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)

**DOSE 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)

**WARNINGS AND PRECAUTIONS**

**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)
- The presence of a sulfite in this product should not deter use. (5.3)
- Administer with caution in patients with heart disease; may aggravate angina pectoris or produce ventricular arrhythmias. (5.4)

**ADVERSE REACTIONS**

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

To report SUSPECTED ADVERSE REACTIONS, contact Mylan Specialty, L.P. at 1-877-446-3679 (1-877-4-INFO-RX) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**DRUG INTERACTIONS**

- Cardiac glycosides or diuretics: observe for development of cardiac arrhythmias. (7)
- Tricyclic antidepressants, monoamine oxidase inhibitors, levodopa, dopamine, and certain antihistamines: potentiate effects of epinephrine. (7)
- Beta-adrenergic blocking drugs: antagonize cardiovascular and bronchodilating effects of epinephrine. (7)
- Alpha-adrenergic blocking drugs: antagonize vasoconstriction 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 angioedema. (7)

See 17 for PATIENT COUNSELING INFORMATION and FDA approved patient labeling

Revised: April 2014

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

**FULL PRESCRIBING INFORMATION**

1 INDICATIONS AND USAGE

EpiPen® and EpiPen Jr® are intended for immediate administration as emergency support therapy only 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 Indications and Usage (1), Dosage and Administration (2) and Patient Counseling Information (17)].

5.2 Incorrect Locations of Injection

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. Large doses or accidental intravenous injection of epinephrine may result in cardiovascular collapse and death due to 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.

- 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 gas gangrene. Cleansing with alcohol does not kill bacterial spores, and therefore, does not lower this risk.

- Do not inject into digits, hands, or feet. Since epinephrine is a strong vasconstrictor, 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 for further treatment of anaphylaxis as emergency supportive therapy and to inform the health care professional in the emergency room of the location of the accidental injection. Treatment of such inadvertent administration should consist of vasodilatation, in addition to further appropriate treatment of anaphylaxis [see Adverse Reactions (6)].

5.3 Allergic Reactions Associated With Sulfite

The presence of a sulfite in this product should not deter use. (5.3)

Epinphrine is the preferred treatment for serious allergic reactions or anaphylaxis even though this product contains sodium metabisulfite, a sulfite that may, in other products, cause allergic-type reactions including anaphylactic reactions or other emergency situations even if the patient is sulfite-sensitive.

Ephinephrine is the preferred treatment for serious allergic reactions or anaphylaxis even though this product contains sodium metabisulfite, a sulfite that may, in other products, cause allergic-type reactions including anaphylactic reactions or other emergency situations even if the patient is sulfite-sensitive. The alternatives to using epinephrine in a life-threatening situation may not be satisfactory.

5.4 Disease Interactions

Some patients may be at greater risk for developing adverse reactions after epinephrine administration. Despite these concerns, it should be recognized that the presence of these conditions is not a contraindication to epinephrine administration. (5.4)

Other Patients and Diseases

- Patients with Heart Disease
- Patients with Cardiac Arhythmias
- Patients with Parkinson's Disease
- Patients with Congestive Heart Failure
- Patients with Cardiac Structural Disease

See Warnings and Precautions (5.1), Drug Interactions (7) and Adverse Reactions (6).

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 for the treatment of anaphylaxis has not been determined. 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 following therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension or hyperthyroidism [see Warnings and Precautions (5.4)].

Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs [see Warnings and Precautions (5.4) and Drug Interactions (7)].

Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease [see Warnings and Precautions (5.4)].

Angina may occur in patients with coronary artery disease [see Warnings and Precautions (5.4)].

Accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area [see Warnings and Precautions (6.2)].
Adverse events experienced as a result of accidental injections may include increased heart rate, local reactions including injection site pallor, coldness and hypoesthesia or injury at the injection site resulting in bruising, bleeding, discoloration, erythema or skeletal injury. Injection into the buttock has resulted in cases of gas gangrene [see Warnings and Precautions (5.2)].

