Injection site *[see Warnings and Precautions (5.2)]*.

### Risks Associated with Certain Coexisting Conditions

Advise patients with coexisting conditions (cardiac arrhythmia and ischemia, coronary artery disease, hypertension, pulmonary edema, hyperthyroidism, renal impairment, Parkinson's disease, diabetes), for increased risks that may be associated with use of epinephrine *[see Warnings and Precautions (5.5)]*.

### Storage and Handling

Epinephrine Injection is light sensitive and should be stored in the individual carrier tube provided to protect it from light. The individual carrier tube is not waterproof. Instruct patients that Epinephrine Injection must be properly disposed of once the blue end caps have been removed or after use *[see How Supplied/Storage and Handling (16)]*.

Manufactured for and Distributed by:

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Bridgewater, NJ 08807

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For inquiries call 1-877-835-5472

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## PATIENT INFORMATION

EPINEPHRINE injection (ep" i nef' rin),  
for intramuscular or subcutaneous use

### Epinephrine Injection USP, 0.3 mg

Each Epinephrine Injection USP, 0.3 mg delivers a single dose of **0.3 mg epinephrine USP, in 0.3 mL (0.3 mg/0.3 mL)**

### Epinephrine Injection USP, 0.15 mg

Each Epinephrine Injection USP, 0.15 mg delivers a single dose of **0.15 mg epinephrine USP, in 0.15 mL (0.15 mg/0.15 mL)**

### For allergic emergencies (anaphylaxis)

Read this Patient Information leaflet carefully before you use Epinephrine Injection and each time you get a refill. There may be new information. You, your parent, caregiver, or others who may be able to administer Epinephrine Injection should know how to use it before you have an allergic emergency. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

#### What is the most important information I should know about Epinephrine Injection?

**1. Epinephrine Injection is a medicine used to treat allergic emergencies (anaphylaxis).** Anaphylaxis can be life-threatening and can happen within minutes. If untreated, anaphylaxis can lead to death.

Allergic emergencies may be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or other unknown causes.

Symptoms of anaphylaxis may include:

- trouble breathing
- wheezing
- hoarseness (changes in the way your voice sounds)
- hives (raised reddened rash that may itch)
- severe itching
- swelling of your face, lips, mouth, or tongue
- skin rash, redness, or swelling
- fast heartbeat
- weak pulse
- feeling very anxious
- confusion
- stomach pain
- losing control of urine or bowel movements (incontinence)
- diarrhea or stomach cramps
- dizziness, fainting, or "passing out" (unconsciousness)

**2. It is recommended that people are prescribed and have immediate access to 2 Epinephrine Injection devices at all times.** Sometimes a single dose of epinephrine may not be enough to treat a serious allergic reaction before seeking emergency medical help. You should also have immediate access to 2 Epinephrine Injection devices in case the first device is activated before the dose can be given. A device that has been activated accidentally cannot be used to treat an allergic emergency (anaphylaxis).

**Note:** Epinephrine Injection has been activated if you see the needle sticking out of the red needle end and the viewing window is blocked.

You may not know when an allergic emergency (anaphylaxis) will happen.

Talk to your healthcare provider if you need additional Epinephrine Injection devices to keep at work, school, or other locations. If you use 1 Epinephrine Injection device to treat an emergency allergic reaction, be sure to replace it so you always have immediate access to 2 devices. Tell your family members, caregivers, and others where you keep your Epinephrine Injection. Make sure they know how to use it before you need it. You may be unable to speak in an allergic emergency.

**3. When you have an allergic emergency (anaphylaxis) use Epinephrine Injection right away.**

Get emergency medical help for further treatment of the allergic emergency (anaphylaxis), if needed, after using Epinephrine Injection. **Before you receive Epinephrine Injection, your healthcare provider should talk to you about when to get emergency help.**

If symptoms do not improve or if they worsen after the first dose, or you accidentally inject Epinephrine Injection into the fingers, toes, hands or feet, **a second dose of Epinephrine Injection may be administered with a second auto-injector starting 5 minutes after the first dose.** If more than 2 doses are needed for an allergic emergency, they must be given by a healthcare provider.

#### What is Epinephrine Injection?

- **Epinephrine Injection is a medicine used to treat life-threatening allergic emergencies (anaphylaxis).** It is delivered using a disposable, prefilled automatic injection device (auto-injector). Each auto-injector contains a single dose of epinephrine.
- Epinephrine Injection is for immediate administration by you or your caregiver. **Get emergency medical help, if needed, after using Epinephrine Injection.** Your healthcare provider should talk to you about when to get emergency help.
- Epinephrine Injection is for people who have been prescribed this medicine by their healthcare provider.
- The Epinephrine Injection 0.3 mg auto-injector is for people who weigh 66 pounds or greater.
- The Epinephrine Injection 0.15 mg auto-injector is for people who weigh 33 pounds to less than 66 pounds.
- It is not known if Epinephrine Injection is safe and effective in children who weigh less than 33 pounds.

