HIGHLIGHTS OF PRESCRIBING INFORMATION

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

EPIPEN® (epinephrine injection), for intramuscular or subcutaneous use
EPIPEN Jr® (epinephrine injection), for intramuscular or subcutaneous use
Initial U.S. Approval: 1939

---------- RECENT MAJOR CHANGES ----------

Dosage and Administration (2.2) 3/2026

---------- INDICATIONS AND USAGE ----------

EpiPen and EpiPen Jr are alpha- and beta-adrenergic receptor agonists indicated in the emergency treatment of type I allergic reactions, including anaphylaxis, in adults and pediatric patients who weigh 15 kg or greater. (1)

---------- DOSAGE AND ADMINISTRATION ----------

The recommended dosage for patients who weigh 15 kg or greater is based on weight. (2.1)

Recommended Dosage

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

- Administer EpiPen or EpiPen Jr intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. (2.2)
- In the absence of clinical improvement or if symptoms worsen after initial treatment, administer a second dose of EpiPen or EpiPen Jr with a new device 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 EpiPen or EpiPen Jr devices at all times. (2.1)
- See full prescribing information for administration information and instructions. (2.2)

---------- DOSAGE FORMS AND STRENGTHS ----------

Injection:

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

---------- CONTRAINDICATIONS ----------

None (4)

---------- WARNINGS AND PRECAUTIONS ----------

- Do not inject intravenously, into buttock, digits, hands, or feet. (5.1)
- To minimize the risk of injection related injury, hold the child's leg firmly in place and limit movement prior to and during injection when administering to young children. (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 Viatris at 1-877-446-3679 (1-877-4-INFO-RX) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- DRUG INTERACTIONS ----------

- Cardiac glycosides, diuretics, or anti-arrhythmics: observe for 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. (8.5)

See 17 for PATIENT COUNSELING INFORMATION and FDA approved patient labeling

Revised: 3/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

EpiPen and EpiPen Jr are 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

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

Table 1. Recommended Dosage of EpiPen or EpiPen Jr Based on Patient's Weight

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

- Since the doses of epinephrine delivered from EpiPen or EpiPen Jr 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 EpiPen or EpiPen Jr 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 EpiPen or EpiPen Jr devices at all times.

2.2 Administration Information and Instructions

- Each EpiPen or EpiPen Jr is a single-dose epinephrine injection for single use.
- Visually inspect the epinephrine solution in the clear window of the EpiPen or EpiPen Jr for particulate matter and discoloration prior to administration. Replace EpiPen and EpiPen Jr if the epinephrine solution appears discolored (pinkish or brown color), cloudy, or contains particles.
- Instruct caregivers of pediatric patients who are prescribed an EpiPen or EpiPen Jr 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 (5.2)]*.
- Inject EpiPen or EpiPen Jr intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Do not inject intravenously, and do not inject into buttocks, digits, hands or feet *[see Warnings and Precautions (5.2)]*.

- If a second dose is needed, administer a new EpiPen or EpiPen Jr starting 5 minutes after the first dose. More than two sequential doses of epinephrine should be administered under direct medical supervision *[see Warnings and Precautions (5.1)]*.
- Refer patients and caregivers to the *Instructions for Use* for detailed administration instructions.

Administration Instructions:

Step 1. Twist to remove safety cap.
Step 2. Firmly push the orange tip of the auto-injector against the outer thigh and hold in place for 3 seconds.

3 DOSAGE FORMS AND STRENGTHS

Injection:
- 0.3 mg (0.3 mg/0.3 mL), clear and colorless solution in single-dose prefilled auto-injector
- 0.15 mg (0.15 mg/0.3 mL), clear and colorless solution in single-dose prefilled auto-injector

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Injection-Related Complications

Inject EpiPen and EpiPen Jr 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 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 EpiPen or EpiPen Jr is injected into the buttock, advise the patient to administer a second dose of EpiPen or EpiPen Jr into the anterolateral 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 Clostridial infections (gas gangrene) *[see Warnings and Precautions (5.2)]*. Cleansing with alcohol does not kill bacterial spores, and therefore, does not lower this 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 EpiPen or EpiPen Jr into the anterolateral thigh, and then go immediately to the nearest emergency room and to 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 (e.g., lacerations, bent needles, and embedded needles) when administering EpiPen or EpiPen Jr. 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 EpiPen 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, 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 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 (7.1)]*.

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 EpiPen and EpiPen Jr contains sodium metabisulfite, 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 EpiPen or EpiPen Jr 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 Injection Site *[see Warnings and Precautions (5.2)]*
- Risks Associated with Use of Epinephrine in Certain Coexisting Conditions *[see Warning and Precautions (5.3)]*
- Allergic Reactions Associated with Sulfite *[see Warnings and Precautions (5.4)]*

Adverse Reactions from Postapproval Use of Epinephrine Products

The following adverse reactions associated with use of epinephrine have been identified in observational trials, case reports, studies, or postmarketing reports. Because these reactions are 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, vomiting

Infections: Clostridial infections (gas gangrene)

Metabolism and Nutrition Disorders: transient hyperglycemia, sweating

Neurological: disorientation, impaired memory, panic, psychomotor agitations, sleepiness, tingling, weakness, hypoesthesia, dizziness, tremor, 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, tripelennamine, 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. Epinephrine is first-line treatment of anaphylaxis and 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, resulted in adverse developmental effects (including gastroschisis and embryonic lethality) at doses approximately 4 times the maximum recommended daily intramuscular, subcutaneous, or intravenous dose *(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 United States 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 pregnant rabbits dosed during the period of organogenesis (on days 3 to 5, 6 to 7 or 7 to 9 of gestation), epinephrine caused teratogenic effects (including gastroschisis) at doses approximately 40 times the maximum recommended intramuscular, subcutaneous, or intravenous dose (on a mg/m^2 basis at a maternal subcutaneous dose of 1.2 mg/kg/day for two to three days). Animals treated on days 6 to 7 had decreased number of implantations.

In an embryofetal development study, pregnant mice were administered epinephrine (0.1 to 10 mg/kg/day) on Gestation Days 6 to 15. Teratogenic effects and embryonic lethality were observed at approximately 8 times the maximum recommended intramuscular, subcutaneous, or intravenous dose (on a mg/m^2 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^2 basis at a subcutaneous maternal dose of 0.5 mg/kg/day for 10 days).

