EpiPen® Auto-Injector: The #1 prescribed brand for 25+ years*

Over the years, doctors have prescribed EpiPen® Auto-Injector more than any other brand of epinephrine auto-injector for those at increased risk for anaphylaxis.* Anaphylaxis (an-a-fil-a-sis) is the medical term for a life-threatening allergic reaction. It can occur minutes after your immune system mistakenly overreacts to an allergen. Know what symptoms to look for.

DO YOU KNOW THE SIGNS AND SYMPTOMS OF ANAPHYLAXIS?

MOUTH
• Itching
• Swelling of lips and/or tongue

THROAT
• Itching
• Tightness/closure
• Coughing

LUNGS
• Shortness of breath
• Wheezing

HEART
• Weak pulse
• Passing out
• Dizziness

SKIN
• Itching
• Redness
• Hives
• Swelling

STOMACH
• Vomiting
• Nausea
• Diarrhea
• Cramps

WHAT CAUSES ANAPHYLAXIS?
Anaphylaxis can be triggered by a number of allergens, including:

PEANUTS  TREE NUTS  MILK  EGGS  SHELLFISH  FISH  WHEAT  SOY  INSECTS  MEDICATIONS  LATEX  EXERCISE

LIFE HAPPENS. Be Prepared.*
Being prepared means having a plan to:
• Avoid known allergens
• Know what symptoms to watch for
• Use an EpiPen® (epinephrine injection, USP) Auto-Injector if a life-threatening allergic reaction occurs
• Get emergency medical help right away

IMPORTANT SAFETY INFORMATION
Use EpiPen® (epinephrine injection, USP) 0.3 mg or EpiPen Jr® (epinephrine injection, USP) 0.15 mg Auto-Injectors right away when you have an allergic emergency (anaphylaxis).
Get emergency medical help right away. You may need further medical attention. Only a healthcare professional should give additional doses of epinephrine if you need more than two injections for a single anaphylactic episode. EpiPen® or EpiPen Jr® should only be injected into the midline of your outer thigh (upper leg), through clothing if necessary. Do not inject into your veins, buttocks, fingers, toes, hands or feet. Hold the leg of young children firmly in place before and during injection to prevent injuries. In case of accidental injection, please seek immediate medical treatment.

Rarely, patients who have used EpiPen® or EpiPen Jr® may develop an infection at the injection site within a few days. Some of these infections can be serious. Call your healthcare professional right away if you have any of the following at an injection site: redness that does not go away, swelling, tenderness, or the area feels warm to the touch.

Tell your healthcare professional about all of your medical conditions, especially if you have asthma, a history of depression, thyroid problems, Parkinson's disease, diabetes, high blood pressure or heart problems, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Be sure to tell your healthcare professional all the medicines you take, especially medicines for asthma. If you have certain medical conditions, your condition may get worse or you may have longer lasting side effects when you use EpiPen® or EpiPen Jr®.

For more information, visit epipen.com.

IMPORTANT SAFETY INFORMATION (continued)
Common side effects include fast, irregular or "bounding" heartbeat, sweating, nausea or vomiting, breathing problems, paleness, dizziness, weakness, shakiness, headache, feelings of over excitement, nervousness or anxiety. These side effects usually go away quickly if you lie down and rest. Tell your healthcare professional if you have any side effect that bothers you or that does not go away.

Please see accompanying full Prescribing Information and Patient Information.

INDICATIONS
EpiPen® and EpiPen Jr® Auto-Injectors are for the emergency treatment of life-threatening allergic reactions (anaphylaxis) caused by allergens, exercise, or unknown triggers, and for people who are at increased risk for these reactions. EpiPen® and EpiPen Jr® are intended for immediate administration as emergency supportive therapy only. Seek immediate emergency medical help right away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional information, please contact us at 800-385-3376.
HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use EPINEPH® and EPINEPH Jr. safely and effectively. See full prescribing information for EPINEPH® and EPINEPH Jr., and EPINEPH (epinephrine injection, USP), Auto-Injector 0.3 mg, EPINEPH (epinephrine injection, USP) Auto-Injector 0.15 mg, for intramuscular or subcutaneous use initial U.S. Approval: 1939

RECENT MAJOR CHANGES
• Dosage and Administration (2) 05/2016
• Warnings and Precautions (5.2, 5.3) 05/2016