#### **What should I tell my healthcare provider before using Epinephrine Injection?**

Before you use Epinephrine Injection, tell your healthcare provider about all your medical conditions. Your healthcare provider may give you more instructions about when and how to use your Epinephrine Injection if you have the following:

- heart problems or high blood pressure
- diabetes
- thyroid problems
- asthma
- a history of depression
- Parkinson's disease
- kidney (renal) problems

You may also receive more instructions if you:

- are pregnant or plan to become pregnant. It is not known if epinephrine will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if epinephrine passes into your breast milk.

Tell your healthcare provider about **all the medicines you take**, including prescription and over-the-counter medicines, vitamins and herbal supplements. Also tell your healthcare provider about all known allergies. Some medicines may increase or decrease the effects of epinephrine, and epinephrine may affect how other medicines work.

Know the medicines you take. Keep a list of all your medicines, including over-the-counter medicines, vitamins and herbal supplements to show your healthcare provider and pharmacist when you get a new medicine.

Use your Epinephrine Injection for treatment of anaphylaxis as prescribed by your healthcare provider, regardless of your medical conditions or the medicine you take.

#### **How should I use Epinephrine Injection?**

- **Use your single-dose Epinephrine Injection exactly as your healthcare provider tells you to use it.**
- **When you have an allergic emergency (anaphylaxis), use Epinephrine Injection right away.** Get emergency medical help, if needed, after using Epinephrine Injection.
- **You may need to use a second Epinephrine Injection if symptoms continue or come back after the first dose. A second dose may be administered starting 5 minutes after the first dose while you wait for emergency medical help, or if the first Epinephrine Injection is activated before the dose can be given.** If you need more than 2 doses of epinephrine for a single anaphylaxis episode, additional doses must be given by a healthcare provider.
- Epinephrine Injection should only be injected into the **middle of the outer thigh (upper leg)**. It can be injected **through clothing** if needed.
- **Do not inject into a vein, buttocks, fingers, toes, hands or feet. If Epinephrine Injection is injected into the fingers, toes, hands or feet, administer a second dose of Epinephrine Injection into the middle of the outer thigh (upper leg). If symptoms worsen or persist, go immediately to the nearest emergency room for further treatment of anaphylaxis.**
- Read and make sure you understand the **Instructions for Use** for information about the correct way to use Epinephrine Injection.
- Your healthcare provider will show you how to safely use Epinephrine Injection.
- It is very important that you hold Epinephrine Injection firmly against the middle of the outer thigh (upper leg) for a **full 10 seconds**. If you do not hold it in place long enough, Epinephrine Injection may not deliver the full dose of medicine.
- **Caution:** Never put your thumb, fingers, or hand over the red needle end. Never press or push the red needle end with your thumb, fingers, or hand. The needle comes out of the red needle end. Accidental injection into the fingers, hands, or feet may cause a loss of blood flow to those areas. If this happens, give a second dose of Epinephrine Injection into the middle of the outer thigh (upper leg) and go immediately to the nearest emergency room. Tell the healthcare provider where on your body the injection occurred.
- **Warning:** After the device is activated, the needle does **not** retract back into the device. **After use, carefully place the used auto-injector into the carrier tube, if possible, and throw away (dispose of) it properly as directed.**

- See the **Instructions for Use** for detailed information on how to safely handle and throw away (dispose of) the used auto-injector.
- Epinephrine Injection is packaged in a carton containing **2 Epinephrine Injections auto-injectors, each in an individual carrier tube.**
- **Do not drop the carrier tube or Epinephrine Injection.** If the carrier tube or Epinephrine Injection is dropped, check for damage or leakage. Throw away (dispose of) and replace Epinephrine Injection if damage or leakage is noticed or suspected.
- You may request a separate **Trainer** at [www.epinephrineautoinject.com](http://www.epinephrineautoinject.com). **The epinephrine injection Trainer has a beige color.** The beige epinephrine injection Trainer contains no medicine and no needle. Practice using the Trainer before an allergic emergency occurs so you know how to use Epinephrine Injection correctly. Always carry your real Epinephrine Injection, USP auto-injector with you in case of an allergic emergency.

**What are the possible side effects of Epinephrine Injection?  
Epinephrine Injection may cause serious side effects.**

**Injection-related complications**

- **Epinephrine Injection should only be injected into the middle of your outer thigh (upper leg).** Do not inject Epinephrine Injection into a vein, buttocks, fingers, toes, hands, or feet. If you accidentally inject Epinephrine Injection into any other part of your body, administer a second dose of Epinephrine Injection into the middle of the outer thigh (upper leg) and go to the nearest emergency room right away. Tell the healthcare provider where on your body the injection occurred.

