About Anaphylaxis: Frequently Asked Questions

Anaphylaxis Overview

Q: What is anaphylaxis?
A: Anaphylaxis (an-a-fi-LAX-is) is a life-threatening allergic reaction that is rapid in onset, either through swelling that shuts off airways or through a significant drop in blood pressure.

Q: What are the common signs and symptoms of anaphylaxis?
A: According to a 2010 article published in The Journal of Allergy and Clinical Immunology, during anaphylaxis, symptoms can range from mild to severe and may affect:

- **Central nervous system** (up to 15% of episodes): feelings of uneasiness, throbbing headache, dizziness, confusion, tunnel vision
- **Airway** (up to 70% of episodes): shortness of breath, chest tightness, wheezing, itchy throat, hoarseness (dysphonia)
- **Skin** (up to 90% of episodes): hives (urticaria), itching (pruritus), flushing, itching and swelling of lips, tongue, uvula/palate
- **Cardiovascular system** (up to 45% of episodes): hypotension, chest pain, fast heart rate (tachycardia), weak pulse, dizziness, fainting
- **Gastrointestinal system** (up to 45% of episodes): nausea, cramping, abdominal pain, vomiting, diarrhea

Q: How quickly do symptoms appear?
A: Symptoms typically appear within minutes to a few hours following contact with an allergen.

Q: How many Americans are at-risk for anaphylaxis?
A: Though data on anaphylaxis incidence and prevalence are sparse and often imprecise, estimates indicate that 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.

Q: How many emergency department visits occur annually as a result of anaphylaxis in the U.S.?
A: A study published in the March 2011 issue of The Journal of Allergy and Clinical Immunology stated that anaphylaxis results in approximately 90,000 annual emergency department visits in the U.S. for food allergies alone.

Indications

EpiPen® (epinephrine injection, USP) 0.3 mg and EpiPen Jr® (epinephrine injection, USP) 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

Use EpiPen® or EpiPen Jr® 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.

Please see additional Important Safety Information on next page.

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Q: How do people know if they may be at-risk for anaphylaxis?
A. Anyone can develop a potentially life-threatening (severe) allergy at any time in life, but certain factors may increase the potential to experience anaphylaxis. These include:
- History of anaphylaxis
- Certain age groups associated with high-risk behavior (adolescents and young adults)
- Diagnosed food allergies along with:
  » Eczema
  » Asthma
  » Severe allergic rhinitis (symptoms include sneezing, itching, watery nose and/or eyes)
- History of lung problems
- Allergy/anaphylaxis causing medications (immunologic) such as, anticonvulsants, insulin (especially those produced from animals), iodine (iodinated), x-ray contrast dyes, penicillin (related antibiotics) and sulfa drugs
- Immunotherapy (allergy shots)

It is important to note that only a healthcare professional can determine an individual’s potential to experience anaphylaxis.

Q: Are some episodes of anaphylaxis more severe than others for the same person?
A: The potential to experience an anaphylactic reaction is based on many factors and cannot always be determined from previous allergic reactions. For example, studies of individuals with peanut allergies have shown that 44-59% of mild allergic reactions may be followed by a severe reaction after a second exposure to the same allergen.

Q: How are people tested for anaphylaxis triggers?
A: In individuals who have experienced anaphylaxis, it is important to confirm the trigger(s). 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.

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.

Challenge tests are incremental healthcare professional-monitored tests to determine the clinical relevance of positive allergen skin tests or in vitro tests.

Anaphylaxis Treatment

Q: How are people treated for anaphylaxis?
A: According to food allergy guidelines by the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH), epinephrine is the only first-line treatment in all cases of anaphylaxis (including from food allergies) and should be available at all times to people at-risk for anaphylaxis. Avoidance of allergic triggers is the critical first step to prevent a serious health emergency; however, accidental exposure may still happen. According to NIAID, if experiencing anaphylaxis, use an epinephrine auto-injector and seek immediate emergency medical attention. Carrying an epinephrine auto-injector does not prevent patients from having an anaphylactic reaction; hence, patients must avoid their allergen at all times.

Q: When should epinephrine be administered?
A: Epinephrine is the only first-line treatment in all cases of anaphylaxis (including from food allergies). If experiencing anaphylaxis, use an epinephrine auto-injector and seek immediate emergency medical attention.

Anaphylaxis occurs when an allergic reaction involves one body system, either respiratory or cardiovascular alone; it may also occur in multiple body systems, such as the skin, gastrointestinal, and/or central nervous system.

It is important to remember that for most patients the benefits of epinephrine treatment outweigh the risks of delayed or no administration. Delays in epinephrine administration have been associated with negative health consequences. Since there are no absolute contraindications to epinephrine administration for an anaphylactic reaction, it is important to administer epinephrine immediately even if all criteria for anaphylaxis diagnosis have not yet been met.

Important Safety Information (cont’d)

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.