In an embryofetal development study with pregnant hamsters dosed during the period of organogenesis from gestation days 7 to 10, epinephrine produced reductions in litter size at doses approximately 7 times the maximum recommended intramuscular, subcutaneous, or intravenous dose (on a mg/m^2 basis at a maternal subcutaneous dose of 0.5 mg/kg/day).

8.2 Lactation

Risk Summary

There are no data on the presence of epinephrine in human milk, the effects on the breastfed infant, or the effects on human 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 EpiPen and EpiPen Jr 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 EpiPen or EpiPen Jr 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 EpiPen and EpiPen Jr are fixed, consider using other forms of injectable epinephrine if doses lower than 0.15 mg are deemed necessary.

The safety and effectiveness of EpiPen or EpiPen Jr have not been established in pediatric patients who weigh less than 15 kg.

8.5 Geriatric Use

Clinical studies of EpiPen or EpiPen Jr for the emergency treatment of type I allergic reactions, including anaphylaxis, were not conducted in subjects aged 65 and over to determine whether they respond differently from younger adult subjects. 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 a greater risk for developing adverse reactions after epinephrine administration *[see Overdosage (10)]*.

10 OVERDOSAGE

Overdosage of epinephrine may 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 α-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

EpiPen (epinephrine injection, USP) 0.3 mg and EpiPen Jr (epinephrine injection, USP) 0.15 mg are single-dose auto-injectors and combination products containing drug and device components.

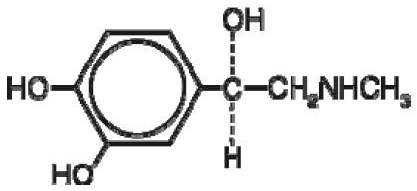
Each EpiPen Auto-Injector, 0.3 mg delivers a single dose of 0.3 mg epinephrine from epinephrine injection, USP 0.3 mg/0.3 mL in a sterile solution.

Each EpiPen Jr Auto-Injector, 0.15 mg delivers a single dose of 0.15 mg epinephrine from epinephrine injection, USP 0.15 mg/0.3 mL in a sterile solution.

Each 0.3 mL in the EpiPen Auto-Injector contains 0.3 mg epinephrine, 0.15 mg edetate disodium, 1.8 mg sodium chloride, 0.53 mg sodium citrate, 0.3 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0.

Each 0.3 mL in the EpiPen Jr Auto-Injector contains 0.15 mg epinephrine, 0.15 mg edetate disodium, 1.8 mg sodium chloride, 0.26 mg sodium citrate, 0.3 mg sodium metabisulfite, hydrochloric acid 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-α-[(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 EpiPen and EpiPen Jr if the epinephrine solution appears discolored (pinkish or brown color), cloudy, or contains particles.

Thoroughly review the patient instructions and operation of EpiPen or EpiPen Jr with patients and caregivers prior to use *[see Patient Counseling Information (17)]*.

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 alleviates pruritus, urticaria, and angioedema. It may also 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

- EpiPen (epinephrine) injection is a clear and colorless solution for intramuscular or subcutaneous use.
- EpiPen Jr (epinephrine) injection is a clear and colorless solution for intramuscular or subcutaneous use.
- EpiPen and EpiPen Jr is available as an auto-injector as described in Table 2.

Table 2. EpiPen and EpiPen Jr Auto-Injectors Package Configurations and Strengths

Package Configuration	Strength	NDC
EpiPen: 2 single-dose prefilled auto-injectors and 1 auto-injector trainer	0.3 mg/0.3 mL	NDC 49502-461-02
EpiPen Jr: 2 single-dose prefilled auto-injectors and 1 auto-injector trainer	0.15 mg/0.3 mL	NDC 49502-462-02

Storage and Handling

- Protect from light. Epinephrine is light sensitive and should be stored in the outer carton provided to protect it from light.
- 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.
- 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 particle.
- Properly dispose all used, unwanted, expired or safety cap removed EpiPen and EpiPen Jr auto-injectors.

17 PATIENT COUNSELING INFORMATION

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

Administration Instructions

- EpiPen and EpiPen Jr is for single use and delivers the entire dose upon activation.
- Instruct patients to inspect the epinephrine solution visually through the clear window of the auto-injector periodically. Replace EpiPen and EpiPen Jr if the epinephrine solution appears discolored (pinkish or brown color), cloudy, or contains particles.
- Instruct caregivers to hold the leg of young children firmly in place and limit movement prior to and during injection to minimize the risk of lacerations, bent needles, and embedded needles *[see Warnings and Precautions (5.1)]*.
- Instruct patients and/or caregivers on proper intramuscular or subcutaneous injection technique using the EpiPen or EpiPen Jr Trainer. The Trainer may be used multiple times and patients and/or caregivers can reset the Trainer by replacing the safety cap.
- Instruct patients and/or caregivers in the appropriate use of EpiPen and EpiPen Jr. Inject EpiPen or EpiPen Jr into the middle of the outer thigh (through clothing, if necessary) *[see Dosage and Administration (2.2) and Instructions for Use].* To inject, patients should twist to remove safety cap, firmly push the orange tip of the auto-injector against the outer thigh and hold in place for 3 seconds.
- Instruct patients and/or caregivers when a second dose of EpiPen/EpiPen Jr is needed. Administer a new EpiPen or EpiPen Jr device into the middle of the outer thigh 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.

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, 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 (5.3)]*.

Storage and Handling

Epinephrine is light sensitive and should be stored in the carton provided to protect it from light. Instruct patients that EpiPen and EpiPen Jr must be used or properly disposed once the safety cap is removed or after use *[see Storage and Handling (16)]*.

Distributed by:
Viatris Specialty LLC
Morgantown, WV 26505 U.S.A.

Manufactured by:
Mylan Laboratories Limited
Bangalore, India

EpiPen® and EpiPen Jr® are registered trademarks of Mylan Inc., a Viatris Company.

