How to use an EpiPen® (epinephrine injection, USP) 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.

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**

Always have access to two EpiPen® Auto-Injectors in all the places you may need them because some people require a second dose. More than two sequential doses of EpiPen® Auto-Injector should be administered only under direct medical supervision.

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 breastfeed. 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, 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 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 EPIPEM® and EPIPEM Jr® safely and effectively. See full prescribing information for EPIPEM® and EPIPEM Jr®.

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

DOSAGE 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)

DOSAGE 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 (3)

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 sulfit in this product should not deter use, (5.4)
• Administer with caution in patients with heart disease; may aggravate angina pectoris or produce arrhythmic arrhythmias. (5.5)

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

Suspected Adverse Reactions, contact Mylan Specialty, L.P. at 1-877-446-3879 (1-887-4-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 cardiotonic 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, 8, 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
EpiPen® and EpiPen Jr® are indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergens of animal or venomous origin, food drugs, plant pollen, latex, shingles, anaphylaxis due to laryngeal spasm, urticaria and angioedema. (1)

EpiPen® and EpiPen Jr® are indicated for immediate emergency assistance to help manage anaphylaxis and those at the risk of developing anaphylaxis. (1)

EpiPen® and EpiPen Jr® are not a substitute for immediate medical care. (1)

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

• Patients greater than or equal to 30 kg (approximately 66 pounds or more): EpiPen® 0.3 mg
• Patients 15 to 30 kg (33 lbs to 66 lbs): EpiPen Jr® 0.15 mg
• Patients 10 to 15 kg (22 lbs to 33 lbs): EpiPen Jr® 0.075 mg

Inject EpiPen® or EpiPen Jr intramuscular or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Instruct caregivers of young children who are uncooperative and kick or move during injection to hold the leg firmly in place and limit movement prior to and during injection. (1)

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 (4)

5 WARNINGS AND PRECAUTIONS
5.1 Emergency Treatment
EpiPen® and EpiPen Jr® are indicated in the emergency administration as emergency supportive therapy and are not considered 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 Indications and Usage (1), Dosage and Administration (2) and Patient Counseling Information (17)].

5.2 Injection-Related Complications
EpiPen® and EpiPen Jr® should only be injected into the anterolateral aspect of the thigh [see Dosage and Administration (2) and Patient Counseling Information (17)].

Do not inject intravenously. 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 kill bacterial spores, and therefore, does not lower this risk.

Do not inject into digits, hands or feet. Since epinephrine is a strong vasocostructor, 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 to inform the healthcare provider in the emergency room of the location of the accidental injection. Treatment of such inadvertent administration is not expected to reverse the effects of epinephrine [see Adverse Reactions (6)].

Hold leg firmly during injection. Lacerations, bent needles, or loss of proper administration as emergency supportive therapy and are not a substitute for immediate medical care.

5.3 Serious Infections at the Injection Site
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)

5.4 Allergic Reactions Associated with Sulfite
The presence of a sulfit in this product should not deter use. (5.4)

5.5 Disease Interactions
Some patients may be at greater risk of developing adverse reactions to epinephrine for single-use injection. Since the doses of epinephrine delivered from EpiPen® or EpiPen Jr® are fixed, consider using other forms of injectable epinephrine if doses lower than 0.15 mg are needed using epinephrine injection. The prescriber should carefully assess each patient to determine the most appropriate dose of epinephrine, recognizing the life-threatening nature of the reactions for which this drug is indicated. Despite these concerns, it should be recognized that the presence of these conditions is not a contraindication to epinephrine administration in an acute, life-threatening situation. Therefore, 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
Subcutaneous or intramuscular dose (on a mg/m² basis at a maternal dose of 1.2 mg/kg/day for two to three days) is recommended daily subcutaneous or intramuscular dose (on a mg/m² basis at a maternal subcutaneous dose of 0.5 mg/kg/day for 4 days). These effects were not seen in mice at approximately 3 times the maximum daily subcutaneous or intramuscular dose (on a mg/m² basis at a subcutaneous maternal dose of 0.5 mg/kg/day for 10 days).

### 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; 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, or patients with cardiac disease or those receiving certain drugs (see Warnings and Precautions (5.3), Drug Interactions (7)). Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease (see Warnings and Precautions (5.5)). Angina may occur in patients with coronary artery disease.

### 7 DRUG INTERACTIONS

**Persons 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)). The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, levotheroxyne sodium, and certain antihistamines, notably chlorpheniramine, triprolamine, and diphenhydramine. 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 the alpha-adrenergic blocking drugs, such as phentolamine.

### 8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

**Teratogenic Effects: Pregnancy Category C.**

There are no adequate and well controlled studies of the acute effect of epinephrine in pregnant women. Epinephrine was teratogenic in rabbits, mice and hamsters. Epinephrine should be administered subcutaneously in rabbits at approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m² basis at a maternal dose of 1.2 mg/kg/day for two to three days) and in mice at approximately 5 times the maximum daily subcutaneous or intramuscular dose (on a mg/m² basis at a maternal subcutaneous dose of 1 mg/kg/day for 10 days), and in hamsters at approximately 5 times the maximum dose. These effects were not seen in mice at approximately 3 times the maximum daily subcutaneous or intramuscular dose (on a mg/m² basis at a subcutaneous maternal dose of 0.5 mg/kg/day for 10 days).

**Nursing Mothers**

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.

### 8.2 Use in Elderly Patients

**Epipen® or Epipen Jr® may be administered to pediatric patients at a dosage appropriate to body weight (see Dosage and Administration (2)). Clinical experience with the use of epinephrine suggests that the adverse reactions seen in children 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.