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About Anaphylaxis: Frequently Asked Questions

Q: How many doses of epinephrine are recommended for an individual to have on hand?
A: Epinephrine takes effect within minutes, but it is rapidly metabolized. As a result, its effect can be short-lived and repeated dosing may be necessary. In fact up to 20% of individuals who receive epinephrine will require more than one dose before symptoms are alleviated. More than two sequential doses of epinephrine for the same episode should be administered only under direct medical supervision. The NIAID food allergy guidelines recommend that all patients at-risk for or who have experienced anaphylaxis have access to two doses of epinephrine at all times. Seek immediate medical attention after use.

Q: Are antihistamines a viable treatment option for anaphylaxis?
A: EpiPen® Auto-Injector is approved for the emergency treatment of anaphylaxis and for people who are at increased risk for anaphylaxis. Antihistamines, such as Benadryl®, are not approved for these uses and should not be substituted for epinephrine. Despite these facts, the use of antihistamines is the most common reason reported for not using epinephrine and may place a patient at significantly increased risk for progression toward anaphylaxis. In addition, the use of certain antihistamines can increase the effects of epinephrine, so talk to your doctor before using antihistamines with EpiPen® Auto-Injector.

Q: What does epinephrine do during an anaphylactic reaction?
A: During anaphylaxis, epinephrine works to relieve life-threatening symptoms by constricting blood vessels to increase blood pressure, relaxing muscles in the lungs to improve breathing, stimulating the heart and reducing hives and swelling that may occur around the face and lips.

Important Safety Information (cont’d)

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®.

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About Food Allergies

Q: What happens when a person has a life-threatening allergic reaction to food?
A: Food allergy-induced anaphylaxis occurs when the immune system is exposed to a specific food that triggers the release of chemicals, including histamine, resulting in symptoms of anaphylaxis. Symptoms may include low blood pressure, difficulty in breathing, nausea and/or vomiting.

Q: How many Americans have food allergies?
A: While the exact prevalence of food allergies is uncertain, it’s estimated that 2.5% of Americans have a clinical food allergy. A study in the July 2011 issue of Pediatrics found that 8% of children have a food allergy — a considerable increase from previously reported figures.

Q: Is there a cure for food allergies?
A: There is no cure for food allergies. Avoidance of allergic triggers is the critical first step to managing severe allergies; however, accidental exposure may still happen. In fact, cross-contact of otherwise safe foods at the time of packaging or food preparation (especially in restaurants) remains a potential hazard for individuals with food allergies. This is why it is important to be prepared with an anaphylaxis action plan, which includes avoiding known allergens, recognizing signs and symptoms, having access to two epinephrine auto-injectors and seeking immediate medical care if anaphylaxis occurs.
Q: Are food allergies on the rise?
A: Food allergies — a common cause of anaphylaxis — are on the rise. A study published in the July 2011 issue of Pediatrics found a considerable increase in food allergy from previously reported figures — it found that 8% of children in the U.S., or approximately one out of 13, have a food allergy. Of those children affected, 38% had a history of a severe reaction, and 30% had allergies to multiple foods. The prevalence of peanut allergies among children under 18 significantly increased from 0.4% in 1997 to 1.4% in 2008 (p < 0.0001).

Q: How many children are at-risk for anaphylaxis from food allergies?
A: A study published in the July 2011 issue of Pediatrics found that an estimated one out of 13 children in the U.S. have a food allergy, a considerable increase from previously reported figures. 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.

Q: What is causing the increase in food allergies?
A: There is no definitive answer as to why food allergies are increasing. One theory, called the hygiene hypothesis, suggests that modern hygienic processes and a generally more sterile environment have reduced exposure to certain bacteria. To compensate, the immune system is conditioned toward an allergic state.

Q: Why is food intolerance often confused with food allergies?
A: According to the NIAID food allergy guidelines, food allergies and food intolerance share some of the same symptoms; however, food intolerance does not involve the immune system. It can cause great discomfort but is not life-threatening. Some people with food intolerances are not able to digest certain foods because their bodies lack the specific enzyme needed to break down that food.

Food Allergies and Anaphylaxis

Q: Can the severity of food allergy-induced anaphylaxis be predicted based on a person's prior reactions?
A: The severity of food allergy-induced anaphylaxis cannot be predicted based on a person's prior reactions. The severity of food-triggered anaphylaxis depends on a number of factors, including the amount eaten, the food form (cooked, raw or processed) and the co-ingestion of other foods. Other considerations include the person’s age, the body’s sensitivity at time of ingestion, the speed at which food is absorbed by the body and whether the person has another life-threatening condition, such as severe or uncontrolled asthma.

Q: What are the most common food allergens associated with anaphylaxis?
A: The most common food allergens that can cause anaphylaxis are cow’s milk, eggs, wheat, soybeans, peanuts, tree nuts (walnuts, cashews, pistachios, pecans, etc.), fish and shellfish.