**Serious infections at the injection site**

- Rarely, people who have used Epinephrine Injection may develop serious skin and soft tissue infections at the injection site within a few days after injection. Call your healthcare provider right away if you notice any of the following at the injection site:
  - redness that does not go away
  - swelling
  - tenderness
  - warmth at the injection site

**Other side effects**

- **If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have more or longer lasting side effects when you use Epinephrine Injection.** Talk to your healthcare provider about all of your medical conditions.

**Common side effects of Epinephrine Injection include:**

- fast, irregular or “pounding” heartbeat
- sweating
- headache
- weakness
- shakiness
- paleness
- feelings of excitement, nervousness or anxiety
- dizziness
- nausea or vomiting
- breathing problems

These side effects may go away with rest. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Epinephrine Injection. For more information, ask your healthcare provider or pharmacist.

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Amneal Pharmaceuticals LLC at 1-877-835-5472.**

**How should I store Epinephrine Injection?**

- Store Epinephrine Injection at **room temperature between 68°F to 77°F (20°C to 25°C).**
- **Keep Epinephrine Injection in the individual carrier tube provided** to protect it from light and damage. The carrier tube is **not waterproof.**
- **Do not expose Epinephrine Injection to extreme heat or cold.** For example, do not store in your vehicle’s glove box and do not store it in the refrigerator or freezer.
- **Periodically examine the solution through the viewing window** of your Epinephrine Injection. The solution should be **clear and colorless.** Replace Epinephrine Injection if the solution appears **discolored (pinkish or brown), cloudy, or contains particles.**
- The blue needle shield cap and blue end cap helps to prevent accidental injection. **Do not remove the blue needle shield cap or blue end caps until you are ready to use Epinephrine Injection.** After the auto-injector is used, throw away the blue end caps immediately, as they may pose a choking hazard for young children.
- **Keep Epinephrine Injection and all medicines out of the reach of children.**

**Disposing of an Expired, Unused or Used Epinephrine Injection**

- Your Epinephrine Injection has an expiration date. **Replace it before the expiration date.**
- Throw away (dispose of) expired, unwanted, or unused Epinephrine Injections in an **FDA-cleared sharps disposal container**. Do not throw away Epinephrine Injection in your household trash. If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
  - Made of heavy-duty plastic,
  - Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - Upright and stable during use,
  - Leak-resistant, and
  - Properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, follow your community guidelines for proper disposal. There may be state or local laws about how you should dispose of used needles and syringes. For more information about safe sharps disposal, visit the FDA website at [www.fda.gov/safesharpsdisposal](http://www.fda.gov/safesharpsdisposal).

**General information about the safe and effective use of Epinephrine Injection:**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Epinephrine Injection for a condition for which it was not prescribed. Do not give Epinephrine Injection to other people. This Patient Information leaflet summarizes the most important information about Epinephrine Injection. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about Epinephrine Injection that is written for health professionals.

For more information and video instructions on the use of Epinephrine Injection, go to [www.epinephrineautoinject.com](http://www.epinephrineautoinject.com) or call 1-877-835-5472.

**What are the ingredients in Epinephrine Injection?**

**Active Ingredient:** epinephrine

**Inactive Ingredients:** sodium chloride, chlorobutanol, sodium bisulfite, hydrochloric acid, sodium hydroxide, and water.

**Important Information**

- **The Epinephrine Injection, 0.3 mg auto-injector has a yellow-colored label.**
- **The Epinephrine Injection, 0.15 mg auto-injector has an orange-colored label.**
- **The Epinephrine Injection Trainer has a beige color, and contains no medicine and no needle.**
- **Your Epinephrine Injection is designed to work through clothing.**
- **The blue needle shield cap and the blue end cap on Epinephrine Injection help to prevent accidental injection of the device. Do not remove the blue needle shield cap and blue end caps until you are ready to use it.**
- **Choking hazard: The blue needle shield cap and blue end caps are small parts that may become a choking hazard for children. Throw away the blue end caps immediately after use.**
- **Only inject into the middle of the outer thigh (upper leg). Never inject into any other part of the body.**
- **Never put your thumb, fingers, or your hand over the red needle end. The needle comes out of the red needle end.**
- **If an accidental injection happens, get medical help right away.**
- **Do not place patient information or any other foreign objects in carrier with the auto-injector, as this may prevent you from removing Epinephrine Injection for use.**

**Incorrect Use and Correct Use of Epinephrine Injection**

Incorrect Use	Correct Use and Important Reminders
Storing Epinephrine Injection outside the carrier tube.	Always keep Epinephrine Injection stored in the individual carrier tube provided to protect it from light and damage. The carrier tube is not waterproof.
Storing of the Epinephrine Injection outside of the recommended storage conditions.	Always keep your Epinephrine Injection stored at room temperature (68°F to 77°F / 20°C to 25°C).