INDICATIONS AND USAGE
EPINEPH® and EPINEPH Jr. contain epinephrine, a non-selective alpha and beta-adrenergic receptor agonist. Indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis. (1)

DOSAGE AND ADMINISTRATION
Patients greater than or equal to 30 kg (66 lbs): EPINEPH® 0.3 mg (2)
Patients 15 to 30 kg (33 lbs to 66 lbs): EPINEPH Jr. 0.15 mg (2)
Inject EPINEPH® and EPINEPH Jr. Intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-use injection. (2)

DOSAGE FORMS AND STRENGTHS
• EPINEPH®: Injection, 0.3 mg: 0.3 mg/0.3 mL epinephrine, USP, pre-filled auto-injector (2)
• EPINEPH Jr.: Injection, 0.15 mg: 0.15 mg/0.3 mL epinephrine, USP, pre-filled auto-injector (2)

CONTRAINDICATIONS
None (4)

WARNINGS AND PRECAUTIONS
• In conjunction with food, seek immediate medical or hospital care (5.1)
• Do not inject intravenously, into buttock, or into digits, hands, or feet. (5.2)
• To minimize the risk of injection-related injury, instruct caregivers to hold the child's leg firmly in place and limit movement prior to and during injection when administering to young children. (5.2)
• 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, (5.3)
• The presence of a sulfa in this product should not dilute users. (5.4)
• Administer only in patients with heart disease; may aggravate angina pectoris or produce ventricular arrhythmias. (5.5)

ADVERSE REACTIONS
Adverse reactions to epinephrine include anxiety, apprehension, excitement, trembling, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Mylan Specialty, L.P. at 1-877-746-3773 (1-877-4-INFO-RX) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
• Cardiac glycosides or diuretics: observe for development of cardiac arrhythmias. (7)
• Tryptoctyline antispasmodics, monoamine oxidase inhibitors, levodopine sodium, and certain antihistamines: potentiate effects of epinephrine. (7)
• Beta-adrenergic blocking drugs: antagonize cardiostimulating and bronchodilating effects of epinephrine. (7)
• Alpha-adrenergic blocking drugs: antagonize vasocostraining and hypertensive effects of epinephrine. (7)
• Ergot alkaloids: may reverse thepressor effects of epinephrine. (7)

USE IN SPECIFIC POPULATIONS
Elderly patients may be at greater risk of developing adverse reactions. (5.2, 5.5)
See 17 for PATIENT COUNSELING INFORMATION and FDA approved patient labeling

Revised: May 2016

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
Epinephrine USP 0.3 mg or 0.15 mg are indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis [e.g., urticaria, angioedema] and certain anaphylactic reactions such as anaphylactoid reactions induced by serum, insect venom, latex or plant products. (1.1, 1.2, 1.3)

2 DOSAGE AND ADMINISTRATION
Selection of the appropriate dosage strength for EPINEPH® 0.3 mg or EPINEPH Jr. 0.15 mg is determined according to patient body weight. (2.1)

Each EPINEPH® or EPINEPH Jr. contains a single dose of epinephrine for single-use injection. (2.2)

3 DOSAGE FORMS AND STRENGTHS
• EPINEPH®: Injection, 0.3 mg/0.3 mL epinephrine injection, USP, pre-filled auto-injector (2)
• EPINEPH Jr.: Injection, 0.15 mg/0.3 mL epinephrine injection, USP, pre-filled auto-injector (2)

4 CONTRAINDICATIONS
None (4)

5 WARNINGS AND PRECAUTIONS
5.1 Emergency Treatment
Epinephrine USP 0.3 mg or 0.15 mg are intended for immediate administration as emergency supportive therapy and are not intended as a substitute for immediate medical care. In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care. More than two sequential doses of epinephrine should only be administered under direct medical supervision [see Warnings and Precautions (5.1)].

5.2 Injection-Related Complications
Injection of epinephrine USP 0.3 mg or 0.15 mg are intended to be injected into the anterolateral aspect of the thigh [see Dosages and Administration (2) and Patient Counseling Information (17)].

5.3 Serious Infections at the Injection Site
Injection of epinephrine USP 0.3 mg or 0.15 mg are intended to be injected into the anterolateral aspect of the thigh [see Dosages and Administration (2) and Patient Counseling Information (17)].