Q: Are some people at higher risk for food allergy-induced anaphylaxis than others?
A: Groups at highest risk for anaphylaxis associated with food allergy include:
- Adolescents and young adults (because of inconsistent behaviors related to avoiding triggers and carrying epinephrine auto-injectors)
- Individuals with known food allergy and a prior history of anaphylaxis
- Individuals with asthma and a food allergy

Important Safety Information (cont’d)

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 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.
About Anaphylaxis: Frequently Asked Questions

Q: How much of a food allergen does it take to cause a reaction?
A: Food allergens are not always obvious or easily identifiable. Even trace amounts of a food allergen can cause a reaction in someone who is allergic. The allergen does not need to be ingested; in some cases, skin contact or inhalation can trigger a reaction. Avoidance of allergic triggers is the critical first step to managing severe allergies; however, accidental exposure may still happen. This is why it is important to be prepared with an anaphylaxis action plan, which includes avoiding known allergens, recognizing signs and symptoms, having access to two epinephrine auto-injectors and seeking immediate emergency medical care.

Q: What should people at-risk for anaphylaxis look for in food labels?
A: By law, the eight major allergens (cow’s milk, eggs, wheat, soybeans, peanuts, tree nuts including walnuts, cashews, pistachios and pecans, fish and shellfish) must be noted on all packaged food labels in the U.S., either in the ingredient list or in a separate allergen statement. However, individuals with food allergies should be aware that advisory or precautionary labeling (i.e., “may contain,” “in a facility that also processes”) is not regulated and is solely voluntary.

Q: Other than food, what are the most common triggers that lead to anaphylaxis?
A: Other common triggers are insect venom, latex, medications and exercise. The cause of anaphylaxis is unidentified in one out of five of U.S. patients, known as idiopathic anaphylaxis.

About EpiPen® and EpiPen Jr® Auto-Injectors

Q: What are the appropriate uses and product features of EpiPen® and EpiPen Jr® Auto-Injectors?
A: EpiPen® and EpiPen Jr® Auto-Injectors are used for the emergency treatment of anaphylaxis. EpiPen® Auto-Injector has been the most prescribed epinephrine auto-injector in the U.S. for more than 25 years.

EpiPen® Auto-Injector is available in two dosage strengths:
- EpiPen® Auto-Injector delivers 0.3 mg epinephrine injection and is intended for individuals who weigh ≥ 66 pounds.
- EpiPen Jr® Auto-Injector delivers 0.15 mg epinephrine injection and is intended for individuals who weigh 33-66 pounds.

EpiPen® and EpiPen Jr® Auto-Injectors are exclusively sold as two-packs, by prescription only.

Q: What is included in an EpiPen 2-Pak® and EpiPen Jr 2-Pak®?
A: Each EpiPen 2-Pak® and EpiPen Jr 2-Pak® contains two single auto-injectors, instructions for use, and a training device and instructions on how to use the training device to help patients become familiar with the administration technique. The training device contains no drug product or needle. The decision to exclusively offer the EpiPen 2-Pak® aligns with clinical food allergy guidelines for patients at-risk for or who have experienced anaphylaxis to have immediate access to two doses of epinephrine.
Instructions for Use
Carefully read these Instructions for Use before use of EpiPen® or EpiPen Jr® Auto-Injector, and make sure your healthcare professional shows you the right way to use it. If you have any questions, ask your healthcare professional.

EpiPen® and EpiPen Jr® Auto-Injectors

EpiPen® Auto-Injector delivers an 0.3 mg epinephrine injection and is intended for individuals who weigh ≥ 66 pounds (33 kilograms or more).

EpiPen Jr® Auto-Injector delivers an 0.15 mg epinephrine injection and is intended for individuals who weigh 33 to 66 pounds (15 to 30 kilograms).

3 Simple Steps
1. Prepare EpiPen® or EpiPen Jr® Auto-Injector for injection.
3. Finalize injection process.
   (See detailed instructions on the following page)

Important Safety Information (cont’d)
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.

Please see additional Important Safety Information on next page.
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About Anaphylaxis: Frequently Asked Questions

1. Prepare EpiPen® Auto-Injector or EpiPen Jr® Auto-Injector for injection.
   - Remove the auto-injector from the clear carrier tube.

   - Hold the auto-injector with orange tip near the outer thigh.
   - Swing and firmly push the orange tip against 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 3 seconds to deliver the drug. 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.

Note:
- The needle comes out of the orange tip.
- Never put your thumb, fingers or hand over the orange tip.
- If you are administering EpiPen® or EpiPen Jr® to a young child, hold patient’s leg and limit movement.

Get emergency medical help right away. You may need further medical attention. You may need a second EpiPen® or EpiPen Jr® Auto-Injector should symptoms persist or recur. More than two sequential doses of epinephrine for a single episode should be administered only under direct medical supervision. Patients should seek medical care if they develop signs or symptoms of infection at the injection site.

Important Safety Information (cont’d)

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®.

