**INDICATIONS**

EpiPen® and EpiPen Jr® Auto-Injectors are for the emergency treatment of life-threatening allergic reactions (anaphylaxis) caused by allergens, exercise, or unknown triggers; and for people who are at increased risk for these reactions. EpiPen® and EpiPen Jr® are intended for immediate administration as emergency supportive therapy only. Seek immediate emergency medical help right away.

**IMPORTANT SAFETY INFORMATION**

Use EpiPen® (epinephrine injection, USP) 0.3 mg or EpiPen Jr® (epinephrine injection, USP) 0.15 mg Auto-Injectors right away when you have an allergic emergency (anaphylaxis). **Get emergency medical help right away.** You may need further medical attention. Only a healthcare professional should give additional doses of epinephrine if you need more than two injections for a single anaphylactic episode.

Please see Important Safety Information and Indications on back cover and accompanying full Prescribing Information and Patient Information.
What is a life-threatening allergic reaction?

Anaphylaxis (an-a-fi-lax-is) is a medical term for a serious allergic reaction that can be life threatening if not treated right away. Anaphylaxis occurs rapidly—within minutes to hours—after exposure to an allergen. Anaphylaxis can be hard to predict. You may be at risk even if you’ve never had a serious allergic reaction before.

Talk to your healthcare professional about the risk of a life-threatening (severe) allergic reaction.

What causes anaphylaxis?

Anaphylaxis can be triggered by a number of allergens, including:

- Peanuts
- Wheat
- Medications
- Milk
- Latex
- Fish
- Stingging insects
- Tree nuts
- Soy
- Shellfish
- Eggs
- Exercise

What should you be aware of?

Certain other conditions or factors may increase the severity of an anaphylactic reaction.

- Asthma
- A previous severe allergic reaction (anaphylaxis)
- Eczema
- Regular lung problems
- Severe allergic rhinitis (symptoms include sneezing and itchy, watery nose and/or eyes)
- Taking a beta blocker and/or blood pressure medicine

Learn more about allergic triggers and anaphylaxis by visiting epipen.com

Please see Important Safety Information and Indications on back cover and accompanying full Prescribing Information and Patient Information.
IMPORTANT SAFETY INFORMATION (continued)

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 Important Safety Information on back cover and accompanying full Prescribing Information and Patient Information.

How do you know it’s a life-threatening allergic reaction?

People may have trouble recognizing the symptoms of anaphylaxis. Doctors generally identify anaphylaxis by the following:

- After exposure to an allergen (over minutes to several hours), the person has respiratory or cardiovascular symptoms, such as experiencing trouble breathing, chest pains or fainting

  OR

- After exposure to an allergen, the person has symptoms from multiple body systems, like a skin rash and nausea

Many people are nervous when the time comes to use an auto-injector. But it’s important to act fast. If experiencing anaphylaxis, use your EpiPen® (epinephrine injection, USP) Auto-Injector right away and seek immediate emergency medical attention.
Get to know your EpiPen® (epinephrine injection, USP) Auto-Injector

IMPORTANT SAFETY INFORMATION (continued)

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®.

Please see Important Safety Information and Indications on back cover and accompanying full Prescribing Information and Patient Information.

Practice, practice, practice!
Every EpiPen 2-Pak® and EpiPen Jr 2-Pak® carton includes an EpiPen® Trainer that does not include medication or a needle. Use the EpiPen® Trainer to teach others how to use an EpiPen® Auto-Injector during an anaphylactic emergency or practice along with the How to Use video found on epipen.com. Or watch it, along with informative videos and real stories from real patients, on youtube.com/epipen.
Get EpiPen® (epinephrine injection, USP) Auto-Injectors for as little as $0 with our savings card

Eligible patients* may pay as little as $0 every time they fill their prescription now through 12/31/2016. This savings card can be used to reduce the amount of your out-of-pocket expense on up to 3 EpiPen 2-Pak® cartons—that’s up to 6 EpiPen® Auto-Injectors! No other purchase is necessary. This offer can be used an unlimited number of times until 12/31/2016. Valid prescription with Prescriber ID# required.

Terms and Conditions.