5.4 Allergic Reactions Associated with Sulfa
*Sections or subsections omitted from the full prescribing information are not listed.*

5.5 Disease Interactions

6 ADVERSE REACTIONS

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8 USE IN SPECIFIC POPULATIONS
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16 HOW SUPPLIED/STORAGE AND HANDLING
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17 PATIENT COUNSELING INFORMATION
*Sections or subsections omitted from the full prescribing information are not listed.*

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
Epinephrine USP 0.3 mg or 0.15 mg are indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis [e.g., urticaria, angioedema] and certain anaphylactic reactions such as anaphylactoid reactions induced by serum, insect venom, latex or plant products. (1.1, 1.2, 1.3)

2 DOSAGE AND ADMINISTRATION
Selection of the appropriate dosage strength for EPINEPH® 0.3 mg or EPINEPH Jr. 0.15 mg is determined according to patient body weight. (2.1)

Each EPINEPH® or EPINEPH Jr. contains a single dose of epinephrine for single-use injection. (2.2)

3 DOSAGE FORMS AND STRENGTHS
• EPINEPH®: Injection, 0.3 mg/0.3 mL epinephrine injection, USP, pre-filled auto-injector (2)
• EPINEPH Jr.: Injection, 0.15 mg/0.3 mL epinephrine injection, USP, pre-filled auto-injector (2)

4 CONTRAINDICATIONS
None (4)

5 WARNINGS AND PRECAUTIONS
5.1 Emergency Treatment
Epinephrine USP 0.3 mg or 0.15 mg are intended for immediate administration as emergency supportive therapy and are not intended as a substitute for immediate medical care. In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care. More than two sequential doses of epinephrine should only be administered under direct medical supervision [see Warnings and Precautions (5.1)].

5.2 Injection-Related Complications
Injection of epinephrine USP 0.3 mg or 0.15 mg are intended to be injected into the anterolateral aspect of the thigh [see Dosages and Administration (2) and Patient Counseling Information (17)].

5.3 Serious Infections at the Injection Site
Injection of epinephrine USP 0.3 mg or 0.15 mg are intended to be injected into the anterolateral aspect of the thigh [see Dosages and Administration (2) and Patient Counseling Information (17)].

5.4 Allergic Reactions Associated with Sulfa
*Sections or subsections omitted from the full prescribing information are not listed.*

5.5 Disease Interactions

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*Sections or subsections omitted from the full prescribing information are not listed.*
which epinephrine should be used.

- Patients with Heart Disease

Epinephrine should be administered with caution to patients who have had an allergic reaction, 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 Drug Interactions (7) and Adverse Reactions (6)].

- Other Patients and Conditions

Epinephrine should be administered with caution to patients with hyperthyroidism, diabetes, elderly individuals, and pregnant women. Patients with Parkinson’s disease may notice a lessening of some symptoms.

6 ADVERSE REACTIONS

Due to the lack of randomized, controlled clinical trials of epinephrine for the treatment of anaphylaxis, the true incidence and nature of adverse events associated with the systemic use of epinephrine is difficult to determine. Adverse reactions reported in observational trials, case reports, and studies are listed below.

Common systemic adverse events: systemically administered epinephrine include anxiety; apprehensiveness; restless; tremor; weakness; dizziness; sweating; palpitations; palp; nausea; vomiting; headache; and/ or respiratory difficulties. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension or hypotension and particularly in elderly patients with cardiovascular disease.

An unusual condition that may develop in some patients who receive epinephrine is angioedema, particularly in elderly patients with cardiovascular disease and renal failures [5]. Asthma patients who develop angioedema while taking epinephrine should be monitored for cardiovascular-related symptoms.

- Minor Isolated Anaphylactic Reactions

Toxic effects of epinephrine at high doses, regardless of dosage form or route of administration, can result in cardiovascular collapse, including death. The cardiovascular effects of epinephrine are also stress-sensitive, such as anaphylactic shock, cardiovascular collapse, and arrhythmias, including ventricular fibrillation. These effects are more pronounced in elderly patients and those with pre-existing cardiovascular disease.