Failing to remove the Epinephrine Injection from the carrier tube before use.	Remove Epinephrine Injection from the carrier tube before use.
Failing to remove both the blue caps in proper sequence before use.	Before use, remove the blue needle shield cap first to expose the red needle end. Then remove the blue end cap.
Failing to remove both blue caps before use.	Epinephrine Injection will not activate or deliver the dose if both blue caps are not removed.
Failing to remove the blue caps in the proper order.	Removing the blue caps in the incorrect order may cause premature activation of Epinephrine Injection.
Failing to remove the blue needle shield cap properly, resulting in the needle sheath remaining in place.	Pull off the blue needle shield cap by grasping the ribbed area and pulling straight off until the red needle end is visible. Do not squeeze the non-ribbed area.
Activating Epinephrine Injection upside down, resulting in injection into the hand.	The needle exits from the red needle end, which must be placed against the middle of the outer thigh (upper leg) at a 90° angle (perpendicular) before and during activation.
Failing to apply enough force to activate Epinephrine Injection.	Press down hard and hold Epinephrine Injection firmly against the outer thigh at a 90° angle for 10 seconds. Do not swing or jab the device.
Expecting an audible click to confirm activation.	You may or may not hear a sound when the injection starts.
Assuming the dose was not delivered because liquid remains in the device.	It is normal for most of the medicine to remain in the auto-injector after the dose is delivered. The dose has been delivered if the needle is visible after use.
Administering at an injection site other than the outer thigh.	Inject Epinephrine Injection only into the middle of the outer thigh (upper leg).
Removing the device at an angle, causing needle bending.	Place the red needle end against the thigh at a 90° angle (perpendicular), press down firmly, and remove the device straight out at a 90° angle after injection.
Failing to hold Epinephrine Injection in place long enough.	Hold Epinephrine Injection firmly in place for a full 10 seconds to ensure dose delivery.
Failing to locate the expiration date.	Remove Epinephrine Injection from the carrier tube. The expiration date is located on the auto-injector label.

For more information and video instructions on the use of Epinephrine Injection, go to [www.epinephrineautoinject.com](http://www.epinephrineautoinject.com) or call 1-877-835-5472.

This Patient Information has been approved by the U.S. Food and Drug Administration

Rev. 03/2026

## Instructions for Use

### EPINEPHRINE injection (ep" i nef' rin), for intramuscular or subcutaneous use

Epinephrine Injection USP, 0.3 mg

Each Epinephrine Injection USP, 0.3 mg delivers a single dose of **0.3 mg epinephrine USP in 0.3 mL (0.3 mg/0.3 mL)**

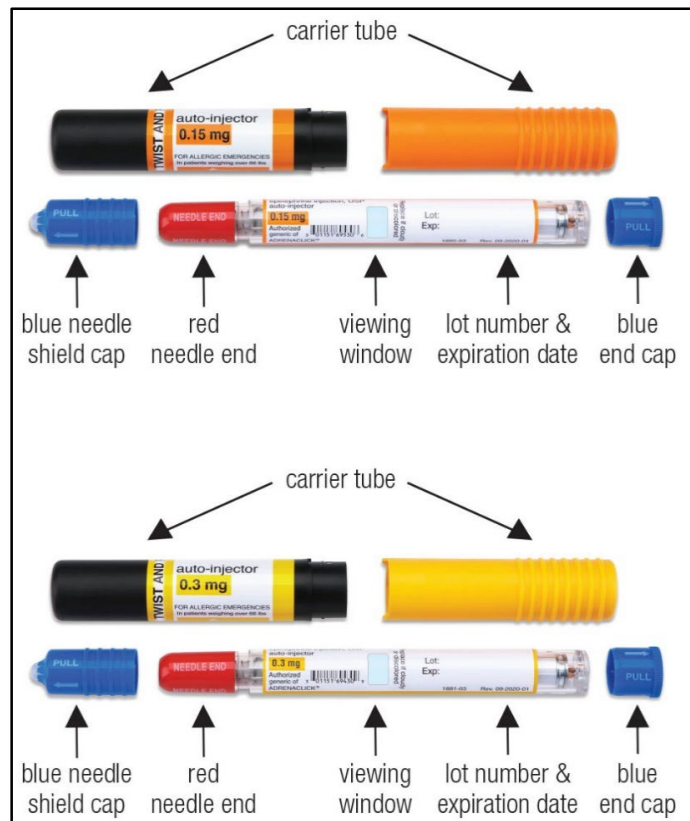
Epinephrine Injection USP, 0.15 mg

Each Epinephrine Injection USP, 0.15 mg delivers a single dose of **0.15 mg epinephrine USP in 0.15 mL (0.15 mg/0.15 mL)**

For allergic emergencies (anaphylaxis)

This Instructions for Use contains information on how to properly administer Epinephrine Injection.

