How to use an EpiPen® (epinephrine injection, USP) Auto-Injector

1 PREPARE

Remove the EpiPen® or EpiPen Jr® Auto-Injector 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.

Hold the auto-injector in your fist with the orange tip pointing downward.
Blue to the sky, orange to the thigh™.

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

NEVER-SEE-NEEDLE® helps with protection. Protects against needle exposure before and after use.

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.

2 ADMINISTER

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).

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.

3 GET EMERGENCY MEDICAL HELP RIGHT AWAY

You may need further medical attention.
If symptoms continue or recur, you may need to use a second EpiPen® or EpiPen Jr® Auto-Injector.

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.

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.

Not actual patient.
Please see additional Important Safety Information and Indications on the back.
Please see accompanying full Prescribing Information and Patient Information.
Every EpiPen 2-Pak® (epinephrine injection, USP) comes with an EpiPen® Trainer
Practice with your Trainer repeatedly to become familiar with it.

The EpiPen® Auto-Injector

Identify the EpiPen® Trainer by:

Label
The EpiPen® Trainer is clearly labeled TRAINER or TRAINING DEVICE.

Color
The EpiPen® Trainer is shaded grey
EpiPen® is yellow & EpiPen Jr® is green

No Window or Liquid

Reset after each use

The grey EpiPen® Trainer contains no medicine and no needle, and SHOULD NOT BE USED during an anaphylactic reaction.

Visit epipen.com to watch our How to Use video and more.

IMPORTANT SAFETY INFORMATION (Continued)

EpiPen® or EpiPen Jr® should only be injected into the middle 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 breastfeeding. Be sure to also tell your healthcare professional all the medicines you take, especially medicines for asthma.

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 EpiPen® or EpiPen Jr®.

Common side effects include fast, irregular or “pounding” heartbeat, sweating, nausea or vomiting, breathing problems, pain, 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 the full Prescribing Information and Patient Information.
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 800-395-3376.

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HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use EPIPEP® and EPIPEP Jr® safely and effectively. See full prescribing information for EPIPEP® and EPIPEP Jr®.

EPIPEP® (epinephrine injection, USP), Auto-Injector 0.3 mg, EPIPEP Jr® (epinephrine injection, USP) Auto-Injector 0.15 mg, for intramuscular or subcutaneous use

Recent U.S. Approval: 1939

RECENT MAJOR CHANGES
0.15 mg, for intramuscular or subcutaneous use
EpiPen

INDICATIONS AND USAGE
EpiPen® and EpiPen 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)

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

DOSEAGE FORMS AND STRENGTHS
EpiPen®: Injection, 0.3 mg: 0.3 mg/0.3 mL epinephrine, USP, pre-filled auto-injector (3)
EpiPen Jr®: Injection, 0.15 mg: 0.15 mg/0.3 mL epinephrine, USP, pre-filled auto-injector (5)

CONTRAINdications
None (4)

WARNINGS AND PRECAUTIONS
• In conjunction with use, 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 sulfite in this product should not deter the use, (5.4)
• Administer with caution in patients with heart disease; may aggravate angina pectoris or produce ventricular arrhythmias. (5.5)

ADVERSE REACTIONS
Anaphylactic and/or other reactions include angioedema, nausea, vomiting, fingertips cyanosis, flushing, chills, headache, and/or respiratory difficulties. (6)

Suspected Adverse Reactions, contact Mylan Specialty, L.P. at 1-877-446-3879 (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)
• Tricyclic antidepressants, monoamine oxidase inhibitors, levothYROxine sodium, and certain antihistamines: potentiate effects of epinephrine. (7)
• Beta-adrenergic blocking drugs: antagonize cardioselective effects and bronchodilating effects of epinephrine. (7)
• Alpha-adrenergic blocking drugs: antagonize vasoconstricting and hypertensive effects of epinephrine. (7)
• Ergot alkaloids: may reverse the pressor effects of epinephrine. (7)

Use in Specific Populations
• Elderly patients may be at greater risk of developing adverse reactions. (5, 5.5)

See 17 for Patient Counseling Information and FDA approved patient labeling

Revised: May 2016

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3 DOSAGE FORMS AND STRENGTHS
• EpiPen®: Injection, 0.3 mg/0.3 mL (0.3 mL, 1:1000) epinephrine injection, USP, pre-filled auto-injector
• EpiPen Jr®: Injection, 0.15 mg/0.3 mL (0.3 mL, 1:2000) epinephrine injection, USP, pre-filled auto-injector

4 CONTRAINDICATIONS
None

5 WARNINGS AND PRECAUTIONS
5.1 Emergency Treatment
EpiPen® and EpiPen Jr® are indicated for immediate administration as emergency supportive therapy and are not intended as a substitute for immediate medical care.