- Sedative Use

Clinical studies for the treatment of anaphylaxis have not been performed in subjects aged 65 and over to determine whether dose adjustment is required in these subjects. However, the elderly may be more sensitive to the effects of epinephrine due to age-related changes in metabolism and renal function. Elderly patients should be monitored closely for adverse reactions, particularly in elderly patients. Overdose may also result in pulmonary edema because of peripheral vasodilation and increased cardiac output.

- Overdose

Overdose of epinephrine may produce extremely elevated arterial blood pressure, which may cause hemolysis, particularly in elderly patients. Overdose may also result in pulmonary edema because of peripheral vasodilation and increased cardiac output.

- Overdose

Overdose of epinephrine may produce extremely elevated arterial blood pressure, which may cause hemolysis, particularly in elderly patients. Overdose may also result in pulmonary edema because of peripheral vasodilation and increased cardiac output.

7 DRUG INTERACTIONS

Patients who receive epinephrine while concomitantly taking cardiac glycosides, diuretics, or antihistamines should be observed carefully for the development of cardiovascular arrhythmias [see Warnings and Precautions (6.5)]. The effects of epinephrine may be potentiated by tri cyclic antidepressants, monoamine oxidase inhibitors, levophedrine, and certain antihistamines, notably hydrochloride, diphenhydramine, and diphenhydramine. The cardiovascular effects of the drug may be potentiated by these agents.

The concomitant use of epinephrine with sympathomimetic agents, such as propranolol, should be avoided because of the potential for cardiovascular toxicity.

The concomitant use of epinephrine with sympathomimetic agents, such as propranolol, should be avoided because of the potential for cardiovascular toxicity.

8 USE IN SPECIFIC POPULATIONS

1 Pregnancy

Teratogenic Effects: Pregnancy Category C.

There are no adequate and well-controlled studies of the acute effect of epinephrine on pregnant women. Epinephrine was teratogenic in rabbits, mice, and hamsters. Epinephrine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus (fetal anomalies, spontaneous abortion, or both). Epinephrine has been shown to have teratogenic effects when administered subcutaneously in rabbits at approximate doses recommended for humans on a milligram per kilogram basis at a maternal subcutaneous dose of 1 mg/kg/day for 10 days, and in hamsters at approximately 5 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/kg basis at a maternal subcutaneous dose of 1 mg/kg/day for 4 days). The maximum recommended daily subcutaneous or intramuscular dose (on a mg/kg basis at a maternal subcutaneous dose of 0.5 mg/kg/day for 10 days).

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

9 Pediatric Use

Epipen® or Epipen Jr® may be administered to pediatric patients 2 years of age or older in a dosage appropriate to body weight [see Dosage and Administration (2)]. Clinical experience with the use of epinephrine in children younger than 2 years of age has not been reported. Epinephrine is not recommended for children younger than 2 years of age due to the risk of cardiac arrhythmias. Therefore, Epipen® should be administered with caution in elderly individuals, who may be at greater risk for developing adverse reactions after epinephrine administration [see Warnings and Precautions (6.3), Overdose (10)].

10 OVERDOSAGE

Overdose of epinephrine may produce extremely elevated arterial blood pressure, which may cause hemolysis, particularly in elderly patients. Overdose may also result in pulmonary edema because of peripheral vasodilation and increased cardiac output.

11 DESCRIPTION

Epipen® (epinephrine injection, USP 0.3 mg and Epipen Jr® [epinephrine injection, USP 0.15 mg are 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 1:1000 (3.0 mg/mL) in a single solution.

Each Epipen Jr® Auto-Injector, 0.15 mg delivers a single dose of 0.15 mg epinephrine from epinephrine injection, USP 1:2000 (0.5 mL) in a single solution.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Epinephrine activates both alpha- and beta-adrenergic receptors.

12.2 Pharmacodynamics

Through its action on alpha-adrenergic receptors, epinephrine causes vasoconstriction, which can lead to loss of intravascular fluid volume and hypotension. Through its action on beta-adrenergic receptors, epinephrine causes bronchodilation and helps to alleviate bronchospasm, wheezing, and dyspnea that may occur during anaphylaxis. Epinephrine also alleviates pruritus, urticaria, and angioedema and may relieve abdominal and genitourinary symptoms associated with anaphylaxis because of its relaxant effects on the smooth muscle of the stomach, intestine, urea, and urinary bladder.

