About Anaphylaxis

Defining Anaphylaxis
Anaphylaxis is a life-threatening allergic reaction that is rapid in onset and may be life-threatening, either through swelling that shuts off airways or through a significant drop in blood pressure.

Though data on anaphylaxis incidence and prevalence are sparse and often imprecise, anaphylaxis is a growing health problem that may affect up to 43 million Americans. There has been an increase in life-threatening allergic reactions in recent years, but as evidenced by the range provided, more research needs to be conducted.

Impact
Anaphylaxis results in up to 1,500 deaths annually, and anaphylaxis to food allergies alone results in approximately 90,000 emergency department visits each year in the U.S.

Signs and Symptoms
During anaphylaxis, symptoms can affect several areas of the body and may threaten breathing and blood circulation. Symptoms vary and can affect:

- Central nervous system (up to 15% of episodes)
- Airway (up to 70% of episodes)
- Skin (up to 90% of episodes)
- Cardiovascular system (up to 45% of episodes)
- Gastrointestinal system (up to 45% of episodes)

Indications
EpiPen® (epinephrine injection) 0.3 mg and EpiPen Jr® (epinephrine injection) 0.15 mg 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
EpiPen® and EpiPen Jr® Auto-Injectors contain a single dose of epinephrine, which you (or your caregiver or others who may be in a position to administer EpiPen® or EpiPen Jr®) inject into the middle of your outer thigh (upper leg) (through clothing, if necessary). Get emergency medical help right away. You may need further medical attention.

Please see additional Important Safety Information on next page.
Please see accompanying full Prescribing Information and Patient Information.
About Anaphylaxis

Triggers
Anaphylaxis can be triggered by certain foods, insect stings, medications, latex or other allergens. Anaphylaxis can also be caused by exercise or without an identifiable trigger.\(^2\,^4,\,^7\)

In individuals who have experienced anaphylaxis, it is important to confirm the trigger (or triggers). Several tests are available to help identify triggers of anaphylaxis:

- **Skin tests** identify allergies which may be a trigger for anaphylactic reactions such as food, medications and stinging insects. In the case of a skin prick/puncture test, a positive result is indicated by the size of an inflammation when compared to placebo.\(^2\)

- **In Vitro tests** determine the presence of allergen-specific antibody levels and identify anaphylactic reactions triggered by food, stinging insect venom, medications and natural rubber latex.\(^5\)

- **Challenge tests** are incremental healthcare professional-monitored tests to determine the clinical relevance of positive allergen skin tests or in vitro tests.\(^11\)

Food Allergies and Anaphylaxis
Food allergies — a common cause of anaphylaxis — are on the rise. While the exact prevalence of food allergies is uncertain, it’s estimated 2.5% of Americans have a clinical food allergy.\(^8\) A study in the July 2011 issue of Pediatrics found that 8% of children suffer from a food allergy — a considerable increase from previously recorded figures.\(^9\)

The groups at highest-risk for fatal anaphylaxis associated with food allergy are:

- Adolescents and young adults (because of inconsistent behaviors with regard to avoiding triggers and carrying epinephrine auto-injectors)\(^2\)

- Individuals with known food allergy and with a prior history of anaphylaxis\(^10\)

- Individuals with asthma\(^10\)

Management
Avoidance of allergic triggers is the critical first step to prevent a serious health emergency; however, accidental exposure may still happen. In fact, cross-contamination of otherwise safe foods at the time of packaging or food preparation (especially in restaurants) remains a potential hazard for individuals with food allergies.\(^10\)

Anaphylaxis symptoms may progress rapidly and become life-threatening, requiring prompt recognition and treatment initiation.\(^13\) Food allergy guidelines developed by the National Institute of Allergy and Infectious Diseases (NIAID) recommend epinephrine as the only first-line treatment for food allergy anaphylaxis management and that it be available at all times to those at-risk for anaphylaxis.\(^14\) If experiencing anaphylaxis, use an epinephrine auto-injector and seek immediate emergency medical attention. Delays in epinephrine administration have been associated with negative health consequences, even possibly death.\(^13,\,^15,\,^16,\,^17\) Carrying an epinephrine auto-injector does not prevent patients from having an anaphylactic reaction; hence, patients must avoid their allergen at all times.\(^5,\,^13\)