### Your Epinephrine Injection

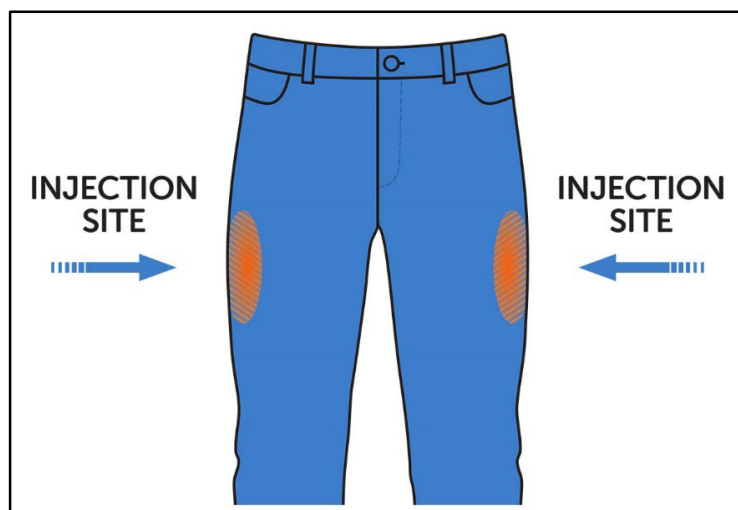


**Figure A.** Epinephrine Injection, USP 0.3 mg (yellow label) and Epinephrine Injection, USP 0.15 mg (orange label), showing the auto-injector and carrier tube components

### Important Information You Need to Know Before Administering Epinephrine Injection

- **Epinephrine Injection is a single-dose auto-injector used for allergic emergencies (anaphylaxis) and should be used right away.**

- **Before you need to use your Epinephrine Injection, make sure your healthcare provider shows you the right way to use it.** Anyone who may be able to administer Epinephrine Injection should also understand how to use it.
- **Check the expiration date on your Epinephrine Injection, as shown in Figure A.** Replace it before the expiration date.
- **Read this Instructions for Use carefully in a non-emergency situation and make sure you understand them before using your Epinephrine Injection.** If you have any questions, ask your healthcare provider.
- **It is very important to hold Epinephrine Injection firmly in place for a full 10 seconds.** If you do not hold it in place long enough, Epinephrine Injection may not have time to deliver the full dose of medicine.
- **Always carry 2 Epinephrine Injection devices.** One dose may not be enough to treat an allergic emergency. You may need to use a second Epinephrine Injection if symptoms continue or come back after the first dose. A second dose may be administered starting 5 minutes after the first dose while you wait for emergency medical help, or if the first Epinephrine Injection is activated before the dose can be given.
- **Inject Epinephrine Injection into the muscle (intramuscular) or under the skin (subcutaneous) in the middle of the outer thigh (upper leg) (see Figure B). Do not inject Epinephrine Injection into any other part of the body.**
- **If you accidentally inject Epinephrine Injection into the fingers, toes, hands or feet,** administer a second dose of Epinephrine Injection into the middle of the outer thigh (upper leg).
- **Epinephrine Injection can be administered through clothing if needed.**

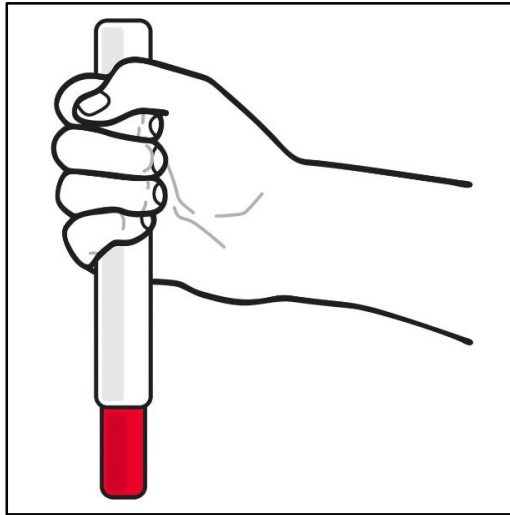


**Figure B.** Inject Epinephrine Injection into the middle of the outer thigh (upper leg)

**Each Epinephrine Injection is for single use only.**

The dose has been delivered if you see the **needle sticking out of the red needle end** after use. It is **normal for most of the medicine to remain in the auto-injector** after the dose is injected.

- **Do not take the Epinephrine Injection apart.**
- **Do not remove the blue needle shield cap and blue end cap until you are ready to use Epinephrine Injection.**
- **Always point the red needle end downward (see Figure C). Never put your thumb, fingers, or hand over the red needle end.** The needle comes out of the red needle end.
- **Accidental injection into the fingers, hands, or feet may cause loss of blood flow to these areas.** If an accidental injection happens, **get emergency medical help right away.**



**Figure C.** Correct way to hold the Epinephrine Injection with red needle end pointing down

### Preparing to Inject Epinephrine Injection

Read the following information while preparing to inject Epinephrine Injection:

- **Epinephrine Injection can be administered through clothing.** Remove any objects or clothing that may block access to the injection site.
- **Check Epinephrine Injection before use.** If the auto-injector appears damaged or broken, **do not use it.** Throw away (dispose of it) and use a new Epinephrine Injection.
- **A separate Epinephrine Injection Trainer is available.** The Trainer is beige in color and contains **no medicine and no needle.** Practice using the Trainer, but **always carry your real Epinephrine Injection** in case of an allergic emergency.
- You may request a separate Trainer at [www.epinephrineautoinject.com](http://www.epinephrineautoinject.com) or call 1-855-374-6374. Instructions for use of the Trainer device are provided on the Trainer label. Additional video instructions are available at [www.epinephrineautoinject.com](http://www.epinephrineautoinject.com).
- Before injection, make sure you know where to inject (see **Figure B**) and how to hold the Epinephrine Injection (see **Figure C**).