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About Anaphylaxis: Frequently Asked Questions

Important Information:

- 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. Keep the blue safety release on until you need to use it.
- Only inject into outer thigh. Never inject into any other part of the body.
- Never put your thumb, fingers, or your hand over the orange tip. The needle comes out of the orange tip. Accidental injection into fingers or toes may result in blood loss to the affected area.
- If an accidental injection happens, get medical help right away.
- Do not place patient information or any other foreign objects in carrier with auto-injector, as this may prevent you from removing the auto-injector for use.

Q: Does EpiPen® Auto-Injector come with instructions?
A: Yes, patient directions for use, which include illustrations are enclosed in each EpiPen 2-Pak®. In addition, directions on how to administer EpiPen® Auto-Injector are printed on the side of the auto-injector itself. In addition, each EpiPen 2-Pak® and EpiPen Jr 2-Pak® contains two single auto-injectors and a training device to help patients become familiar with the administration technique. The training device has a grey color and contains no drug product or needle. Patients should ask their healthcare professional to demonstrate how to use EpiPen® Auto-Injector. If a patient can’t administer it, have the healthcare professional show a friend or relative.

Q: Can the EpiPen® Auto-Injector be reused?
A: No, although liquid remains in an EpiPen® Auto-Injector following an injection, it cannot be reused. A patient should take used EpiPen® or EpiPen Jr® Auto-Injectors to the emergency room or healthcare professional’s office for proper disposal.

Q: Do EpiPen® and EpiPen Jr® Auto-Injectors expire? If so, what should a patient do when it expires?
A: Like any medication, EpiPen® Auto-Injector has an expiration date, which is printed on the side of the auto-injector and end side of the carton. The effectiveness of this drug may decrease after the expiration date; therefore, care should be taken to refill the prescription before the expiration date. Individuals can register at epipen.com to receive expiration reminders.

Q: Where’s the best place to keep EpiPen® Auto-Injector?
A: EpiPen® Auto-Injector is transportable, but it should be kept at room temperature (25°C, 77°F) until the marked expiration date, when it should be replaced. The effectiveness of this drug may decrease after the expiration date. Therefore, care should be taken to refill the prescription before the expiration date. The EpiPen® Auto-Injector should be protected from light and never refrigerated or kept where it might be exposed to extreme temperatures, such as in the glove compartment of a car.

Q: Is the EpiPen® Auto-Injector carrier tube waterproof?
A: No, the EpiPen® Auto-Injector carrier tube has no rubber seal, so it is not waterproof.

Important Safety Information (cont’d)

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.**

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You are encouraged to report negative side effects of prescription drugs to the FDA.
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For additional information, please contact us at 800-395-3376.
Q: What signs and symptoms prompt the use of EpiPen® Auto-Injector?  
A: Signs and symptoms of anaphylaxis that may prompt the use of EpiPen® Auto-Injector include hives or redness of the skin, tightness in the throat, breathing problems and/or a decrease in blood pressure. These may occur in any two body systems: central nervous system, skin, airway, cardiovascular system or gastrointestinal system. It is important to talk to your healthcare professional and make an anaphylaxis action plan.

Q: Who should receive a prescription for EpiPen 2-Pak® or EpiPen Jr 2-Pak®?  
A: EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors are for the emergency treatment of 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 self-administration as emergency supportive therapy only. Seek immediate emergency medical treatment after use.

Q: How many EpiPen® Auto-Injectors have been dispensed in the U.S.?  
A: Since 1990, more than 72 million EpiPen® Auto-Injectors have been dispensed in the U.S.

Q: When did EpiPen® Auto-Injector receive approval by the U.S. Food and Drug Administration?  
A: EpiPen® Auto-Injector was approved by the U.S. Food and Drug Administration on Dec. 22, 1987. It has been the #1 prescribed epinephrine auto-injector in the U.S. for more than 25 years.

Q: Should all EpiPen® Auto-Injector patients have their own anaphylaxis action plan?  
A: Yes, EpiPen® Auto-Injector patients should work with their healthcare professional to create an anaphylaxis action plan, which includes avoiding known allergens, recognizing signs and symptoms, having access to two epinephrine auto-injectors and seeking immediate emergency medical care. EpiPen® Auto-Injector is not a substitute for emergency medical treatment. Patients should seek emergency medical attention immediately following administration. These plans may be personalized to each patient to include their allergic triggers, other medical conditions, other medications they’re currently taking, the specific dose of epinephrine prescribed to them and contact information for caregivers or family members.

Q: What happens if someone who has not been experiencing anaphylaxis is mistakenly injected with EpiPen® Auto-Injector?  
A: If someone is mistakenly injected, get medical help right away. Epinephrine is a naturally-occurring hormone, also known as adrenaline. Common side effects of epinephrine include faster, irregular or pounding heartbeat; sweating; nausea and vomiting; breathing problems; paleness; dizziness; weakness or shakiness; headache; and feelings of over excitement, nervousness or anxiety.

Q: At what age can a child self-administer the EpiPen® Auto-Injector?  
A: Parents should speak with their child’s healthcare professional to determine what is appropriate for each child.

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**Important Safety Information**
Use EpiPen® or EpiPen Jr® 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.