#### 8.5 Geriatric Use

**Clinical studies for the treatment of anaphylaxis have not been performed in subjects aged 65 or older to determine whether they respond differently from younger 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, 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 (5.5)).**

### 10 OVERDOSAGE

**Overdose of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in patients with hypertension or hyperthyroidism (see Warnings and Precautions (5.3)).** Rapid effect of epinephrine in pregnant women.

**Overdose of epinephrine 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/or respiratory support. Epinephrine overdosage may 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. Transient or persistent tachycardia and/or arrhythmias of administration of a beta-adrenergic blocking drug such as propranolol. Overdosage sometimes results in extreme pallor and coldness of the skin, metabolic acidosis, and kidney failure. Suitable corrective measures must be taken in such situations.

### 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 (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 Epipen® Auto-Injector and Epipen Jr® Auto-Injector 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.

**Epipen® Auto-Injector 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 2.5-2.9.**

Each Epipen Jr® Auto-Injector 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 2.5-2.9.

**Epinephrine is a sympathomimetic catecholamine. Chemically, epinephrine is C10H15O4N.**

**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 Information and Instructions for Use.)

### 12 CLINICAL PHARMACOLOGY

#### 12.1 Mechanism of Action

Epinephrine acts on both alpha- and beta-adrenergic receptors. Epinephrine lessens the vasoconstriction and increased vascular permeability that occurs during anaphylaxis, which can lead to loss of intravascular fluid volume and hypotension. Thromboxane synthesis on beta-adrenergic receptors, epinephrine causes bronchial smooth muscle relaxation and helps alleviate bronchospasm, wheezing and dyspnea that may occur during anaphylaxis.

Epinephrine causes pupil, ptosis, miosis, urticaria, and angioedema and may relieve gastrointestinal and genitourinary symptoms associated with anaphylaxis because of its relaxant effects on the smooth muscle of the stomach, intestines, uterus, and 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 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 and Salmonella bacteria reverse mutation assay.

The potential for epinephrine to impair fertility has not been evaluated. This should not prevent the use of epinephrine under the conditions noted under Indications and Usage (1).

### 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 49502-500-02, a pack that contains two Epipen® Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 mL) and one Epipen Jr® Auto-Injector (epinephrine injection. USP, 1:2000, 0.3 mL) and one Epipen Jr® Auto-Injector trainee device.**

**Epipen 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° to 25°C (68° to 77°F); excursions permitted to 15° 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 contains particles.**

### 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 who are at risk of or with a history of severe allergic reactions (anaphylactic reaction to bee, wasp, or hornet stings or bites) should be instructed to contact their physician to receive immediate medical care in conjunction with administration of Epipen®.

**Instruct patients and/or caregivers in the appropriate use of Epipen® and Epipen Jr® to be injected into the middle of the outer thigh (through clothing, if necessary).**

**EpiPen® or Epipen Jr® should be injected into the middle of the outer thigh (through clothing, if necessary).**

**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 during an injection (see Warnings and Precautions (5.2)).**

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 Epipen® shows instructions for use and a diagram depicting the injection process.

**Instruct patients and/or caregivers to use and practice with**
Instruct patients to inspect the epinephrine solution visually.

### Storage and Handling

Epinephrine may produce symptoms and signs that include an increase in heart rate, a rise in blood pressure, a rush of forceful heartbeats, palpitations, sweating, nausea and vomiting, difficulty breathing, pallor, dizziness, 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 Parkinson's disease may notice a temporary worsening of symptoms [see Warnings and Precautions (5.5)].

### Accidental Injection

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

### Patient Information

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


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### PATIENT INFORMATION and INSTRUCTIONS FOR USE

**EpiPen®**

(epinephrine injection, USP) Auto-Injector 0.3 mg

Eppen® = one dose of 0.30 mg epinephrine (USP) 1:1000, 0.3

**EpiPen Jr®**

(epinephrine injection, USP) Auto-Injector 0.15 mg

Eppen® = one dose of 0.15 mg epinephrine (USP) 1:2000, 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 get a refill. There may be new information. You, your parent, caregiver, or other 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 cause breathing and biting insects, allergy injections, foods, medicines, exercise, or unknown causes.

2. 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
   - loss of control of urination or bowel movements (incontinence)
   - dizziness or stomach cramps
   - dizziness, fainting, or “passing out” (unconsciousness)

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

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

5. 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.

6. 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 automatic injectors approved to treat life-threatening, allergic emergencies including anaphylaxis in people who are at risk for or have a history of serious allergic emergencies. Each device contains a single dose of epinephrine auto-injector. 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.

EpiPen Auto-Injector (0.3 mg) is for patients who weigh 66 pounds or more (30 kilograms or more).

EpiPen Jr Auto-Injector (0.15 mg) is for patients who weigh about 33 pounds (15 to 30 kilograms).

It is not known if EpiPen® and EpiPen Jr® are safe and effective for 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 EpiPen® and EpiPen Jr® 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 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, 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 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 come out when you push the carrier tube 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:

- 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 come out when you push the carrier tube and carrier tube, and replace if damage or leakage is noticed or suspected.

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” heartbeat
- sweating
- headache
- weakness
- shakiness
- paleness
- 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 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 have to use more than 1 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 touch the orange tip [see Warnings and Precautions (5.3)].

Get a refill. There may be new information. You, your parent, caregiver, or other who may be 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.

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 cause breathing and biting insects, allergy injections, foods, medicines, exercise, or unknown causes.

2. Symptoms of anaphylaxis may include:
   - trouble breathing
   - wheezing
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

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.

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 the emergency room or to your 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 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.

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.