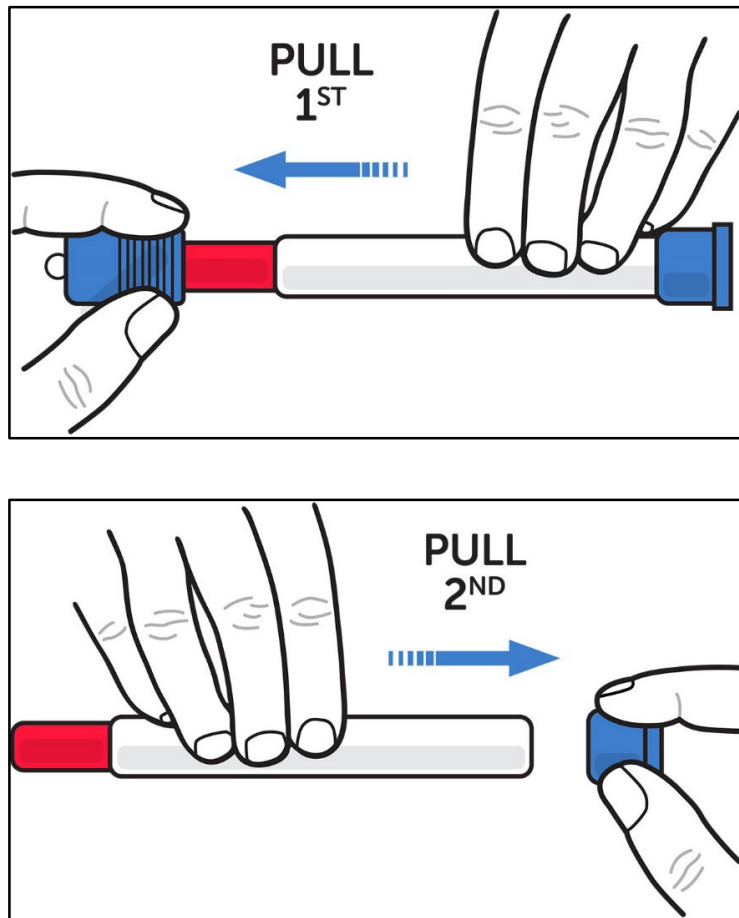
### Make sure Epinephrine Injection has not been used.

Epinephrine Injection has already been used if:

- the needle is sticking out of the **red** needle end, and
- the viewing window is blocked

### Preparing to Inject a Child

- If you are administering Epinephrine Injection to a young child, **hold their leg firmly in place before and during the 10 second injection** to reduce the risk of injury.
- Ask your healthcare provider to show you how to:
  1. Remove the blue needle shield cap first and then the blue end cap (see **Figure D**)
  2. Hold the young child firmly in place (restrain movement).
  3. With 1 hand, grip the auto-injector with the **RED** needle end pointing down.
  4. Inject in the middle of the outer thigh (upper leg) (see **Figure B**).



**Figure D.** Pull off the blue needle shield cap first and then the blue end cap

- Keep the Epinephrine Injection away from young children. The Epinephrine Injection is not a toy. Use by young children should be supervised by an adult.
- After the Epinephrine Injection is used, throw away both the blue needle shield cap and blue end cap immediately. These parts may pose a choking hazard for young children.

### Checking the Solution Color

Examine the solution in the viewing window of your Epinephrine Injection regularly. See the information below:



**Figure E. Solution Viewing Window**

### How to check the Solution Color:

- Remove Epinephrine Injection from the carrier tube. See **Figure F**.

- The solution can be seen through the viewing window located near the middle of the Epinephrine Injection. See **Figure E**.
- To check the solution color, hold the auto-injector in a well-lit area and look into the viewing window.

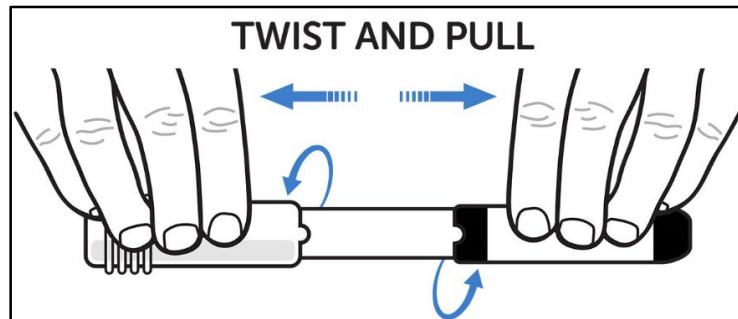
### Solution Appearance

✓ Use Epinephrine Injection if the solution is clear and colorless.