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 has been shown to have mutagenic potential in vitro and to be an oxidative mutagen in a WP55 bacterial reverse mutation assay. Epinephrine was positive in the DNA Repair Test with S. typhimurium strain TA100 and E. coli strain WP2uvrA. NCI. 1996, 49002-500-02, a patch that contains two Epipen Jr® Auto-Injectors (epinephrine injections, USP, 1:2000, 0.3 mL) and one Epipen Jr® Auto-Injector trainer device. Epipen Jr® Auto-Injectors (epinephrine injections, USP, 1:2000, 0.3 mL) and one Epipen Jr® Auto-Injector trainer device. Epipen Jr® Penetrator and Epipen Jr® Penetrator also include an S-clip to clip two carbon bar tubes together. RX only

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Epipen® Auto-Injectors (epinephrine injections, USP, 1:1000. 0.3 mL are available as Epipen 2-Pak, NDC 45902-002-02, a patch that contains two Epipen Jr® Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 mL) and one Epipen Jr® Auto-Injector trainer device. Epipen Jr® Auto-Injectors (epinephrine injections, USP, 1:2000, 0.3 mL) and one Epipen Jr® Auto-Injector trainer device. Epipen Jr® Penetrator and Epipen Jr® Penetrator also include an S-clip to clip two carbon bar tubes together. RX only

16.2 Storage and Handling

Protect from light. Epinephrine is light sensitive and should be stored in the container tube provided to protect it from light. Store at 20 °C to 25°C (68° to 77°F). Excursions permitted to 15 °C to 30°C (59° 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 oily.

17 PATIENT COUNSELING INFORMATION

[See FDA-Approved Patient Labeling (Patient Information and Instructions for Use)]

A healthcare provider should review the patient instructions and operation of Epipen® and Epipen Jr® in detail, with the patient or caregiver.

Epinephrine is essential for the treatment of anaphylaxis. Patients and caregivers are at risk of anaphylaxis (anaphylaxis) to insect stings or bites, foods, drugs, and other allergens, as well as idiopathic and exercise-induced anaphylaxis, should be carefully instructed about the circumstances under which epinephrine should be used. Administration and Training

Instruct patients and/or caregivers in the appropriate use of Epipen® or Epipen Jr®. The device should be injected into the middle of the outer thigh (through clothing, if necessary). Each device is a single-use injection. Advise patients to seek immediate medical care in conjunction with administration of Epipen® or Epipen Jr®.

Instruct caregivers to hold the leg of young children firmly in place and limit movement prior to and during injection. Lacerations, bites, and other wounds should be cleansed before using, and then completely dried before using, 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 oily.

Complete patient information, including dosage, directions for proper administration and precautions can be found inside each Epipen® or Epipen Jr® carton. A printed label on the surface of each Epipen® shows instructions for use and a diagram depicting the injection process. Instruct patients and/or caregivers to use and practice with
the Trainer device to familiarize themselves with the use of Epipen® in an allergic emergency. The Trainer may be used multiple times. A Trainer device is provided in 2-Pak cartons. 

Adverse Reactions

Epinephrine may produce symptoms and signs that include an increase in heart rate, the sensation of a more forceful heartbeat, palpitations, sweating, nausea and vomiting, difficulty breathing, shortness of breath, weakness or shakiness, headache, apprehension, nervousness, or anxiety. These signs and symptoms usually subside rapidly, especially with rest, quiet and recumbency. Patients with hypertension or hyperthyroidism may develop more severe or persistent effects, and patients with coronary artery disease could experience angina. Patients with diabetes may develop increased blood glucose levels following epinephrine administration. Patients with Parkes-Weber disease may notice a temporary worsening of symptoms [see Warnings and Precautions (6.9)].

Accidental Injection

Advisors patients to seek immediate medical care in the event of an accidental injection. Since epinephrine is a strong vasconstrictor when injected into the digits, hands, or feet, treatment should be directed at vasodilatation if there is such an accidental injection to these areas [see Warnings and Precautions (6.2)].

Serious Infections at the Injection Site

Rare cases of serious skin and soft tissue infections, including necrotizing fasciitis and myonecrosis caused by Clostridium species, have been reported at the injection site following epinephrine injection for anaphylaxis. 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 [see Warnings and Precautions (6.3)].