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Q: Where should a child keep EpiPen® Auto-Injector while at school?
A: Children and their appropriate school personnel should have immediate access to his/her EpiPen® Auto-Injector at all times and should discuss school regulations for carrying epinephrine auto-injectors, as they may vary. School personnel should be informed of a child’s history of anaphylaxis and the specific trigger(s) affecting the child.

Q: Does Mylan offer an online resource for patients?
A: Epipen.com offers an online resource center with helpful information about anaphylaxis and EpiPen® Auto-Injector. Patients can register on epipen.com to receive expiration reminders that prompt them to renew or refill their prescriptions before they expire. In addition, patients can receive reminders to see their doctor for follow-up evaluation and can receive a complimentary carrying case.

EpiPen® Auto-Injector has gone mobile. The free EpiPen® Auto-Injector app is now available on iTunes® and Google Play™. Avoidance is the first critical step when it comes to managing your life-threatening (severe) allergies. The My EpiPlan® app can help you track the allergens you and your family need to avoid, the location of your EpiPen® Auto-Injectors, expiration dates, emergency contact information and more.

Q: Does Mylan have a patient assistance program?
A: Mylan has a patient assistance program available for qualifying patients. Patients can find out if they are eligible for the program by emailing customer.service@mylan.com or calling the customer service line to speak with a representative at 1-800-395-3376.

Q: Is there a customer service line?
A: If a person has questions, he or she can call the customer service line to speak with a representative at 1-800-395-3376.

Q: How should EpiPen® Auto-Injector be properly mentioned in a news article?
A: It’s important to remember that, although well-known, EpiPen® Auto-Injector is a brand name, not a generic, and should only be used in connection with Mylan’s epinephrine auto-injector devices. When writing EpiPen® Auto-Injector, include a registered trademark. Options are as follows:

- EpiPen®, EpiPen Jr®, EpiPen 2-Pak® and EpiPen Jr 2-Pak® are registered trademarks owned by the Mylan companies.

“EpiPen®” is a brand, not a noun. If used on its own, it should refer to the brand or the family of products, not the specific device. When used without “Auto-Injector,” the EpiPen® name should not be pluralized or used with an article. Examples:

- You can say “How to use EpiPen®” but NOT “How to use an EpiPen®”
- You can say “Carry 2 EpiPen® Auto-Injectors” but NOT “Carry 2 EpiPens”
- You can say “More doctors prescribe EpiPen®” but NOT “More patients carry EpiPens”

Important Safety Information (cont’d)

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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.

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LIFE HAPPENS.  
Be Prepared.

Being prepared means having a plan to:
• Avoid known allergens
• Know what symptoms to watch for
• Have access to two epinephrine auto-injectors, such as EpiPen® (epinephrine injection, USP) Auto-Injector, at all times
• Get emergency medical help right away

Important Safety Information (cont’d)

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 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.
DOSAGE FORMS AND STRENGTHS

• Epipen® Injection, 0.3 mg: 0.3 mL epinephrine, USP, pre-filled auto-injector (3)

• Epipen Jr® Injection, 0.15 mg: 0.15 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 sulfite in this product should not deter use. (5.4)

• Administer with caution in patients with heart disease; may aggravate angina pectoris or produce ventricular arrhythmias. (5.5)

ADVERSE REACTIONS

Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and respiratory difficulties. (8)

To report SUSPECTED ADVERSE REACTIONS, contact Mylan Specialty, L.P. at 1-877-446-3679 (1-877-INFODX) or FDA at 1-800-FDA-1098 or www.fda.gov/medwatch.

DRUG INTERACTIONS

• Cardiac: glycosides or diuretics: observe for development of cardiac arrhythmias. (7)

• Tricyclic antidepressants, monoamine oxidase inhibitors, levothryoxine sodium, and certain antihistamines: potentiate effects of epinephrine. (7)

• Beta-adrenergic blocking drugs: antagonize cardioaccelerating and bronchodilating effects of epinephrine. (7)

• Alpha-adrenergic blocking drugs: antagonize vasoconstricting and hypertensive effects of epinephrine. (7)

• Epinephrine may reverse the pressor effects of epinephrine. (7)

USE IN SPECIFIC POPULATIONS

• Elderly patients may be at greater risk of developing adverse reactions (5.5, 8.9)

3 FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

• Do not inject intravenously, into buttock, or into digits, hands or feet. (5.2)

• Do not inject into digits, hands or feet. Since epinephrine is a strong vasoconstrictor, accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area. Advise the patient to go immediately to the nearest emergency room and to inform the healthcare provider in the emergency room of the location of the accidental injection. Treatment of such inadvertent administration is supportive and includes vasodilatation, in addition to further appropriate treatment of anaphylaxis [see Adverse Reactions (3)].

• Hold leg firmly during injection. 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 cooperative and kick or move during an injection. To minimize the risk of injection related injury when administering Epipen® to young children, instruct caregivers to hold the child’s leg firmly in place and limit movement prior to and during injection.