**12 DRUG INTERACTIONS**

Patients who receive epinephrine while concomitantly taking cardiac glycosides, diuretics, or anti-arrhythmics should be observed carefully for the development of cardiac arrhythmias [see Warnings and Precautions (5.4)]. The effects of epinephrine may be potentiated by tricyclic antidepressants, the dopamine oxidase inhibitors, levodopa, lithium carbonate, and certain anti-arrhythmics, notably chlorpromazine, trimethaphan, and diphendyline. The cardiovascular and bronchodilating effects of epinephrine are antagonized by beta-adrenergic blocking drugs, such as propranolol.

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

Ergot alkaloids may also reverse the pressor effects of epinephrine.

**8 USE IN SPECIFIC POPULATIONS**

**8.1 Pregnancy**

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 used during pregnancy only if the potential benefit justifies the risk to the fetus (fetal, toxemia, spontaneous abortion, or both).

Epinephrine has been shown to have teratogenic effects when administered subcutaneously in rabbits at approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m² basis) at a gestational dose of 1.2 mg/kg/day for two to three days, in mice at approximately 7 times the maximum daily subcutaneous or intramuscular dose (on a mg/m² basis at a gestational 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/m² basis at gestational dose of 0.5 mg/kg/day for 4 days).

These effects were not seen in mice at approximately 3 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m² basis at a gestational dose of 0.5 mg/kg/day for 10 days).

**8.3 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.

**8.4 Pediatric Use**

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 reported in adults. The potential benefit of Epipen® and Epipen Jr® in the treatment of anaphylactic reactions in children should be weighed against the possible increased risk of developing panic reactions due to the lower dosage levels available in the pediatric form of the product [see Warnings and Precautions (5.4)].

**8.5 Geriatric Use**

Clinical studies for the treatment of anaphylaxis have not been performed in subjects aged 65 and over to determine whether they respond differently from younger subjects. However, other 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 to elderly individuals, who may be at greater risk for developing adverse reactions after epinephrine administration [see Warnings and Precautions (5.4), Overdosage (10)].

**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 W2P bacterial reverse mutation assay. Epinephrine was positive in the DNA Repair test with S. typhimurium, but not in the Salmonella bacterial reverse mutation assay. The potential for epinephrine to impair fertility has not been evaluated.

**16 HOW SUPPLIED/STORAGE AND HANDLING**

**16.1 How Supplied**

Epipen® Auto-Injectors (epinephrine injections, USP; 1.000, 0.3 mg) are available as Epipen 2-Pak®, NDC 49502-500-02, a pack that contains two Epipen® Auto-Injectors (epinephrine injections, USP; 1.000, 0.3 mg) and one Epipen® Trainer. Epipen 2-Pak® and Epipen Jr 2-Pak® also includes an S-clip to clip two carrier tubes together. Rx only.

16.2 Storage and Handling

Phenylephrine hydrochloride is light sensitive and should be stored in the carrier tube provided to protect it from light. Store at 20° to 25°C (88° 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 device 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 complete descriptive form should be provided to the patient and/or caregiver that details the appropriate use of EpiPen® and Epipen Jr® in detail, with the patient or caregiver.

Epinephrine is essential for the treatment of anaphylaxis. Patients are at risk of a severe history of allergic reactions (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

Patients and/or caregivers should be instructed in the appropriate use of Epipen® and Epipen Jr®. Epipen® 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®. 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 the Epipen® shows instructions for use and a diagram depicting the injection process. Patients and/or caregivers should be instructed to use the Epipen® Trainer to familiarize themselves with the use of Epipen® prior to the emergency event. A printed label on the surface of the Epipen Jr® shows instructions for use and a diagram depicting the injection process. Patients and/or caregivers should be instructed in the appropriate use of EpiPen Jr®. EpiPen® Jr® 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 Jr®.