Storage and Handling

Instruct patients to inspect the epinephrine solution visually through the clear edges of the auto-injector periodically. Replace Epipen® and Epipen Jr® if the epinephrine solution appears discolored (pinkish or brown color), cloudy, or contains particles. Epinephrine is light-sensitive and should be stored in the carrier tube provided to protect it from light. The carrier tube is not waterproof. Instruct patients that Epipen® and Epipen Jr® must be used or properly disposed of once the blue overcapping is removed or after use [see Storage and Handling (16.2)].

Complete patient information, including dosage, directions for proper administration and precautions can be found inside each Epipen® Auto-injector carton.


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May 2016. EPIH200 0019282

PATIENT INFORMATION and INSTRUCTIONS FOR USE

Epipen® (epinephrine injection, USP) Auto-Injector 0.3 mg

Epipen® – one dose of 0.3 mg epinephrine USP 1:1000, 0.3 mL

Epipen Jr® (epinephrine injection, USP) Auto-Injector 0.15 mg

Epipen Jr® – one dose of 0.15 mg epinephrine USP 1:2000, 0.15 mL

For allergic emergencies (anaphylaxis)

Patient Information

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. You, your parent, caregiver, or others who may be in a position to administer 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 the Epipen® and Epipen Jr®?

1. Epipen® and Epipen Jr® contain epinephrine, a medicine used to treat allergic emergencies (anaphylaxis).

Anaphylaxis can be life threatening, can happen within minutes, and can be caused by stinging and biting insects, allergy injections, foods, medicines, exercises, 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 weak or faint
- confusion
- stomach pain
- inability to urinate or bowel movements
- diarrhea or stomach cramps
- dizziness, fainting, or passing out (unconsciousness)

2. Always carry your Epipen® or Epipen Jr® with you because you may not know when anaphylaxis may happen.

Talk to your healthcare provider if you need additional units to keep at work, school, or other locations.

Tell your family members, caregivers, and others where you keep your Epipen® or Epipen Jr® and 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 Epipen® or Epipen Jr® right away.
- Get emergency medical help right away. You may need further emergency medical care. You may need to use a second Epipen® or Epipen Jr® if symptoms continue or recur. Only a healthcare provider should give additional doses of epinephrine if you need more than 2 injections for a single anaphylaxis episode.

What are Epipen® and Epipen Jr®?

Epipen® and Epipen Jr® are disposable, pre-filled automatic injection devices (auto-injectors) used to treat life-threatening, allergic emergencies including anaphylaxis in people who are at risk for or have a history of severe allergic emergencies. Each device contains a single dose of epinephrine.

Epipen® and Epipen Jr® are for immediate self- or caregiver administration and do not take the place of emergency medical care. You should get emergency help right away after using Epipen® and Epipen Jr®.

Epipen® and Epipen Jr® are for people who have been prescribed this medicine by their healthcare provider.

The Epipen® Auto-Injector (0.3 mg) is for patients who weigh 65 pounds or more (30 kilograms or more). The Epipen Jr® Auto-Injector (0.15 mg) is for patients who weigh about 33 to 68 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 the Epipen® or Epipen Jr®?

Before you use Epipen® or Epipen Jr®, tell your healthcare provider about all your medical conditions, but especially if you:

- have heart problems or high blood pressure
- have diabetes
- have thyroid problems
- have asthma
- have a history of depression
- have pancreatitis
- have any other medical conditions
- 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 of all known allergies.

Especially tell your healthcare provider if you take certain stimulants.

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, and other medicines may affect how Epipen® or Epipen Jr® work.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Use your Epipen® or Epipen Jr® for treatment of anaphylaxis as prescribed by your healthcare provider, regardless of your medical condition or the medicines you take.

How should I use Epipen® and Epipen Jr®?

- Each Epipen® or Epipen Jr® auto-injector contains only 1 dose of medecine.

- 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.

- Read the Instructions for Use at the end of this Patient Information Leaflet about the right way to use Epipen® and Epipen Jr®.

- Your healthcare provider will show you how to safely use the Epipen® or Epipen Jr® Auto-Injector.

- Use your Epipen® or Epipen Jr® exactly as your healthcare provider tells you to use it. You may need to use a second Epipen® or Epipen Jr® if symptoms continue or recur. Only a healthcare provider should give additional doses of epinephrine if you need more than 2 injections for a single anaphylaxis episode.