U.S. Patent Nos. 11,793,938; 12,023,468; and 12,329,934

VSL:EPINE:RX5

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PATIENT INFORMATION

EPIPEN® [/epeepen/]
(epinephrine injection, USP) Auto-Injector 0.3 mg
EpiPen® = one dose of 0.3 mg epinephrine, USP 0.3 mg/0.3 mL

EPIPEN JR® [/epeepen/ /joonyer/]
(epinephrine injection, USP) Auto-Injector 0.15 mg
EpiPen Jr® = one dose of 0.15 mg epinephrine, USP 0.15 mg/0.3 mL

For allergic emergencies (anaphylaxis)

Read this Patient Information leaflet carefully before using the EpiPen or EpiPen Jr auto-injector and each time you get a refill. There may be new information. Anyone who may be able to administer the EpiPen or EpiPen Jr auto-injector 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 EpiPen and EpiPen Jr?

1. EpiPen and EpiPen Jr are single-dose automatic injection devices (auto-injectors) that contain epinephrine. Epinephrine 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. This allergic emergency can be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or 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. **Always carry 2 EpiPen or 2 EpiPen Jr auto-injectors** with you because sometimes a single dose of epinephrine may not be enough to treat a serious allergic reaction before seeking medical care. You also need to always carry 2 auto-injectors with you in case the first auto-injector is accidentally activated before the dose can be given. **A device that has been activated by accident cannot be used in an allergic emergency (anaphylaxis)**.

   Note: The EpiPen or EpiPen Jr auto-injector has been activated when the safety cap is removed and a “click” is heard, the orange needle end of the auto-injector is extended, or the medicine viewing window is blocked with a red indicator. These things can also happen if the

EpiPen or EpiPen Jr auto-injector is activated by accident. Do not remove the safety cap until you need to use the EpiPen or EpiPen Jr auto-injector, to help prevent accidental activation.

You may not know when anaphylaxis will happen. Talk to your healthcare provider if you need more auto-injectors to keep at work, school, or other locations. If you use 1 EpiPen or 1 EpiPen Jr to treat an emergency allergic reaction, be sure to replace it so you always carry 2 auto-injectors. Tell your family members, caregivers, and others where you keep your EpiPen or EpiPen Jr auto-injectors. 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 your EpiPen or EpiPen Jr auto-injector right away.**
   Get emergency help for further treatment of the anaphylactic episode, if needed, after using EpiPen or EpiPen Jr auto-injector. You can use a second EpiPen or EpiPen Jr auto-injector if symptoms continue or come back or if the first auto-injector is activated before the dose can be given. For this reason, you should carry 2 EpiPen or 2 EpiPen Jr auto-injectors with you at all times. If you need more than 2 doses for an allergic emergency, they must be given by a healthcare provider.

What are EpiPen and EpiPen Jr auto-injectors?

- EpiPen and EpiPen Jr auto-injectors are disposable, prefilled auto-injectors used to treat life-threatening, allergic emergencies in people who are at risk for or have a history of serious allergic emergencies. Each device contains 1 dose of epinephrine.
- EpiPen and EpiPen Jr auto-injectors are for immediate administration by you or your caregiver. They do not take the place of emergency medical care. You should get emergency help if needed after using your EpiPen or EpiPen Jr auto-injector.
- EpiPen and EpiPen Jr auto-injectors are for people who have been prescribed this medicine by their healthcare provider.
- The EpiPen (0.3 mg) auto-injector is for people who weigh 66 pounds or more (30 kilograms or more).
- The EpiPen Jr (0.15 mg) auto-injector is for people who weigh about 33 to 66 pounds (15 to 30 kilograms).
- It is not known if EpiPen and EpiPen Jr are safe and effective in children who weigh less than 33 pounds (15 kilograms).

What should I tell my healthcare provider before using EpiPen or EpiPen Jr?

Before you use your EpiPen or EpiPen Jr auto-injector, tell your healthcare provider about all your medical conditions. Your healthcare provider may give you more instructions about when and how to use EpiPen or EpiPen Jr if you have the following:

- heart problems or high blood pressure
- diabetes
- thyroid problems
- asthma
- a history of depression
- Parkinson’s disease

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.

Tell your healthcare provider about all of your known allergies.

Especially tell your healthcare provider if you take certain asthma medicines.

EpiPen or EpiPen Jr and other medicines may affect each other, causing side effects. EpiPen or EpiPen Jr may affect the way other medicines work. Other medicines may affect how EpiPen or EpiPen Jr works.

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 EpiPen or EpiPen Jr auto-injector for treatment of anaphylaxis as prescribed by your healthcare provider, regardless of your medical conditions or the medicines you take.

How should I use the EpiPen or EpiPen Jr auto-injector?

- Use your single-dose EpiPen or EpiPen Jr auto-injector exactly as your healthcare provider tells you to use it. You may need to use a second EpiPen or EpiPen Jr auto-injector if symptoms continue or come back while you wait for emergency help or if the first auto-injector is activated before the dose can be given. If you need more than 2 doses of epinephrine for a single anaphylaxis episode, more doses must be administered by a healthcare provider.
- EpiPen or EpiPen Jr should be injected into the middle of your outer thigh (upper leg). It can be injected through your clothing if needed. **Do not** inject into a vein or into the buttocks, fingers, toes, hands or feet.
- Read and make sure you understand the Instructions for Use to learn the right way to use the EpiPen and EpiPen Jr auto-injector.
- Your healthcare provider will show you how to safely use the EpiPen or EpiPen Jr auto-injector.
- **It is very important that you hold the EpiPen or EpiPen Jr auto-injector down firmly on the middle of the outer thigh (upper leg) for at least 3 full seconds. If you do not hold it in place long enough, the EpiPen or EpiPen Jr auto-injector might not have time to deliver the correct dose of medicine.**
- **Caution: Never put your thumb, fingers or hand over the orange needle end.** Never press or push the orange needle end with your thumb, fingers or hand. The needle comes out of the orange needle end. Accidental injection into fingers, hands or feet may cause a loss of blood flow to these areas. If an accidental injection happens, give a second dose of EpiPen or EpiPen Jr, and go immediately to the nearest emergency room.
- **Warning: A device that has been activated by accident cannot be used in an allergic emergency (anaphylaxis).** If this happens, replace it with a new EpiPen or EpiPen Jr.
- Your EpiPen and EpiPen Jr auto-injector may come in a package with a gray trainer and separate Trainer Instructions for Use. The gray trainer contains no medicine and no needle. Keep the trainer and the real EpiPen and EpiPen Jr auto-injectors away from young children. The real EpiPen and EpiPen Jr auto-injectors and trainer are not toys. For young children, use of the trainer and the real EpiPen and EpiPen Jr auto-injectors should be supervised by an adult. Regularly practice with your gray trainer in non-emergency situations to make sure you can safely use the real EpiPen or EpiPen Jr auto-injector in an emergency. Always carry your 2 real EpiPen or EpiPen Jr auto-injectors with you in case of an allergic emergency. Additional training information is available at **www.epipen.com**.
- Do not drop the EpiPen auto-injector or EpiPen Jr auto-injector. If damage or leakage is noticed or suspected, throw away (dispose of) the EpiPen or EpiPen Jr auto-injector and replace it.