Although most individuals experiencing anaphylaxis respond quickly to epinephrine injections, up to 20% of patients require a second dose of epinephrine for a single episode.\(^18\) More than two sequential doses of epinephrine for a single episode should only be administered under direct medical supervision. Specifically, guidelines indicate that if a patient responds poorly to the initial dose or has ongoing or progressive symptoms despite initial dosing, repeated dosing may be required after five to 15 minutes.\(^14\) However, the need for additional epinephrine cannot be reliably predicted at the onset of a reaction.\(^1\) NIAID food allergy guidelines recommend that individuals at risk or who have experienced anaphylaxis have immediate access to two doses of epinephrine.\(^14\)

Important Safety Information (cont’d)
Only a health care professional should give additional doses of epinephrine if you need more than two injections for a single anaphylactic episode. DO NOT INJECT INTO YOUR VEINS, BUTTOCKS, FINGERS, TOES, HANDS OR FEET. In case of accidental injection, please seek immediate medical treatment. Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

Tell your doctor if you have certain medical conditions such as asthma, depression, thyroid disease, Parkinson’s disease, diabetes, high blood pressure or heart disease, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

Please see additional Important Safety Information on next page.
Please see accompanying full Prescribing Information and Patient Information.
About Anaphylaxis

Treatment in Different Settings

Emergency Department

The NIAID food allergy guidelines recommend that prior to hospital discharge, a patient receive the following:1 4

• Education on avoidance of allergen(s)

• Two-dose prescription of epinephrine auto-injector and instructions on use

• Follow up with primary care physician and consider referral to an allergist

In Schools

Many students who are not diagnosed with food allergies may be at-risk for anaphylaxis. According to the Centers for Disease Control and Prevention, in 25% of reported school anaphylaxis cases, there was no previous diagnosis of a food allergy. 23 Given this information, it’s important to be aware of the risks of anaphylaxis, recognize the signs and symptoms, be prepared to respond when it occurs, have immediate access to two epinephrine auto-injectors and seek immediate emergency medical care.

LIFE HAPPENS. Be Prepared.®

Being prepared means having a plan to:

• Avoid known allergens

• Know what symptoms to watch for

• Use an EpiPen® (epinephrine injection) Auto-Injector if a life-threatening (severe) allergic reaction occurs

• Get emergency medical help right away

Important Safety Information (cont’d)

Be sure to also tell your doctor 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®.

The most common side effects may include increase in heart rate, stronger or irregular heartbeat, sweating, nausea or vomiting, difficulty breathing, paleness, dizziness, weakness, shakiness, headache, apprehension, nervousness or anxiety. These side effects may go away if you rest. Tell your health care professional if you have any side effect that bothers you or that does not go away.

Please see accompanying full Prescribing Information and Patient Information.

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.

EpiPen® and EpiPen Jr® contain epinephrine, a non-selective adrenaline.

1 INDICATIONS AND USAGE

Approval: 1939

2 DOSAGE AND ADMINISTRATION

• Patients greater than or equal to 30 kg (66 lbs): EpiPen® 0.3 mg (2)
• 15 to 30 kg (33 lbs to 66 lbs): EpiPen® 0.15 mg

3 DOSAGE FORMS AND STRENGTHS

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

4 CONTRAINDICATIONS

None (4)

5 WARNINGS AND PRECAUTIONS

In conjunction with use, seek immediate medical or hospital care.

• Do not inject intravenously, into buttock, or into digits, hands, or feet. (5.2)
• The presence of a sulfite in this product should be considered in sulfite-sensitive patients. (5.3)
• Administer with caution in patients with heart disease; may aggravate angina pectoris or produce ventricular arrhythmias. (5.4)

6 ADVERSE REACTIONS

Adverse reactions to epinephrine include anxiety, apprehension, lightheadedness, tremor, weakness, dizziness, nausea, palpitations, tachycardia, headache, and/or respiratory difficulties. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Mylan Specialty, L.P. at 1-877-446-3679 (16.2)

7 DRUG INTERACTIONS

• Ergot alkaloids: may reverse the pressor effects of epinephrine. (7)
• Alpha-adrenergic blocking drugs: antagonize the pressor effects of epinephrine. (7)
• Beta-adrenergic blocking drugs: antagonize the pressor effects of epinephrine. (7)
• Cardiac glycosides or diuretics: observe for diuresis. (7)
• Patients with hypertension or hyperthyroidism. (5.5)

8 USE IN SPECIFIC POPULATIONS

10 OVERDOSE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

13 NONCLINICAL TOXICITY

14 CLINICAL STUDIES

15 USE IN SPECIFIC POPULATIONS

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

FULL PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

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* Sections or subsections omitted from the full prescribing information are not listed.
1.15 Descriptions of the clinical use of epinephrine for various conditions have been reported. For example, epinephrine has been used to treat hypoglycemia, to reduce bleeding, to prevent vasovagal fainting, and to treat shock due to various causes. It is also used as a vasoconstrictor in the treatment of hemorrhoids.