- Caution: Never put your thumb, fingers, or hand over the orange tip. Never press or push the orange tip with your thumb, fingers, or hand. The needle comes out of the orange tip. Accidental injection into finger, hand or feet may cause a loss of blood flow to these areas. If this happens, go immediately to the nearest emergency room. Tell the healthcare provider where on your body you received the accidental injection.

- Your Epipen® and Epipen Jr® Auto-Injector may come packaged with an Epipen® Trainer and separate Trainer Instructions for Use. The Epipen® Trainer has a gray cover with blue and white marking and contains no medicine and no needle. Periodically practice with your Epipen® Trainer before an allergic emergency happens to make sure you are able to safely use the real Epipen® and Epipen Jr® Auto-Injector in an emergency. Always carry your real Epipen® or Epipen Jr® Auto-Injector with you in case of an allergic emergency. Additional training resources are available at www.epipen.com.

4. Do not throw the carrier tube or auto-injector. If this carrier tube or auto-injector is dropped, check for damage and leakage. Dispose of the auto-injector and carrier tube, and replace if damage or leakage is noticed or suspected.

What are the possible side effects of the Epipen® and Epipen Jr®?

Epipen® and Epipen Jr® may cause serious side effects.

The Epipen® or Epipen Jr® should only be injected into the middle of your outer thigh (upper leg). Do not inject the Epipen® or Epipen Jr® into your:

- veins
- buttocks
- fingers, toes, hands, or feet

If you accidentally inject Epipen® or Epipen Jr® into any other part of your body, go to the nearest emergency room right away. Tell the healthcare provider where on your body you received the accidental injection.

- Rarely, patients who have used Epipen® or Epipen Jr® may develop 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 have any of the following at an injection site:

- redness that does not go away
- swelling
- tenderness
- the area feels warm to the touch
- cuts on the skin, bent needles, and needles that remain in the skin after the injection, have happened in young children who do not cooperate and kick or move during an injection. If you inject a young child with Epipen® or Epipen Jr®, hold the child’s leg firmly in place before and during the injection to prevent injuries. Ask your healthcare provider to show you how to properly hold the leg of a young child during injection.

- 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®. Talk to your healthcare provider about all your medical conditions.

- Common side effects of Epipen® and Epipen Jr® include:

  - fast, irregular or "pounding" heart beat
  - 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 the EpiPen® or EpiPen Jr®. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store EpiPen® and EpiPen Jr®?
- Store EpiPen® and EpiPen Jr® at room temperature between 68°F to 77°F (20°F to 25°C).
- 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.
- Examine the contents in the clear window of your auto-injector periodically. The solution should be clear. If the solution is discolored (pinkish or brown color) or contains solid particles, replace the unit.
- Always keep your EpiPen® or EpiPen Jr® Auto-Injector in the carrier tube to protect it from damage; however, the carrier tube is not waterproof.
- The blue safety release helps to prevent accidental injection. Keep the blue safety release on until you need to use EpiPen® or EpiPen Jr®.

Your EpiPen® or EpiPen Jr® has an expiration date. Replace it before the expiration date.

Keep EpiPen® and EpiPen Jr® and all medicines out of the reach of children.

General Information about the safe and effective use of EpiPen® and EpiPen Jr®

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

This Patient Information Leaflet summarizes the most important information about EpiPen® and EpiPen Jr®. 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® that is written for health professionals.

For more information and video instructions on the use of EpiPen® and EpiPen Jr®, go to www.epipen.com or call 1-800-385-3376.

What are the ingredients in EpiPen® and EpiPen Jr®?

Active Ingredients: Epinephrine

Inactive Ingredients: sodium chloride, 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.
- The EpiPen® Trainer has a grey color and contains no medicine and no needle.
- Your auto-injector is designed to work through clothing.
- The blue safety release on the EpiPen® and EpiPen Jr® Auto-Injector helps to prevent accidental injection of the device. Do not remove the blue safety release until you are ready to use it.
- 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 orange tip. The needle comes out of the orange tip.
- If an accidental injection happens, get medical help right away.
- Do not place patient information or any other foreign objects in the carrier tube with the Auto-Injector; this may prevent you from removing the Auto-Injector for use.