5.1 Emergency Treatment

Epipen® Jr® and Epipen® Jr™ are indicated for immediate administration as emergency supportive therapy and are not intended as a substitute for immediate medical care. In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care. More than two sequential doses of epinephrine should only be administered under direct medical supervision [see Indications and Usage (1), Dosage and Administration (2) and Patient Counseling Information (7)].

5.2 Injection-Related Complications

Epipen® Jr® and Epipen® Jr™ should only be injected into the anterolateral aspect of the thigh [see Dosage and Administration (2) and Patient Counseling Information (7)].

Dosage and Administration

Injection, 0.15 mg: 0.15 mg/0.3 mL epinephrine, USP, pre-filled auto-injector

Patient Counseling Information

Injection into the buttock may

Injection into the buttock may

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. (5.4)

Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. Rapidly acting vasodilators counteract the marked pressor effects of epinephrine if there is 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. (5.4)

Do not inject into digits, hands or feet. Since epinephrine is a strong vasoconstrictor, accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area. Advise the patient to go immediately to the nearest emergency room and to inform the healthcare provider in the emergency room of the location of the accidental injection. Treatment of such inadvertent administration is supportive and includes vasodilatation, in addition to further appropriate treatment of anaphylaxis [see Adverse Reactions (3)].

• Hold leg firmly during injection. 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 cooperative and kick or move during an injection. To minimize the risk of injection related injury when administering Epipen® to young children, instruct caregivers to hold the child’s leg firmly in place and limit movement prior to and during injection.

5.3 Serious Infections at the Injection Site

Rare cases of serious skin and soft tissue infections, including necrotizing fasciitis (flesh-eating bacteria) caused by Clostridia (gas gangrene), have been reported at the injection site following epinephrine injection for anaphylaxis. Clostridium spore can be killed by heat introduced into the deep tissue with subcutaneous or intramuscular injection. While cleansing with alcohol may reduce presence of bacteria on the skin, alcohol cleansing 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 vasoconstrictor, accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area. Advise the patient to go immediately to the nearest emergency room and to inform the healthcare provider in the emergency room of the location of the accidental injection. Treatment of such inadvertent administration is supportive and includes vasodilatation, in addition to further appropriate treatment of anaphylaxis [see Adverse Reactions (3)].

• Hold leg firmly during injection. 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 cooperative and kick or move during an injection. To minimize the risk of injection related injury when administering Epipen® to young children, instruct caregivers to hold the child’s leg firmly in place and limit movement prior to and during injection.

5.4 Local Infections

In addition to further appropriate treatment of anaphylaxis, infections have been reported following epinephrine injection, USP, pre-filled auto-injector

5.5 Adverse Reactions

Increased intracranial pressure: Injection into the head or neck may be associated with increased intracranial pressure. (7)

5.6 Injection Anaphylaxis

Injection into the head or neck may be associated with increased intracranial pressure. (7)

5.7 Injection Site Reactions

Injection into the head or neck may be associated with increased intracranial pressure. (7)

5.8 Injection-Related Infected Sites

Injection into the head or neck may be associated with increased intracranial pressure. (7)
Epinephrine should be administered with caution to patients who have heart disease, including patients with cardiac arrhythmias, angina pectoris, or a history of myocardial infarction. Due to the lack of randomized, controlled clinical trials, the 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: apprehension, restlessness, tremor, weakness, dizziness, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but may also occur in persons with hypertension or hyperthyroidism [see Warnings and Precautions (5.5)]. Bradycardia, cardiac arrest, or death have been reported in patients with underlying cardiovascular disease or those receiving certain drugs [see Warnings and Precautions (5.5) and Drug Interactions (7)]. Bradycardia may also occur in elderly patients with cardiovascular disease [see Warnings and Precautions (5.5)]. Lacerations, bent needles, and embedded needles have been reported when Epipen® has been injected into the thighs of young children who are uncooperative and kick or move during the injection [see Warnings and Precautions (5.5)]. Injection into the buttock has resulted in cases of gas gangrene [see Warnings and Precautions (5.5)]. Rare cases of serious skin and soft tissue infections, including necrotizing fasciitis and myonecrosis caused by Clostridium (gas gangrene) have been reported following epinephrine injection, including Epipen®, in the thigh [see Warnings and Precautions (5.5)].

The vasoconstricting and hypertensive 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. Engal allopurinol 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 potential risk to the fetus. (fetal death, limb anomalies, cleft palate). Epinephrine has been shown to have teratogenic effects when administered subcutaneously in rabbits at approximately 10 times the 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. These doses are 10 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 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 these same immunded daily subcutaneous or intramuscular dose (on a mg/m² basis) at a subcutaneous maternal 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 in children is limited. 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 on subjects aged 65 and over 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 to patients who may be at greater risk for developing adverse reactions after epinephrine administration [see Warnings and Precautions (5.5)]. Overdosage (10)

10 OVERDOSAGE

Overdosage of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients with cardiovascular disease [see Warnings and Precautions (5.5)]. Accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area [see Warnings and Precautions (5.5)].