**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, pallor, dizziness, weakness or shockiness, headache, apprehension, nervousness, or anxiety. These signs and symptoms usually subside rapidly, however, with rest, quiet and recumbency. Patients with hypertension or hyperthyroidism may develop more severe or persistent effects, and patients with coronary artery disease could become symptomatic.

**Storage and Handling**

Instruct patients to inspect the epinephrine solution visually through the clear window of the auto-injector periodically. Epipen® and Epipen Jr® should be replaced 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 auto-injector carrier tube is not waterproof. Patients should be instructed 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 precautions can be found inside each Epipen® or Epipen Jr® carton.
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 health care professional 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 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 (in the way you voice sounds)
   - hives (raised reddish rash that may itch)
   - severe itching
   - swelling of your face, lips, mouth, or tongue
   - skin rash, redness, or swelling
   - fast heartbeat
   - weak pulse
   - feeling very anxious
   - confusion
   - stomach pain
   - losing control of urine or bowel movements (incontinence)
   - diarrhea or stomach cramps
   - dizziness, fainting, or “passing out” (unconsciousness)

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

   Talk to your health care professional 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 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 health care professional 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 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 serious 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 the their health care professional.
- 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 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 health care professional before using the EpiPen® or EpiPen Jr®?**

Before you use EpiPen® or EpiPen Jr®, tell your health care professional 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 will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if epinephrine passes into your breast milk.

**Tell your health care professional about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tell your health care professional of all known allergies. Especially tell your health care professional 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® works. Know the medicines you take. Keep a list of them to show your health care professional and pharmacist when you get a new medicine.**

Use your EpiPen® or EpiPen Jr® for treatment of anaphylaxis as prescribed by your health care professional, regardless of your medical conditions 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 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 health care professional will show you how to safely use the EpiPen® or EpiPen Jr® Auto-Injector.
- Use your EpiPen® or EpiPen Jr® exactly as your health care professional tells you to use it. You may need to use a second EpiPen® or EpiPen Jr® if symptoms continue or recur. Only a health care professional 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, hands or feet may cause a loss of blood flow to these areas. If this happens, go immediately to the nearest emergency room. Tell the health care professional 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 color and is a training aid that will help you practice the injection. The grey EpiPen® Trainer 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.
- 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. 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 health care professional where on your body you received the accidental 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 health care professional about all your medical conditions.

**Common side effects of EpiPen® and EpiPen Jr® include:**

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

These side effects may go away with rest. Tell your health care professional 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 health care professional or pharmacist.

Call your health care professional 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 health care professional. You can ask your pharmacist or health care professional 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 gray 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 of the needle before the orange tip is 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

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 health care professional 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 health care professional.

Your EpiPen® and EpiPen Jr® Auto-Injector

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.

Grasp the auto-injector in your fist with the orange tip pointing downward.

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

Step 2. Administer EpiPen® or EpiPen Jr®

Hold the auto-injector with orange tip near the middle of the outer thigh (upper leg).

Swing and firmly push the orange tip against the middle of the outer thigh until it ‘clicks’.

Keep the auto-injector firmly pushed against the thigh at a 90° angle (perpendicular) to the thigh.

Hold firmly against the thigh for approximately 10 seconds to deliver the medicine. The injection is now complete.

Remove the auto-injector from the thigh. The orange tip will extend to cover the needle.

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 health care professional.

Tell the health care professional that you have received an injection of epinephrine. Show the health care professional where you received the injection.

Give your used EpiPen® or EpiPen Jr® Auto-Injector to the health care professional for inspection and proper disposal.

Ask for a refill, if needed.

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.

Note:

• The used auto-injector with extended needle cover will not fit in the carrier tube.

• EpiPen® or EpiPen Jr® are single-use injectable devices that deliver a fixed dose of epinephrine. The auto-injector cannot be reused. 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® or 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.

• 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

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