What are the possible side effects of EpiPen or EpiPen Jr?

EpiPen and EpiPen Jr may cause serious side effects.

- EpiPen or EpiPen Jr should only be injected into the middle of your outer thigh (upper leg). Do not inject EpiPen or EpiPen Jr into your:
  - veins
  - buttocks

- fingers, toes, hands or feet

  A second dose of epinephrine is needed if you accidentally inject EpiPen or EpiPen Jr into the buttock and symptoms continue or return, or you accidentally inject EpiPen or EpiPen Jr into the fingers, hands or feet. If you accidentally inject EpiPen or EpiPen Jr into any place other than the middle of your outer thigh, go to the nearest emergency room right away. Tell the healthcare provider where on your body you received the accidental injection.
- Rarely, people who have used the EpiPen or EpiPen Jr auto-injector may get infections at the injection site within a few days of an injection. Some of these infections can be serious. Call your healthcare provider right away if you see any of the following at an injection site:
  - redness that does not go away
  - swelling
  - tenderness
  - the area feels warm to the touch
- If you inject a young child with an EpiPen or EpiPen Jr auto-injector, hold their leg firmly in place before and during the 3 second injection to prevent injuries like cuts on the skin, bent needles and needles that remain in the skin. Follow the Instructions for Use for the right way to use the EpiPen and EpiPen Jr auto-injector. Ask your healthcare provider to show you how to:
  1. Hold the young child firmly in place (restrain).
  2. With 1 hand, grip the auto-injector with the orange needle end pointing down.
  3. With the other hand, twist to remove the safety cap.
- If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you use your EpiPen or EpiPen Jr auto-injector. Talk to your healthcare provider about all your medical conditions.

Common side effects of EpiPen and EpiPen Jr include:
- fast, irregular or “pounding” heartbeat
- sweating
- headache
- weakness
- shakiness
- paleness
- feelings of over 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 EpiPen or EpiPen Jr. 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.

How should I store EpiPen or EpiPen Jr auto-injectors?

- Store EpiPen and EpiPen Jr auto-injectors at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep this medicine out of the sight and reach of young children.
- Keep in the outer carton to protect from light. When exposed to air or light, epinephrine changes quickly to a pinkish or brown color and should not be used.
- Do not expose to extreme cold or heat. For example, do not store in your vehicle’s glove box or trunk. Do not store in the refrigerator or freezer.

- Examine the contents in the medicine viewing window of your EpiPen or EpiPen Jr auto-injector regularly. The medicine should be clear. If the medicine is discolored (pinkish or brown color) or contains solid particles, replace the auto-injector.
- Always keep your 2 EpiPen or 2 EpiPen Jr auto-injectors in the outer carton to prevent damage to the device.
- The safety cap helps to prevent accidental injection. Keep the safety cap in place until you need to use the EpiPen or EpiPen Jr auto-injector.

Disposing of an Expired, Unused or Used EpiPen or EpiPen Jr Auto-Injector

Your EpiPen or EpiPen Jr auto-injector has an expiration date. Replace the pack of auto-injectors before the expiration date. Throw away (dispose of) expired, unwanted, or unused EpiPen and EpiPen Jr auto-injectors in an FDA-cleared sharps disposal container right away after use. Do not throw away the EpiPen or EpiPen Jr 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, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal

Visit the FDA's website (https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know) for more information about how to throw away unused, unwanted or expired medicines.

After using your EpiPen or EpiPen Jr auto-injector in an allergic emergency, get emergency medical help right away. Take your used EpiPen or EpiPen Jr auto-injector with you to give to your healthcare provider for disposal.

General information about the safe and effective use of EpiPen and EpiPen Jr auto-injectors.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use the EpiPen or EpiPen Jr auto-injector for a condition for which it was not prescribed. Do not give your EpiPen or EpiPen Jr auto-injector to other people.

This Patient Information leaflet summarizes the most important information about the EpiPen and EpiPen Jr auto-injectors. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about EpiPen and EpiPen Jr auto-injectors that is written for health professionals.

What are the ingredients in EpiPen and EpiPen Jr?

Active Ingredients: epinephrine
Inactive Ingredients: edetate disodium, sodium chloride, sodium citrate, sodium metabisulfite, hydrochloric acid, and water

Important Information

- The EpiPen auto-injector has a yellow colored label.
- The EpiPen Jr auto-injector has a green colored label.

- Your EpiPen or EpiPen Jr auto-injector is designed to work through clothing.
- **It is very important that you hold the EpiPen or EpiPen Jr auto-injector down firmly on the middle of the outer thigh (upper leg) for at least 3 full seconds. If you do not hold it in place long enough, the EpiPen or EpiPen Jr auto-injector might not deliver the correct dose of medicine.**
- If an accidental injection happens, get emergency medical help right away.
- Each EpiPen or EpiPen Jr auto-injector can be used only 1 time (single-use). The auto-injectors deliver a fixed dose of epinephrine and cannot be reused. Do not try to reuse EpiPen or EpiPen Jr after the device has been activated. The correct dose has been administered if the orange needle end is extended to cover the needle and the medicine viewing window is blocked with a red indicator.
- **Incorrect Use and Correct Use of EpiPen and EpiPen Jr**