5.2 Injection Related Injury
• 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 if there is such inadvertent administration.

5.3 Severe Allergic Reactions
• Do not inject into buttock. Injection into the buttock may not provide effective treatment of anaphylaxis. Advise the patient to 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). Cleaning with alcohol does not kills spores, and methanol therefore, does not lower this risk.

5.4 Intradermally
• 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. Advise the patient to 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 may be necessary. In addition, to further appropriate treatment of anaphylaxis see Adverse Reactions (6).

5.5 Local Reactions
• Hold leg firmly during injection. Lacerations, bent needles, or broken needles have been reported when EpiPen® and EpiPen Jr® have been injected into the thigh of young children who are uncooperative and kick or move during an injection. To minimize the risk of injection related injury when administering EpiPen® to young children, instruct caregivers to hold the child’s leg firmly in place and limit movement prior to and during injection.

5.6 Intramuscularly
• Do not inject into buttock. Significant bruising may occur following 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 Clostridial infection, do not inject EpiPen® or EpiPen Jr® into the buttock [see Warnings and Precautions (5.2)]. Advise patients to seek medical care if they develop signs or symptoms of infection, such as persistent redness, warmth, swelling, or tenderness at the injection site.

5.7 Intradermal injection is not recommended.

5.8 Intranasal and Ophthalmic Studies
• EpiPen® and EpiPen Jr® are indicated for immediate administration as emergency supportive therapy and are not a substitute for immediate medical care.

6.1 Phlebitis
• Phlebitis may occur with subcutaneous injection. Advise the patient to 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 may be necessary. In addition, to further appropriate treatment of anaphylaxis see Adverse Reactions (6).

7.1 Geriatric Use
• The presence of a sulfite in this product should not deter the use, (5.4)
• Administer with caution in patients with heart disease; may aggravate angina pectoris or produce ventricular arrhythmias. (5.5)

ADVERSE REACTIONS
Anaphylactic and/or other reactions include angioedema, nausea, vomiting, fingertips cyanosis, flushing, chills, headache, and/or respiratory difficulties. (6)

Suspected Adverse Reactions, contact Mylan Specialty, L.P. at 1-877-446-3879 (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)
• Tricyclic antidepressants, monoamine oxidase inhibitors, levothyroXine sodium, and certain antihistamines: potentiate effects of epinephrine. (7)
• Beta-adrenergic blocking drugs: antagonize cardioselective effects and bronchodilating effects of epinephrine. (7)
• Alpha-adrenergic blocking drugs: antagonize vasoconstricting and hypertensive effects of epinephrine. (7)
• Ergot alkaloids: may reverse the pressor effects of epinephrine. (7)

Use in Specific Populations
• Elderly patients may be at greater risk of developing adverse reactions. (5, 5.5)

See 17 for Patient Counseling Information and FDA approved patient labeling

Revised: May 2016

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5.3 Serious Infections at the Injection Site
Rare cases of serious skin and soft tissue infections, including Clostridial (gas gangrene) can be 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 intramuscular injection may result in bacterial contamination and subsequent 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 Clostridial infection, do not inject EpiPen® or EpiPen Jr® into the buttock [see Warnings and Precautions (5.2)]. Advise patients to seek medical care if they develop signs or symptoms of infection, such as persistent redness, warmth, swelling, or tenderness at the injection site.

5.4 Allergic Reactions Associated With SulFite
The presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other life-threatening situations even if the patient is sulfite-sensitive.

Epinephrine is the preferred treatment for serious allergic reactions or other life-threatening situations even though this product 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. Therefore, patients with these conditions, and/or any other person who might be in a position to administer EpiPen® or EpiPen Jr® to a patient experiencing anaphylaxis should be carefully instructed in regard to the circumstances under
which epinephrine should be used.

- **Patients with Heart Disease**

Epinephrine should be administered with caution to patients who have heart disease, including patients with cardiac arrhythmias, coronary artery disease, hyperthyroidism, 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 asystole or ventricular arrhythmias.

- **Patients with Diabetes**

Epinephrine should be used with caution to patients who have diabetes mellitus, as it may cause transient hyperglycemia.

- **Pregnant Women**

Pregnant women. Patients with Parkinson’s disease may notice a temporary worsening of symptoms.