Adverse events reported as a result of accidental injections may include increased heart rate, local reactions including injection site pallor, coldness and hypopesthesia or injury at the injection site as resulting in bruising, bleeding, discoloration, edema, erythema or sloughing of skin. Lacerations, bent needles, and embedded needles have been reported when Epipen® has been injected into the thigh of young children who are uncooperative and kick or move during the injection [see Warnings and Precautions (5.5)]. Injection into the buttock has resulted in cases of gas gangrene [see Warnings and Precautions (5.5)].

11 DESCRIPTION

Epinephrine (epinephrine injection, USP) 0.15 mg, 0.3 mg and 0.5 mg 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® Auto-Injector trainer device. Epipen Jr® Auto-Injector (epinephrine injections, USP, 1:2000, 0.3 mL) is available as Epipen Jr 2-Pak®, NDC 49502-501-02, a pack that contains two Epipen Jr® Auto-Injectors (epinephrine injections, USP, 1:2000, 0.3 mL) and one Epipen Jr® Auto-Injector trainer device. Epipen 2-Pak® and Epipen Jr 2-Pak® also include an S-clip to clip two carrier tubes together. RX only

16 HOW SUPPLIED/STORAGE AND HANDLING

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® Auto-Injector trainer device. Epipen Jr® Auto-Injector (epinephrine injections, USP, 1:2000, 0.3 mL) is available as Epipen Jr 2-Pak®, NDC 49502-501-02, a pack that contains two Epipen Jr® Auto-Injectors (epinephrine injections, USP, 1:2000, 0.3 mL) and one Epipen Jr® Auto-Injector trainer 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) during a maximum of 14 days (Controlled Room Temperature). Do not refrigerate. Before using, check to make sure the solution in the auto-injector is clear and colorless. Replace if the auto-injector 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 (anaphylaxis) to insect stings or bites, foods, drugs, and other allergens, as well as idiopathic and exercise-induced anaphylaxis, should be carefully instructed about the circumstances under which epinephrine should be used. Administration and Training

Instruct patients and/or caregivers in the appropriate use of Epipen® and Epipen Jr®. Epipen® and Epipen Jr® should be injected into the middle of the outer thigh (through clothing, if necessary). Each device is a single-use device. Advise patients to seek immediate medical care in conjunction with administration of Epipen®. Instruct caregivers to hold the leg of young children firmly in place and limit movement prior to and during injection. Lacerations, bent needles, and embedded needles have been reported when Epipen® and Epipen Jr® have been injected into the thigh of young children who are uncooperative and kick or move during an injection [see Warnings and Precautions (5.5)]. Complete patient information, including dosage, directions for proper administration and precautions can be found inside of 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
the Trained device to familiarize themselves with the use of EpiPen® and EpiPen Jr® Auto-Injector. The Trainer may be used multiple times. A Trainer device is provided in 2-Pak cartons.

Adverse Reactions
Epinephrine may produce symptoms and signs that include an increase in heart rate, the sensation of a more forceful heartbeat, palpitations, sweating, nausea and vomiting, difficulty breathing, pallor, dizziness, weakness or shakiness, headache, apprehension, nervousness, or anxiety. These symptoms and signs 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
Advises patients to seek immediate medical care in the event of 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 such an accidental injection to these areas [see Warnings and Precautions (5.2)].

Serious Infections at the Injection Site
Rares cases of serious skin and systemic infections, including necrotizing fasciitis and myositis 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 (5.9)].

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

Complete patient information, including dosage, directions for proper administration and precautions can be found inside each EpiPen® Auto-Injector carton. Manufactured for Mylan Specialty L.P., Morgantown, WV 26505, U.S.A., by Mylan Specialty LLC, Mylan Specialty L.P. of Morgantown, WV 26505, U.S.A. Copyright © 2016 Mylan Specialty LLC. All rights reserved.

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PATIENT INFORMATION and INSTRUCTIONS FOR USE

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

EpiPen Jr®
(epinephrine injection, USP) Auto-Injector 0.15 mg EpiPen Jr® one dose of 0.15 mg epinephrine (USP 1:2000, 0.3 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 refil. There may be new information. You, your parent, caregiver, or others who may be in 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®?

EpiPen® and EpiPen Jr® contain epinephrine, a medicine used to treat immediate allergic reactions (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• loss of 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 occur.

Talk to your healthcare provider if you need additional units to keep at work, school, or other locations. Tell your family members, caregivers, and others where you keep your EpiPen® or EpiPen Jr® and how to use it before you need it. You may be unable to speak in an allergic emergency.

3. When you have a severe 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 injection devices (auto-injectors) used to treat life-threatening, allergic emergencies including anaphylaxis in people who are at risk for or have a history of severe allergic emergencies. Each device contains a single dose of epinephrine.

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

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

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

• The EpiPen Jr® Auto-Injector (0.15 mg) is for patients who weigh about 33 to 66 pounds (15 to 30 kilograms).