Incorrect Use	**Correct Use and Important Reminders**
Storage outside the outer carton or storage of the EpiPen or EpiPen Jr auto-injector in extreme cold or heat.	Always keep your EpiPen or EpiPen Jr stored at room temperature and in the outer carton to protect from light. Wrong storage may stop the EpiPen or EpiPen Jr from working. If the device has been in extreme cold or heat, the EpiPen or EpiPen Jr should be replaced.
Failing to remove the safety cap before use.	Remove the safety cap before use. EpiPen or EpiPen Jr will not activate with the safety cap in place.
Activating the auto-injector upside down which will cause an injection into the hand.	The needle exits from the orange end of the EpiPen and EpiPen Jr auto-injector, which should be in contact with the outer thigh (upper leg) at a 90˚angle (perpendicular) to the thigh before and during activation. The orange needle end will extend to cover the needle after activation. If you can still see the needle, do not try to reuse the auto-injector.
Failing to apply enough force to activate the EpiPen or EpiPen Jr auto-injector.	EpiPen and EpiPen Jr should be administered by pushing the auto-injector firmly against the outer thigh. EpiPen and EpiPen Jr auto-injectors make a distinct click sound when pushed against the thigh. The click sound signals that the injection has started. The correct dose has been administered if the orange needle end is extended and the window is blocked with a red indicator.
Administering at an injection site other than the outer thigh.	Administer EpiPen or EpiPen Jr in the outer thigh only.
Failing to hold the auto-injector in place for a full 3 seconds.	Hold the EpiPen or EpiPen Jr auto-injector in place for a full 3 seconds following activation (count slowly 1, 2, 3).

For more information and video instructions on the use of EpiPen and EpiPen Jr auto-injectors, go to **www.epipen.com** or call 1-800-395-3376.

Distributed by: Viatris Specialty LLC, Morgantown, WV 26505 U.S.A.
Manufactured by: Mylan Laboratories Limited, Bangalore, India

U.S. Patent Nos. 11,793,938; 12,023,468; and 12,329,934

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 3/2026

VSL:PL:EPINE:RX2

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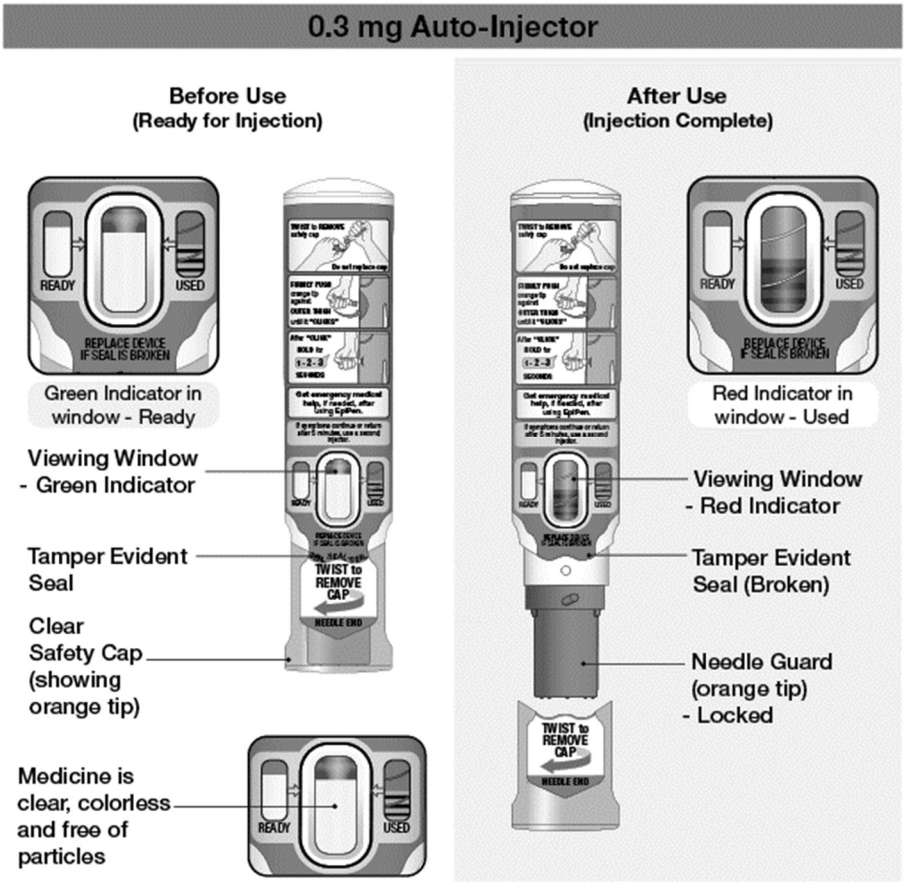
INSTRUCTIONS FOR USE

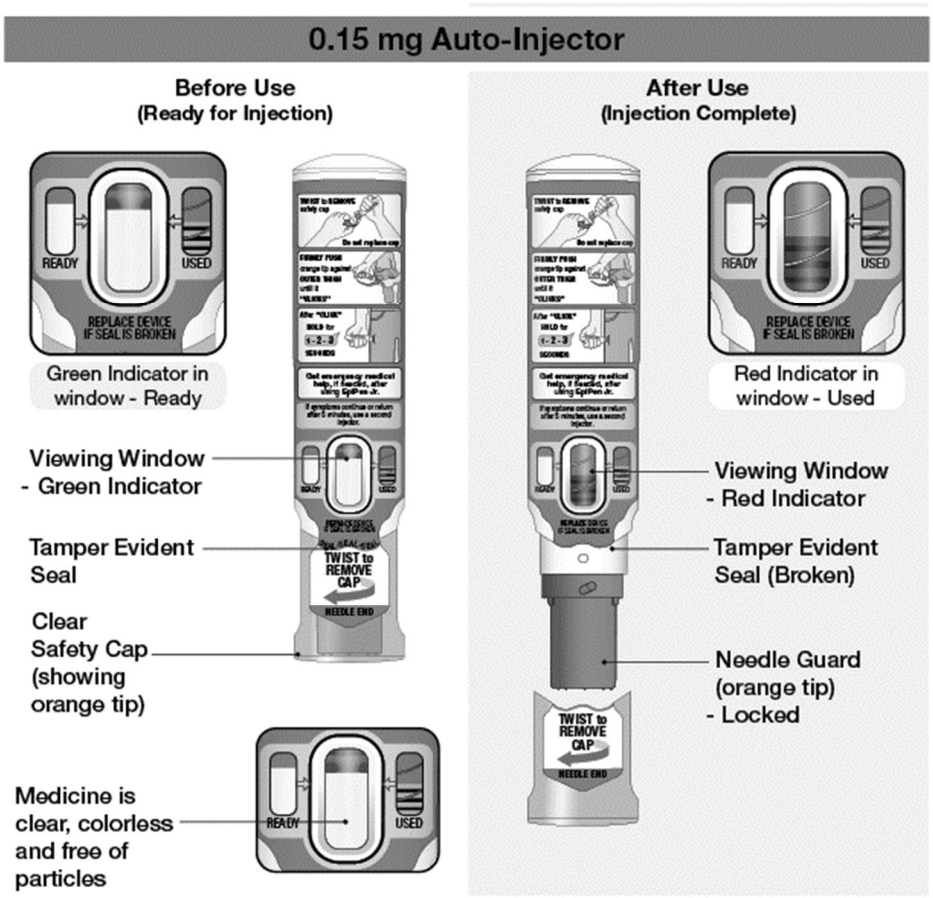
EPIPEN® [/epeepen/]
(epinephrine injection, USP) Auto-Injector 0.3 mg
EpiPen® = one dose of 0.3 mg epinephrine, USP 0.3 mg/0.3 mL
for intramuscular or subcutaneous use