6 ADVERSE REACTIONS

Due to the lack of randomized, controlled clinical trials of epinephrine for the treatment of anaphylaxis, the true incidence of adverse reactions 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 adverse reactions to systemically administered epinephrine include anxiety, apprehensiveness; restlessness; tremor; weakness; dizziness; sweating; palpitations; pallor; nausea and 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 hyperthyroidism (see Warnings and Precautions (5.5)). Cardiac arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs (see Warnings and Precautions (5.2)). Bradycardia may be induced in diabetics, elderly individuals, and pregnant women. Patients with Parkinson’s disease may notice a temporary worsening of symptoms.

10 OVERDOSAGE

Overdose of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in patients with impaired cerebral blood flow. Overdose may also result in pulmonary edema because of peripheral vascular constriction together with cardiac stimulation. Treatment consists of rapidly acting vasodilators or alpha-adrenergic blocking drugs and respiratory support. Epinephrine overdosage can also cause transient bradycardia followed by tachycardia, and these may be accompanied by potentially fatal cardiac arrhythmias. Premature ventricular contractions may appear within one minute after injection and may be followed by multifocal ventricular tachycardia (pre fibrillation rhythm). Subsidence of the ventricular effects may be followed by atrial tachycardia and occasionally by atrioventricular block. Treatment of life-threatening arrhythmias consists of administration of a beta-adrenergic blocking drug such as propranolol. Overdose sometimes results in extreme pallor and coldness of the skin, metabolic acidosis, and kidney failure. Life-sustaining corrective measures must be taken in such situations.

11 DESCRIPTION

Epinephrine (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 (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 1:2000 (0.3 mL) in a sterile solution.

The epinephrine solution in each contain 2 ml epinephrine solution. Approximately 1.7 mL remains in the auto-injector after activation, but is not available for future use, and should be discarded.

Epinephrine solution contains 0.3 mg epinephrine, 1.8 mg sodium chloride, 0.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0.

Epinephrine solution contains 0.15 mg epinephrine, 1.8 mg sodium chloride, 0.5 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 C18H21NO3S. The molecular weight is 321.4.

Epinephrine is a stimulant of the alpha- and beta-adrenergic receptors, causing bronchial smooth muscle relaxation and helps to restore vascular tone.

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

12 NONCLINICAL TOXICOLOGY

12.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies to evaluate the carcinogenic potential of epinephrine have not been performed. Epinephrine and other catecholamines have been shown to have mutagenic potential in vitro and to be an oxidative mutagen in a WP2 bacterial reverse mutation assay.

Epinephrine was positive in the DNA Repair Test with B. subtilis (MC 1061), an indicator assay in the Salmonella bacterial reverse mutation assay.

The potential for epinephrine to impair fertility has not been evaluated.

There should not prevent the use of epinephrine under the conditions noted under Indications and Usage (1).

16 HOW SUPPLIED/STORAGE AND HANDLING

Epinephrine solutions are supplied as Epipen 2-Pak® and EpiPen Jr (epinephrine injection, USP, 1:1000, 0.3 mL) as EpiPen 2-Pak®, NDC 49502-500-02, a pack that contains two EpiPen® Auto-Injectors (epinephrine injection, USP, 1:1000, 0.3 mg) and one Epipen Jr® Auto-Injector (epinephrine injection, USP, 1:2000, 0.3 mL) as EpiPen Jr® Auto-Injectors, NDC 49502-501-02, a pack that contains two EpiPen Jr® Auto-Injectors and one EpiPen Jr® (epinephrine injection, USP, 1:1000, 0.3 mL) as EpiPen Jr® Auto-Injector device.

Epinephrine is available as EpiPen Jr 2-Pak® and EpiPen Jr 2-Pak® also include an S-clip to clip two carrier tubes together. Rx only.

16.2 Storage and Handling

Protect from light. Epinephrine is light sensitive and should be stored in the carrier tube 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) (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 discolored.

17 PATIENT COUNSELING INFORMATION

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

A healthcare provider should review the patient instructions and options for EpiPen® and Epipen Jr® in detail, with the patient or caregiver.

Epinephrine is essential for the treatment of anaphylaxis.

Patients who are at risk of or have a history of severe allergic reactions (anaphylaxis) to bee stings or bites and who have previously experienced serious adverse reactions to 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 Use

Instruct patients and/or caregivers in the appropriate use of EpiPen® and Epipen Jr®. Epipen Jr® should be injected into the middle of the outer thigh (through clothing, if necessary). Each EpiPen Jr® is preloaded and includes a full auto-injector device. Lacerations, bent needles, and embedded needles have been reported when EpiPen® and EpiPen Jr® have been injected into the thigh of young children who are uncooperative and kick or move during an injection [see Warnings and Precautions (5.2)].
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 at injection sites that include an increase in heart rate and an increase of a more forceful heartbeat, palpitations, sweating, nausea and vomiting, difficulty breathing, pallor, dizziness, weakness or shockness, 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 chest angina. Patients with diabetes may develop increased blood glucose levels following epinephrine administration. Patients with Parkinson's disease may notice a decrease in blood pressure, a decrease in heart rate, and a feeling of flushing. Patients with hypertension or diabetes may notice an increase in heart rate, the sensation of a more forceful heartbeat, palpitations, sweating, nausea and vomiting.