It is not known if EpiPen® and EpiPen Jr® are safe and effective in children who weigh less than 33 pounds (15 kilograms).

What should I tell my healthcare provider before using the EpiPen® or EpiPen Jr®?

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

• have heart problems or high blood pressure
• have diabetes
• have thyroid problems
• have asthma
• have a history of depression
• have Parkinson’s disease
• have any other medical conditions
• are pregnant or plan to become pregnant. It is not known if epinephrine 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 if you have any 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 and pharmacist when you get a new medicine.

Use your EpiPen® or EpiPen Jr® for treatment of anaphylaxis as prescribed by your healthcare provider, regardless of your medical 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 healthcare provider will show you how to safely use the EpiPen® or EpiPen Jr® Auto-Injector.

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

Caution: Never put your thumb, fingers, or hand over the orange tip. Never press or push the orange tip with your thumb, fingers, or hand. The needle comes out of the orange tip. Accidental injection into finger, 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 healthcare provider where on your body you received the accidental injection.

• Your EpiPen® and EpiPen Jr® Auto-Injector may come packaged with an EpiPen® Trainer and separate Trainer Instructions for Use. The EpiPen® Trainer has a grey color. The grey EpiPen® Trainer contains epinephrine and no needle. Periodically practice with your EpiPen® Trainer before an allergic reaction happens so 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 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 or go 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 injection, have happened in young children who do not cooperate and kick or move during an injection. If you inject a young child with EpiPen® or EpiPen Jr®, hold their leg firmly in place before and during the injection to prevent injuries. Ask your healthcare provider to show you how to properly hold the leg of a young child during injection.

• If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have lasting side effects when you use your EpiPen® or EpiPen Jr®.

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

• fast, irregular or “bounding” heart beat
• sweating
• headache
• weakness
• shakiness
• palpense
• feelings of over excitements, nervousness or anxiety
• dizziness
• nausea or vomiting
• breathing problems
INSTRUCTIONS FOR USE

EPIPen® (epinephrine injection, USP) Auto-Injector 0.3 mg EpiPen® = one dose of 0.30 mg epinephrine (USP, 1:1000, 0.3 mL)

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

For allergic emergencies (anaphylaxis)

Read these Instructions for Use carefully before you use EpiPen® or EpiPen Jr®. Before you need to use your EpiPen® or EpiPen Jr®, make sure your healthcare provider shows you the right way to use it. Parents, caregivers, and others who may be in a position to administer EpiPen® or EpiPen Jr® Auto-injector should also understand how to use it. If you have any questions, ask your healthcare provider.

These side effects may go away with rest. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of the EpiPen® or EpiPen Jr®. For more information, ask your healthcare provider or pharmacist.

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

How should I store EpiPen® and EpiPen Jr®?

• Store EpiPen® and EpiPen Jr® at room temperature between 68° to 77°F (20° to 25°C).
• Protect from light.
• Do not expose to extreme cold or heat. For example, do not store in your vehicle’s glove box and do not store in the refrigerator or freezer.
• Examine the contents in the clear window of your auto-injector periodically. The solution should be clear. If the solution is discolored (pinkish or brown color) or contains solid particles, replace the unit.
• Always keep your EpiPen® or EpiPen Jr® Auto-Injector in the carrier tube to protect it from damage; however, the carrier tube is not waterproof.
• The blue safety release helps to prevent accidental injection. Keep the blue safety release on until you need to use EpiPen® or EpiPen Jr®.
• Your EpiPen® or EpiPen Jr® has an expiration date. Replace it before the expiration date.

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

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

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

This Patient Information Leaflet summarizes the most important information about EpiPen® and EpiPen Jr®. If you would like more information, talk to your healthcare provider.

You can ask your pharmacist or healthcare provider for information about EpiPen® and EpiPen Jr® that is written for health professionals.

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

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

Active Ingredients: Epinephrine

Inactive Ingredients: sodium chloride, sodium metabisulfite, hydrochloric acid, and water.

Important Information

• The EpiPen® Auto-Injector has a yellow colored label.
• The EpiPen Jr® Auto-Injector has a green colored label.
• The EpiPen® Trainer has a grey color and contains no medication 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 hand over the orange tip. The needle comes out of the orange tip.
• If an accidental injection happens, get medical help right away.
• Do not place patient information or any other foreign object in the carrier tube with the Auto-injector, as this may prevent you from removing the Auto-Injector for use.

INSTRUCTIONS FOR USE

EpiPen® (epinephrine injection, USP) Auto-Injector 0.3 mg EpiPen® = one dose of 0.30 mg epinephrine (USP, 1:1000, 0.3 mL)

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

For allergic emergencies (anaphylaxis)

Read these Instructions for Use carefully before you use EpiPen® or EpiPen Jr®, Before you need to use your EpiPen® or EpiPen Jr®, make sure your healthcare provider shows you the right way to use it. Parents, caregivers, and others who may be in a position to administer EpiPen® or EpiPen Jr® Auto-injector should also understand how to use it as well. If you have any questions, ask your healthcare provider.