EPIPEN JR® [/epeepen/ /joonyer/]
(epinephrine injection, USP) Auto-Injector 0.15 mg
EpiPen Jr® = one dose of 0.15 mg epinephrine, USP 0.15 mg/0.3 mL
for intramuscular or subcutaneous use

For Allergic Emergencies (Anaphylaxis)

Read this Instructions for Use carefully before you use your EpiPen or EpiPen Jr auto-injector. Before you need to use your EpiPen or EpiPen Jr auto-injector, make sure a healthcare provider shows you the right way to use it. Parents, caregivers, and others who may be in a position to administer EpiPen or EpiPen Jr auto-injector should also understand how to use it as well.
If you have any questions, ask a healthcare provider.





Important Information - Before Use:

- Your EpiPen or EpiPen Jr auto-injectors may come packed with an EpiPen trainer. The trainer has a gray color. The gray trainer contains no medicine and no needle.
- Practice with your gray trainer periodically, but always carry your EpiPen or EpiPen Jr auto-injectors in case of an allergic emergency (anaphylaxis).
- Store your trainer in a different location to your EpiPen or EpiPen Jr auto-injectors to avoid any risk of mix-up at time of allergic emergency.
- If you will be administering EpiPen Jr to a young child, ask a healthcare provider to show you how to properly hold the leg in place while administering a dose.
- Do not try to take the EpiPen or EpiPen Jr auto-injectors apart.
- Do not drop the EpiPen or EpiPen Jr auto-injector. If the auto-injector is dropped, check for damage and leakage. Contact your healthcare provider to replace the auto-injector if damage or leakage is noticed or suspected.
- **Keep the EpiPen or EpiPen Jr auto-injectors and all medicines out of the reach of children.**
- An overdose of epinephrine could cause harm, do not administer a second dose unless symptoms continue or return after the first dose, or you accidentally inject EpiPen or EpiPen Jr into the fingers, toes, hands or feet. If a second dose is needed, give the second dose with a new auto-injector starting 5 minutes after the first dose.

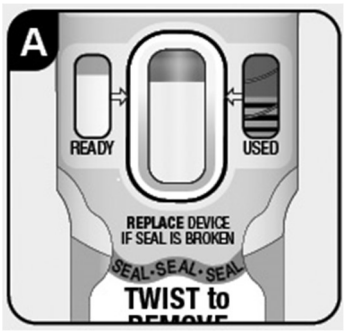
Storage:

- Store your EpiPen or EpiPen Jr auto-injectors at room temperature between 68°F to 77°F (20°C to 25°C).
- Store in the outer carton that comes with your EpiPen or EpiPen Jr auto-injectors, to protect from light.

- Do not expose to extreme cold or heat. For example, **do not** store in your vehicle's glove box and **do not** store in the refrigerator or freezer.

Inspect Your Auto-Injector:

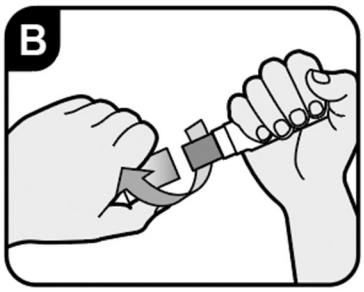
- Check the medicine through the auto-injector viewing window (See Figure A) and make sure the medicine is clear, colorless and free of particles. Do not use the medicine if it is discolored (pinkish or brown color), cloudy, or has particles floating in it. Replace the auto-injector if this happens.
- Check the tamper evident seal (See Figure A), for signs of tampering. Replace the auto-injector if the seal is broken.
- Check the expiration date located in the black panel on the side of your EpiPen or EpiPen Jr auto-injector. Replace the auto-injector if the expiration date has passed.



A dose of EpiPen or EpiPen Jr auto-injector requires 3 steps: Prepare, Administer and Get emergency help if needed.

Step 1: Prepare

1.1 Remove auto-injector from carton.
1.2 Read instructions on the auto-injector label.
1.3 Twist to remove safety cap (See Figure B).
Do not remove safety cap if not preparing for an injection.

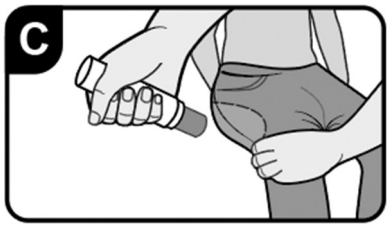


Note:

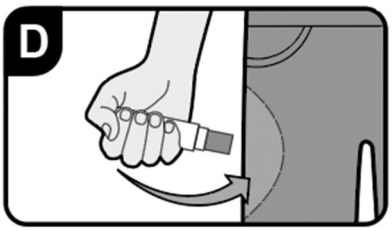
- The safety cap is made to fit tightly. Twist firmly to remove.
Do not replace the safety cap after it is removed.
- To avoid an accidental injection, never put your thumb, fingers or hand over the orange tip.
- Do not inject EpiPen or EpiPen Jr into your:
  - veins
  - buttocks
  - fingers, toes, hands or feet
- **If you accidentally inject EpiPen or EpiPen Jr into the buttock and symptoms continue or return, or you accidentally inject EpiPen or EpiPen Jr into the fingers, hand or feet, give a second dose in the outer thigh and get medical help right away**.