Warnings and Precautions (5.3)

See Warnings and Precautions (5.3). Treatment should be directed at vasodilatation if there is evidence of shock or anaphylaxis. Patients with Parkinson's disease may notice a decrease in blood pressure, a decrease in heart rate, and a feeling of flushing. Patients with hypertension or diabetes may notice an increase in heart rate, the sensation of a more forceful heartbeat, palpitations, sweating, nausea and vomiting.

Precautions (5.5)

See Warnings and Precautions (5.5). Administration. Patients with Parkinson's disease may notice a decrease in blood pressure, a decrease in heart rate, and a feeling of flushing. Patients with hypertension or diabetes may notice an increase in heart rate, the sensation of a more forceful heartbeat, palpitations, sweating, nausea and vomiting.

Serious Infections at the Injection Site
Rare cases of serious skin and soft tissue infections, including necrotizing fasciitis and myonecrosis caused by Clostridium (gas gangrene), 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 (5.3)).

Storage and Handling

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. 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 once the blue safety release is removed or after use (see Storage and Handling [16.2]).

Complete patient information, including dosage, directions for proper administration, and more detailed instructions on how to use the EpiPen® can be found inside each EpiPen® Auto-Injector carton.

Manufactured for Mylan Specialty L.P., Morgantown, WV 26505, U.S.A. by Meridian Medical Technologies, Inc., Columbia, MD 21046, U.S.A., a Pfizer company

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

EpiPen® is one dose of 0.3 mg epinephrine (USP: 1:1000, 0.3 mg/0.3 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 use it. 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, 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)
- dizziness 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 medical attention. 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, prefilled auto-injectors with the epinephrine solution inside the tube or auto-injector. In an allergic emergency, including threats, anaphylaxis, patients who have used EpiPen®, EpiPen Jr®, or 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 66 pounds or more (30 kilograms or more).

The EpiPen Jr® Auto-Injector (0.15 mg) is for patients 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 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 Parkinson's disease
- have any other medical conditions
- are pregnant or plan to become pregnant. 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 known allergies, especially if you take certain medicines. EpiPen® or EpiPen Jr® may cause serious side effects. 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 the EpiPen® or EpiPen Jr® into:

- 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 their 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 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” heartbeat
- sweating
- headache
- weakness
- shakiness
- palpitations
- feelings of over excitement, nervousness or anxiety
- dizziness
- nausea or vomiting
- breathing problems

How should I use EpiPen® and EpiPen Jr®?

Each EpiPen® or EpiPen Jr® Auto-Injector contains only 1 dose of medicine.

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 these 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 pull 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 grey color. The grey EpiPen® Trainer contains no medicine and is only for training. It is not a substitute for training with a 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 EpiPen® or EpiPen Jr® Auto-Injector with you in case of an allergic emergency. Additional training resources are available at www.epipen.com.

Do not drop the carrier tube or auto-injector. If the 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.

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:

- veins
- buttocks
- fingers, toes, hands, or feet
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° to 77°F (20° 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 1-800-395-3376.

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, as 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 0.30 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 allergic 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.

Your EpiPen® and EpiPen Jr® Auto-Injector

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.

Step 2. Administer EpiPen® or EpiPen Jr® to a young child, hold the leg firmly in place while administering an injection.

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 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 re-use 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 needle. 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. Manufactured for: Mylan Specialty L.P., Morgantown, WV 26505, U.S.A. by Meridian Medical Technologies, Inc., Columbia, MD 21046, U.S.A., a Pfizer company. EpiPen® and EpiPen Jr® are registered trademarks of Mylan Inc. licensed exclusively to its wholly-owned affiliate, Mylan Specialty L.P. of, Morgantown, WV 26505, U.S.A. Copyright © 2016 Meridian Medical Technologies. All rights reserved. Revised: May 2016

MS-P/L-EPI/R2
EPI-2016-0247
Register your EpiPen® or EpiPen Jr® Auto-Injector at Epipen.com

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. Register up to 6 EpiPen® or EpiPen Jr® Auto-Injectors and receive automatic Refill Reminder Alerts.
- Receive periodic information related to allergies and allergens.
- Instructional Video

For more information about EpiPen® or EpiPen Jr® Auto-Injectors and proper use of the product, call Mylan at 1-877-446-3679 or visit www.epipen.com.