INSTRUCTIONS FOR USE EpiPen®
(epinephrine injection, USP) Auto-Injector 0.3 mg EpiPen® = one dose of 0.3 mg epinephrine (USP) 1:1000, 0.3 mL)

EpiPen Jr®
(epinephrine injection, USP) Auto-Injector 0.15 mg EpiPen Jr® = one dose of 0.15 mg epinephrine (USP) 1:2000, 0.3 mL)

For anaphylactic emergencies (anaphylaxis)

Read these Instructions for Use carefully before you use EpiPen® or EpiPen Jr®. Before you need to use your EpiPen® or EpiPen Jr®, make sure your 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 your healthcare provider.

A dose of EpiPen® or EpiPen Jr® requires 3 simple steps: Prepare, Administer and Get emergency medical help

Step 1. Prepare EpiPen® or EpiPen Jr® for injection

Remove the EpiPen® or EpiPen Jr® from the clear carrier tube.

Flip open the yellow cap of your EpiPen® or the green cap of your EpiPen Jr® carrier tube.

Tip and slide the auto-injector out of the carrier tube.

Grasp the auto-injector in your fist with the orange tip (needle end) pointing downward.

With your other hand, remove the blue safety release by pulling straight up without bending or twisting it.

Note:
- The needle comes out of the orange tip.
- To avoid an accidental injection, never put your thumb, fingers or hand over the orange tip. If an accidental injection happens, get medical help right away.

Step 2. Administer EpiPen® or EpiPen Jr®

If you are administering EpiPen® or EpiPen Jr® to a young child, hold the leg firmly in place while administering an injection.

Place the orange tip against the middle of the outer thigh (upper leg) at a right angle (perpendicular) to the thigh. Swing and push the auto-injector firmly until it "clicks." The click signals that the injection has started.

Hold firmly in place for 3 seconds (count slowly 1, 2, 3). The injection is now complete.

Remove the auto-injector from the thigh. The orange tip will extend to cover the needle. If the needle is still visible, do not attempt to reuse it.

Massage the injection area for 10 seconds.

Step 3. Get emergency medical help now. You may need further medical attention. You may need to use a second EpiPen® or EpiPen Jr® Auto-Injector if symptoms continue or recur.

- Take your used auto-injector 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 your used EpiPen® or EpiPen Jr® Auto-Injector to the healthcare provider for inspection and proper disposal.
- Ask for a refill, if needed.

Note:
- The used auto-injector with extended needle cover will not fit in the carrier tube.
- EpiPen® and EpiPen Jr® are single-use injectable devices that deliver a fixed dose of epinephrine. The auto-injector cannot be reused. Do not attempt to reuse EpiPen® after the device has been activated. It is normal for most of the medicine to remain in the auto-injector after the dose is injected. The correct dose has been administered if the orange needle tip is extended and the window is blocked.
- Your EpiPen® and EpiPen Jr® Auto-Injector may come packaged with an EpiPen® Trainer and separate Trainer Instructions for Use. The EpiPen® Trainer has a grey color. The grey EpiPen® Trainer contains no medicine and no needles. Practice with your EpiPen® Trainer, but always carry your real EpiPen® or EpiPen Jr® Auto-Injector in case of an allergic emergency.

- If you will be administering EpiPen® or EpiPen Jr® to a young child, ask your 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-Injector apart.

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


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M.S.PR. EPIF15-0247
Register your EpiPen® or EpiPen Jr® Auto-Injector at

EpiPen®
(epinephrine injection, USP) Auto-Injector 0.3 mg EpiPen® = one dose of 0.3 mg epinephrine (USP) 1:1000, 0.3 mL)

EpiPen Jr®
(epinephrine injection, USP) Auto-Injector 0.15 mg EpiPen Jr® = one dose of 0.15 mg epinephrine (USP) 1:2000, 0.3 mL)

MyEpiPen.com

MyEpiPen.com and find out more about:

- Free EpiPen® Auto-Injector Refill Reminder Program. It is important to keep your auto-injector up-to-date.
- Use it up to 6 EpiPen® or EpiPen Jr® Auto-Injectors and receive automatic Refill Reminder Alerts.
- Receive periodic information related to allergies and anaphylaxis.
- Instructional Video

For more information about EpiPen® or EpiPen Jr® Auto-Injectors and proper use of the product, call Mylan at 1-877-448-3679 or visit www.epipen.com.