Step 2: Administer

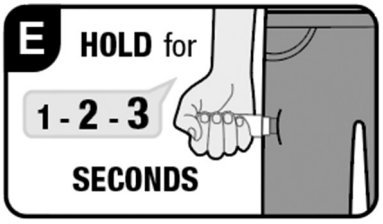
2.1 Hold leg firmly in place (if administering to child) (See Figure C).



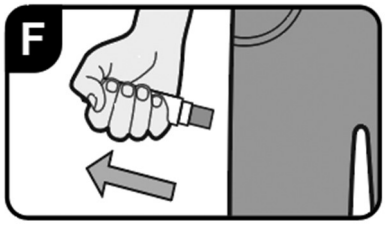
2.2 Firmly push the orange tip of the auto-injector against the **outer thigh** until you hear a click (See Figure D).
The click signals that the injection has started.



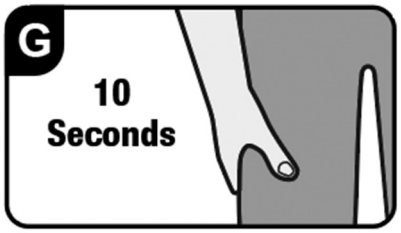
2.3 Hold in place for **3 seconds** (count slowly 1, 2, 3) (See Figure E).
The injection is now complete.



2.4 Remove auto-injector from injection site (See Figure F). The orange tip will extend to cover the needle.



2.5 Massage injection site for 10 seconds (See Figure G).



Step 3: Get emergency help if needed

3.1 Get emergency help for further treatment of the anaphylactic episode, if needed, after using EpiPen or EpiPen Jr. Before you receive EpiPen or EpiPen Jr, your healthcare provider should talk to you about when to get emergency help.

Remember you may need a second auto-injector

- A second dose of epinephrine is needed if you accidentally inject EpiPen or EpiPen Jr into the buttock and symptoms continue or return, or you accidentally inject EpiPen or EpiPen Jr into the fingers, hands or feet. If needed, give the dose with a second auto-injector starting 5 minutes after the first dose.
- Two auto-injectors should always be carried in case a second dose is required.

Important Information - After Use:

- EpiPen and EpiPen Jr auto-injectors are single-use injectable devices that deliver a fixed dose of epinephrine.
- **The auto-injector cannot be reused.** Do not attempt to reuse EpiPen or EpiPen Jr after the auto-injector has been activated.
- After the auto-injector has been used, the safety cap cannot be replaced.
- The correct dose has been administered if the orange needle tip is extended and the viewing window is blocked with a red indicator.

Dispose and Replace:

- Take your used EpiPen or EpiPen Jr auto-injector to a healthcare provider for inspection and proper disposal.
- Tell a healthcare provider that you have received an injection of epinephrine. Show a healthcare provider where you received the injection.
- Ask for a refill, if needed.

Distributed by: Viatris Specialty LLC, Morgantown, WV 26505 U.S.A.
Manufactured by: Mylan Laboratories Limited, Bangalore, India

U.S. Patent Nos. 11,793,938; 12,023,468; and 12,329,934

This Instructions for Use has been approved by the U.S. Food and Drug Administration. Revised: 3/2026

VSL:IFU:EPINE:RX4

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OVERCODING AREA

NO VARNISH ZONE

- Following details also shall be overprinted along with batch details:

GTIN:
S/N
EXP: YYYY-MM
LOT: XXXXXXX

Font size of the lot number and Expiry date should be minimum of "6 points"

NDC 49502-**461**-02

EpiPen®
(epinephrine injection, USP)

0.3 mg/0.3 mL

Sterile
For Intramuscular or Subcutaneous Use

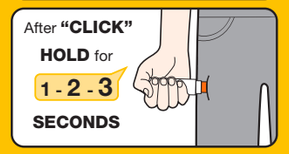
2 x 0.3 mg Single-Dose Auto-Injectors

For Allergic Emergencies (Anaphylaxis)

Patients greater than or equal to 30 kg (66 lbs)

Always carry two auto-injectors.

How To Use



Get emergency medical help, if needed, after using **EpiPen.**

If symptoms continue or return after 5 minutes, use a second injector.

Two auto-injectors should always be carried in case a second dose is required.

See enclosed leaflet for complete instructions for use.

Replace if medicine is discolored.

Store at 68°F to 77°F (20°C to 25°C).
Do not refrigerate or freeze.
Protect from heat and light.

VIATRIS™

Each EpiPen® delivers 0.3 mg epinephrine from epinephrine injection, USP 0.3 mg/0.3 mL. Each 0.3 mL also contains 0.15 mg edetate disodium, 1.8 mg sodium chloride, 0.53 mg sodium citrate and 0.3 mg sodium metabisulfite.

Recommended Dosage: See Prescribing Information.

The EpiPen auto-injector and Trainer are not toys and should be used under adult supervision.

Never put thumb, fingers or hand over orange tip.

NDC 49502-461-02

Distributed by:
Viatris Specialty LLC
Morgantown, WV 26505 U.S.A.

Made in India

Code No.: XXX/XXXX/XX/XXXX/XXXXX

EPIPEN is a registered trademark of Mylan Inc., a Viatris Company.

U.S. Patent Nos. 11,793,938; 12,023,468; and 12,329,934

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OPEN HERE

OPEN HERE

SEPARATE

NDC 49502-**461**-02

EpiPen®
(epinephrine injection, USP)

0.3 mg/0.3 mL

Sterile
For Intramuscular or Subcutaneous Use

New Device Read Trainer Instructions for Use Before Using

2 x 0.3 mg Single-Dose Auto-Injectors

For Allergic Emergencies (Anaphylaxis)

Patients greater than or equal to 30 kg (66 lbs)

Always carry two auto-injectors. Store in their supplied carton.

Rx only

VIATRIS™

SEPARATE

TRAINER
FOR PRACTICE ONLY

New Device Read Trainer Instructions for Use Before Using

1 x Trainer

Store your trainer separate to your auto-injectors.

TRAINER
FOR PRACTICE ONLY

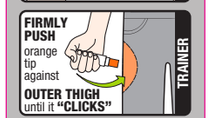
1 x Trainer

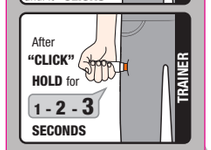
Separate the trainer and store in a different location to your EpiPen auto-injectors to avoid any risk of mix-up at a time of emergency.