✗ Do not use the Epinephrine Injection if the solution is discolored (pinkish or brown color), cloudy, or contains solid particles. Throw away (dispose of it) and use a new Epinephrine Injection (see “**Disposing of an Expired, Unused or Used Epinephrine Injection**” on the Patient Information).

### Injecting Epinephrine Injection

**Step 1.** Remove Epinephrine Injection from the carrier tube. See **Figure F**.



**Figure F**

**Step 2.** Pull off the blue needle shield cap first by grasping at the ribbed area and pulling. You will now see a red needle end. Then pull off the blue end cap. See **Figure G**.

### Important:

- The needle comes out of the red needle end.
- To avoid an accidental injection, never put your thumb, fingers or hand over the red needle end.
- If an accidental injection occurs, administer a second dose of Epinephrine Injection into the middle of the outer thigh (upper leg) and get emergency medical help right away.

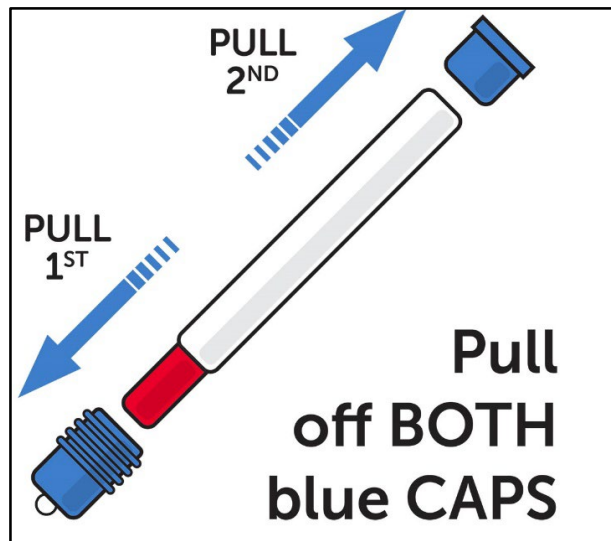


Figure G

### Step 3. Inject the Epinephrine Injection

#### Self Administration (see Figure H) or Caregiver Administration (see Figure I)

- Grasp the Epinephrine Injection firmly in your fist with the red needle end pointing downward. See **Figure C**.
- **Place the red needle end against the middle of the outer thigh** (upper leg) at a 90° angle (perpendicular) to the thigh. The injection may be given through clothing if necessary.
- **Press Down Hard** and **hold Epinephrine Injection firmly against the thigh for a full 10 seconds** to deliver the medicine. See **Figure H** and **Figure I**.