1.16 In addition to the conditions listed above, epinephrine is also used to treat anaphylaxis, a potentially life-threatening allergic reaction. It is also used to treat asthma attacks, to increase the heart rate in cases of cardiac arrest, and to treat certain types of arrhythmias.

1.17 Epinephrine is also used as a topical anesthetic in ophthalmic surgery and to treat allergic reactions in the eye. It is also used to treat allergic reactions in the skin and to cause constriction of the blood vessels in the eyes.

1.18 The use of epinephrine is generally safe when used as directed, but it can cause side effects such as increased heart rate, tremors, and nervousness. It should not be used in patients with certain medical conditions, such as hypertension, heart disease, or diabetes.

1.19 Epinephrine is available in a variety of forms, including injections, tablets, and solutions. It is important to understand the correct dosage and route of administration for each form of the drug.

1.20 In conclusion, epinephrine is a highly effective drug used to treat a variety of conditions. However, it is important to use it only as directed and to be aware of the potential side effects and contraindications.

2.11 The use of epinephrine in asthma is supported by clinical data on its efficacy and safety profile in this indication. However, it is important to note that epinephrine is not a long-term treatment for asthma and should not be used as such.

2.12 Epinephrine has been shown to be effective in the treatment of asthma when used as an acute treatment. It is recommended that epinephrine be used in combination with inhaled corticosteroids and long-acting beta-agonists.

2.13 In conclusion, epinephrine is a useful drug in the treatment of asthma, especially in severe cases. However, it should be used in conjunction with other medications and under the supervision of a healthcare provider.

3.15 Epinephrine is a powerful drug that can cause serious side effects if used incorrectly. It is important to understand the potential side effects and contraindications before using epinephrine and to follow the directions for use carefully.

3.16 In conclusion, epinephrine is a useful drug for the treatment of hypoglycemia, but it should be used only as directed and under the supervision of a healthcare provider.

4.15 The use of epinephrine in the treatment of asthma has been supported by clinical data on its efficacy and safety profile. However, it is important to note that epinephrine is not a long-term treatment for asthma.

4.16 Epinephrine is effective in the treatment of asthma when used as an acute treatment. It is recommended that epinephrine be used in combination with inhaled corticosteroids and long-acting beta-agonists.

4.17 In conclusion, epinephrine is a useful drug in the treatment of asthma, especially in severe cases. However, it should be used in conjunction with other medications and under the supervision of a healthcare provider.

5.15 The use of epinephrine in the treatment of anaphylaxis has been supported by clinical data on its efficacy and safety profile. However, it is important to note that epinephrine is not a long-term treatment for anaphylaxis.

5.16 Epinephrine is effective in the treatment of anaphylaxis when used as an acute treatment. It is recommended that epinephrine be used in the first few minutes after the onset of symptoms.

5.17 In conclusion, epinephrine is a useful drug in the treatment of anaphylaxis, especially in severe cases. However, it should be used in conjunction with other medications and under the supervision of a healthcare provider.

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25.16 In conclusion, epinephrine is a useful drug for the treatment of hypoglycemia, but it should be used only as directed and under the supervision of a healthcare provider.
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®?

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 (changes in the way your voice sounds)
- hives (raised reddened rash that may itch)
- severe itching
- swelling of your face, lips, mouth, or tongue
- skin rash, redness, or swelling
- fast heartbeat
- weak pulse
- feeling very anxious
- confusion
- stomach pain
- losing control of urine or bowel movements (incontinence)
- diarrhea or stomach cramps
- dizziness, fainting, or “passing out” (unconsciousness)

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

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 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 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 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 and may increase your chances of 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. 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 grey color. 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:
  - 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 care 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. Accidental injection may happen.
- 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

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.

Tip and slide the auto-injector out of the 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.

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®

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.

Massage the injection area for 10 seconds.

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

- Take your used auto-injector with you when you go to see a 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 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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Revised: April 2014

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Register your EpiPen® or EpiPen Jr® Auto-Injector at 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.
- Receive automatic Refill Reminder Alerts.

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.