TRAINER
FOR PRACTICE ONLY

How To Use

CONTAINS:
- **NO MEDICINE**
- **NO NEEDLE**





TO RESET TRAINER

See enclosed leaflet for complete instructions for use.

TRAINER
FOR PRACTICE ONLY

1 x Trainer

Store your trainer separate to your auto-injectors.

NDC 49502-**461**-02

EpiPen®
(epinephrine injection, USP)

0.3 mg/0.3 mL

Scan to learn more

TRAINER
FOR PRACTICE ONLY

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NDC 49502-462-02

EpiPen Jr®
(epinephrine injection, USP)

0.15 mg/0.3 mL

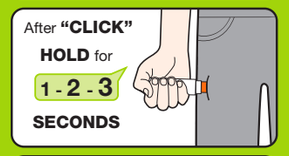
Sterile
For Intramuscular or Subcutaneous Use

2 x 0.15 mg Single-Dose Auto-Injectors

For Allergic Emergencies (Anaphylaxis)
Patients 15 to 30 kg (33 to 66 lbs)

Always carry two auto-injectors.

How To Use



Get emergency medical help, if needed, after using **EpiPen Jr.**

If symptoms continue or return after 5 minutes, use a second injector.

Two auto-injectors should always be carried in case a second dose is required.

See enclosed leaflet for complete instructions for use.

Replace if medicine is discolored.

Store at 68°F to 77°F (20°C to 25°C).
Do not refrigerate or freeze.
Protect from heat and light.

VIATRIS™

OVERCODING AREA
NO VARNISH ZONE
• Following details also shall be overprinted along with batch details:

GTIN:
S/N
EXP: YYYY-MM
LOT: XXXXXXX

Font size of the lot number and Expiry date should be minimum of "6 points"

Each EpiPen Jr® delivers 0.15 mg epinephrine from epinephrine injection, USP 0.15 mg/0.3 mL. Each 0.3 mL also contains 0.15 mg edetate disodium, 1.8 mg sodium chloride, 0.26 mg sodium citrate and 0.3 mg sodium metabisulfite.

Recommended Dosage: See Prescribing Information.

The EpiPen Jr auto-injector and Trainer are not toys and should be used under adult supervision.

Never put thumb, fingers or hand over orange tip.

3 49502-462-02 3

Distributed by:
Viatris Specialty LLC
Morgantown, WV 26505 U.S.A.

Made in India
Code No.: XXX/XXXX/XX/XXXX/XXXXX

U.S. Patent Nos. 11,793,938; 12,023,468; and 12,329,934
VSL:46202:2C:1T:RX3 1xxxxxx

OPEN HERE OPEN HERE

SEPARATE

NDC 49502-462-02

EpiPen Jr®
(epinephrine injection, USP)
0.15 mg/0.3 mL
Sterile
For Intramuscular or Subcutaneous Use

New Device
Read Instructions for Use Before Using

2 x 0.15 mg Single-Dose Auto-Injectors

For Allergic Emergencies (Anaphylaxis)
Patients 15 to 30 kg (33 to 66 lbs)

Always carry two auto-injectors. Store in their supplied carton.

Rx only

VIATRIS™

SEPARATE

NDC 49502-462-02

EpiPen Jr®
(epinephrine injection, USP)
0.15 mg/0.3 mL

Scan to learn more

TRAINER
FOR PRACTICE ONLY

TRAINER
FOR PRACTICE ONLY

New Device
Read Trainer Instructions for Use Before Using

1 x Trainer

Store your trainer separate to your auto-injectors.

TRAINER
FOR PRACTICE ONLY

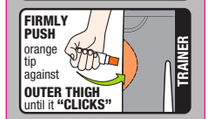
1 x Trainer

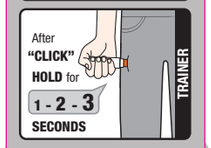
Separate the trainer and store in a different location to your EpiPen Jr auto-injectors to avoid any risk of mix-up at a time of emergency.

TRAINER
FOR PRACTICE ONLY

How To Use

CONTAINS:
• **NO MEDICINE**
• **NO NEEDLE**





See enclosed leaflet for complete instructions for use.

1 x Trainer

Store your trainer separate to your auto-injectors.

TRAINER
FOR PRACTICE ONLY

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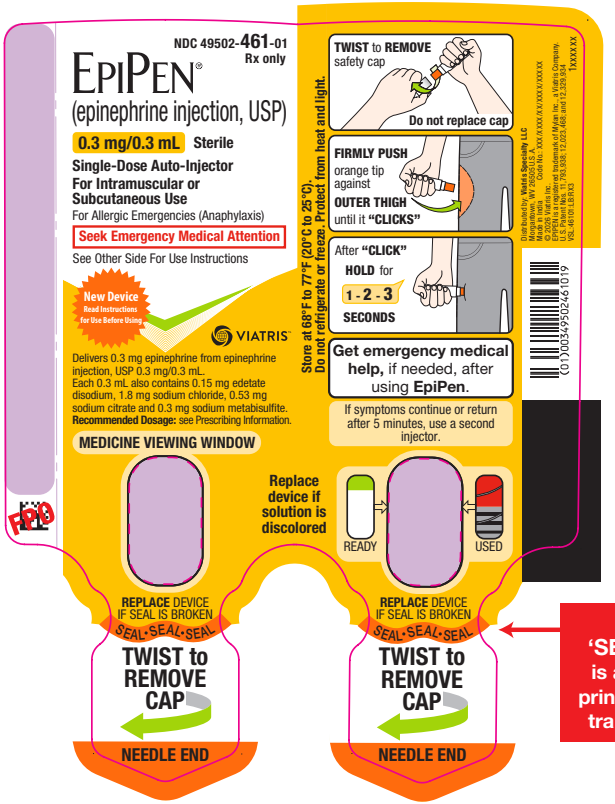

Prompt "LOT" & "EXP" will be printed along with Variable Data Coding online (see e.g. below)

LOT: XXXXXXX
EXP: YYYY-MM

NOTE
'SEAL · SEAL · SEAL' is a pattern created by printer and should not be translated from english

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

KELLY D STONE
03/19/2026 02:34:52 PM