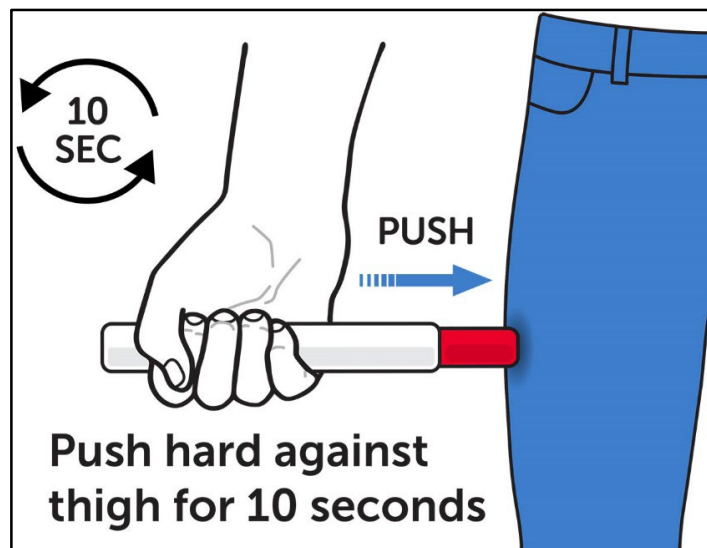


Figure H – Self Administration

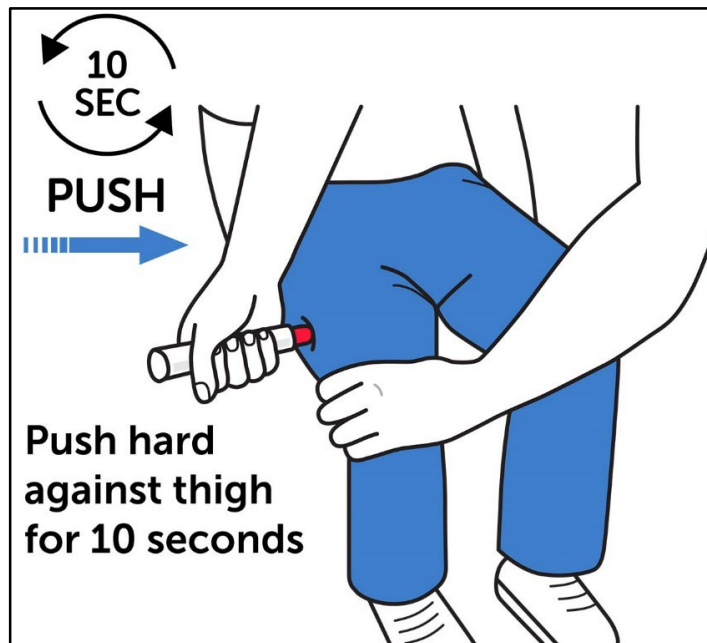


Figure I – Caregiver Administration

- Only inject into the middle of the outer thigh (upper leg). **Do not** inject into any other part of the body.

#### Step 4. Remove the Auto-Injector

**Pull Epinephrine Injection straight out at a 90° angle (perpendicular) from the outer thigh (upper leg).**

- Massage the injection area for 10 seconds.
- **Check the red needle end.** The injection is complete and the correct dose has been delivered if you see the needle sticking out of the **red** needle end.
- **If you do not see the needle, use a new Epinephrine Injection and repeat Step 3.**
- Do **not** reuse the same Epinephrine Injection.

#### Step 5. Get emergency medical help if needed.

Get emergency medical help for further treatment of the allergic emergency (anaphylaxis), if needed, after using Epinephrine Injection. Before you receive Epinephrine Injection, your healthcare provider should talk to you about when to get emergency medical help.

#### Step 6. After use

**Warning:** After Epinephrine Injection is activated, the needle does **not** retract back into the device.

**After use, carefully place the used Epinephrine Injection back into the carrier tube to cover the needle.**

- Place the labeled half of the carrier tube on a flat surface, with the opening facing upward.
- Using 1 hand, carefully slide the red needle end of Epinephrine Injection into the labeled half of the carrier tube until the needle is fully covered. See **Figure J**.

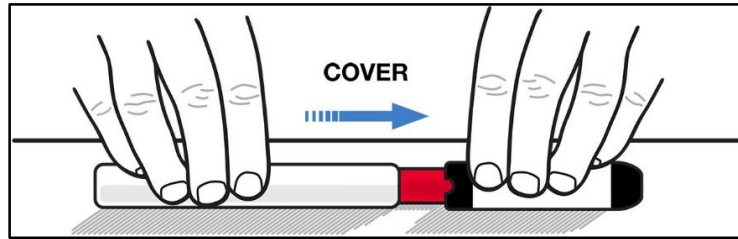


Figure J

- After the needle is inside the labeled half of the carrier tube, firmly push the unlabeled half of the carrier tube over the non-needle end of Epinephrine Injection until it is securely closed. See **Figure K**.

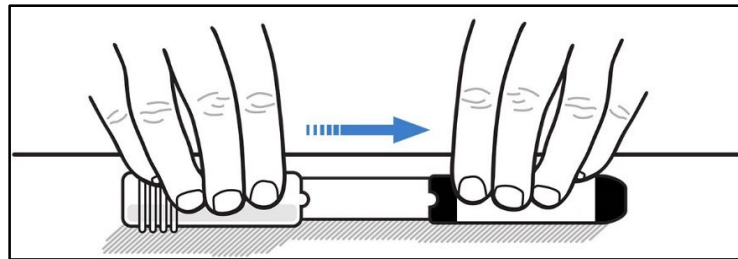


Figure K

- Take your used Epinephrine Injection with you when you go to see a healthcare provider.
- Tell the healthcare provider that you have received an injection of epinephrine. Show the healthcare provider where you received the injection.
- Give the used Epinephrine Injection to the healthcare provider for inspection and proper disposal.
- Ask your healthcare provider if you need a new prescription.

### Storing Epinephrine Injection

- Store Epinephrine Injection at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep Epinephrine Injection in the carrier tube to protect it from light and damage. The carrier tube is not waterproof.
- Do not expose Epinephrine Injection to extreme heat or cold. For example, do not store in your vehicle's glove box and do not store it in the refrigerator or freezer.
- **Keep Epinephrine Injection and all medicines out of the reach of children.**

### Disposing of Epinephrine Injection

**Important:** The blue needle shield cap and blue end cap are small parts and may pose a choking hazard for children. Throw away the blue needle shield cap and blue end cap immediately after using Epinephrine Injection.

- Epinephrine Injection has an expiration date. Replace it before the expiration date.
- For instructions on how to throw away (dispose of) expired, unused, or used Epinephrine Injection, see the section titled “**Disposing of an Expired, Unused or Used Epinephrine Injection**” on the Patient Information side of this leaflet.

For more information and video instructions on the use of Epinephrine Injection, visit [www.epinephrineautoinject.com](http://www.epinephrineautoinject.com) or call 1-877-835-5472.

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