*This SAVINGS card can be redeemed only by patients or patient guardians who are 18 years of age or older who are a resident of the United States and its territories. Not valid for cash paying patients (except for commercially insured patients without coverage for EpiPen® Auto-Injector) and patients who are covered by any state or federally funded healthcare program, including but not limited to any state pharmaceutical assistance program, Medicare (Part D or otherwise), Medicaid, MediGap, VA or DOD, or TriCare. This SAVINGS card is not health insurance. The SAVINGS card is not transferable and the amount of the benefit cannot exceed the patient’s out-of-pocket expenses. Cannot be combined with any other rebate/coupon, free trial, or similar offer for the specified prescription. Program expires 12/31/2016. Program managed by McKesson Corporation on behalf of Mylan Specialty L.P. Product dispensed pursuant to program rules and federal and state laws. Void where prohibited. The parties reserve the right to amend or end this program at any time without notice.

Download your savings card today
Visit epipencoupon.com for complete Terms and Conditions.

IMPORTANT SAFETY INFORMATION

Use EpiPen® (epinephrine injection, USP) 0.3 mg or EpiPen Jr® (epinephrine injection, USP) 0.15 mg Auto-Injectors right away when you have an allergic emergency (anaphylaxis). Get emergency medical help right away. You may need further medical attention. Only a healthcare professional should give additional doses of epinephrine if you need more than two injections for a single anaphylactic episode. EpiPen® or EpiPen Jr® should only be used in the thigh (upper leg), through clothing if necessary. Do not inject into your veins, buttocks, fingers, toes, hands or feet. Hold the leg of young children firmly in place before and during injection to prevent injuries. In case of accidental injection, please seek immediate medical treatment.

Rarely, patients who have used EpiPen® or EpiPen Jr® may develop an infection at the injection site within a few days. Some of these infections can be serious. Call your healthcare professional right away if you have any of the following at an injection site: redness that does not go away, swelling, tenderness, or the area feels warm to the touch. Tell your healthcare professional about all of your medical conditions, especially if you have asthma, a history of depression, thyroid problems, Parkinson’s disease, diabetes, high blood pressure or heart problems, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Be sure to also tell your healthcare professional all the medicines you take, especially medicines for asthma. If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you use EpiPen® or EpiPen Jr®.

Common side effects include fast, irregular or “pounding” heartbeat, sweating, nausea or vomiting, breathing problems, paleness, dizziness, weakness, shakiness, headache, feelings of over excitement, nervousness or anxiety. These side effects usually go away quickly if you lie down and rest. Tell your healthcare professional if you have any side effect that bothers you or that does not go away. Please see full Prescribing Information and Patient Information.

INDICATIONS

EpiPen® and EpiPen Jr® Auto-Injectors are for the emergency treatment of life-threatening allergic reactions (anaphylaxis) caused by allergens, exercise, or unknown triggers; and for people who are at increased risk for these reactions. EpiPen® and EpiPen Jr® are intended for immediate administration as emergency supportive therapy only. Seek immediate emergency medical help right away.

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 AND ADMINISTRATION

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

Inject EpiPen® and EpiPen Jr® intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-use injection.

DOSAGE FORMS AND STRENGTHS

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

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

• In conjunction with use, seek immediate medical or hospital care.
• Do not inject intravenously, into buttck, 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, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties. (6)

5.2 Injection-Related Complications

• To minimize the risk of injection related injury when administering EpiPen®, one should instruct the patient to go immediately to the nearest emergency room to inform the healthcare provider in the emergency room of the location of the accidental injection. Treatment of such inadvertent injection should include indicating 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

Rapidly acting vasodilators can counteract the marked pressor effects of epinephrine if there is such inadvertent administration. 

Do not inject into the buttck. Injection into the buttck may not provide effective treatment of anaphylaxis. Advise the patient to go immediately to the nearest emergency room for further treatment of anaphylaxis. Additionally, injection into the buttck has been associated with Clostridial infections (gas gangrene). Cleansing with alcohol does not kill all bacterial spores, and therefore, does not lower this risk.

Do not inject into digits, hands or feet. Since epinephrine is a strong vasocostrictor, accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area. Advise the patient to go immediately to the nearest emergency room to inform the healthcare provider in the emergency room of the location of the accidental injection. Treatment of such inadvertent injection should include indicating 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 Allergic Reactions Associated With Sulfite

The presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations even if the patient is sulfite-sensitive.

EpiPen® is the preferred treatment for serious allergic reactions or other emergency situations even though this product contains sodium metabisulfite, a sulfite that may, in other products, cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons. Therefore, patients with these conditions, and/or any other person who might be in a position to administer EpiPen® or EpiPen Jr® to a patient experiencing anaphylaxis should be carefully instructed in regard to the circumstances under
which epinephrine should be used.

- **Patients with Heart Disease**
  Epinephrine should be administered with caution to patients who have heart disease, including patients with cardiac arrhythmias, congestive heart failure, hypertension, or hypotension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, epinephrine may precipitate or aggravate angina pectoris as well as produce arterial vasoconstrictive effects [see Drug Interactions (7) and Adverse Reactions (8)].

- **Other Patients and Diseases**
  Epinephrine should be administered with caution to patients with thyrotoxicosis, hyperthyroidism, diabetes mellitus, pregnant women. Patients with Parkinson’s disease may notice a temporary worsening of symptoms.

6 ADVERSE REACTIONS

Due to the lack of randomized, controlled clinical trials of epinephrine for the treatment of anaphylaxis, the true incidence of adverse reactions associated with the systemic use of epinephrine is difficult to determine. Adverse reactions reported in observational trials, case reports, and studies and are listed below.

Common adverse reactions to systemically administered epinephrine include anxiety, apprehensiveness; restlessness; tremor; weakness; dizziness; sweating; palpitations; pallor; nausea; vomiting; headache; and/or respiratory difficulties. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension or hyperthyroidism [see Warnings and Precautions (5.1)] and/or to persons with underlying cardiac disease or those receiving certain drugs [see Warnings and Precautions (5.5)].

Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs [see Warnings and Precautions (5.5)]. Adverse reactions reported in observational trials, case reports, and studies are listed below.

10 OVERDOSE

Overdose of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in patients with hypertension or organic heart disease. Epinephrine overdose may also result in pulmonary edema because of peripheral vascular constriction together with cardiac stimulation. Treatment consists of rapidly acting vasodilators or alpha-adrenergic blocking drugs and/or respiratory support. Epinephrine overdose can also cause transient bradyarrhythmia followed by tachycardia, and these may be accompanied by potentially fatal cardiac arrhythmias. Premature ventricular contractions may appear within one minute after injection and may be followed by multifocal ventricular tachycardia (pre fibrillation rhythm). Subsidence of the ventricular effects may be followed by atrial tachycardia and occasionally by atrioventricular block.

Treatment of drug overdose consists of administration of a beta-adrenergic blocking drug such as propranolol. Overdose sometimes results in extreme pallor and coldness of the skin, metabolic acidosis, and kidney failure. Therefore, corrective measures must be taken in such situations.

11 DESCRIPTION

Epinephrine (epinephrine injection, USP) 0.3 mg and 0.15 mg are auto-injectors and combination products containing drug and device components.

Each EpiPen® Auto-Injector, 0.3 mg delivers a single dose of 0.3 mg epinephrine from epinephrine injection, USP 1:1000 (0.3 mL) in a sterile solution.

Each EpiPen Jr® Auto-Injector, 0.15 mg delivers a single dose of 0.15 mg epinephrine from epinephrine injection, USP 1:2000 (0.3 mL) in a sterile solution.

The pH range for EpiPen® Auto-Injector and EpiPen Jr® Auto-Injector each contain 2 mL epinephrine solution. Approximately 1.7 mL remains in the auto-injector after activation, but is not available for future use, and should be discarded.

Epinephrine and other catecholamines have been shown to have mutagenic potential in vitro and to be an oxidative mutagen in a WP2 bacterial reverse mutation assay. Epinephrine was positive in the DNA Repair Test with B. subtilis WP2, and mutagenic in the Salmonella bacterial reverse mutation assay. The potential for epinephrine to impair fertility has not been evaluated.

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

16 HOW SUPPLIED/STORAGE AND HANDLING

6.1 How Supplied

EpiPen® Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 mL) are available as EpiPen 2-Pak® NDC 49502-500-02, a pack that contains two EpiPen® Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 mL) and one EpiPen® Auto-Injector trainer device.

EpiPen Jr® Auto-Injectors (epinephrine injections, USP, 1:2000, 0.3 mL) are 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 Epi Pen Jr 2-Pak® also include an S-clip to clip two carrier tubes together. Rx only

6.2 Storage and Handling

Protect from light. Epinephrine is light sensitive and should be stored in the carrier tube provided to protect it from light. Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See Controlled Room Temperature). Do not refrigerate. Before using, check to make sure the solution in the auto-injector is clear and colorless. Replace the auto-injector if the solution is discolored (pinkish to brown color), cloudy, or turbid.

17 PATIENT COUNSELING INFORMATION

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

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

EpiPen® is essential for the treatment of anaphylaxis.

Patients who are at risk of or have a history of severe allergic reactions (anaphylaxis) to bee or wasp stings or bites, or who have other allergies, 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® should be injected into the middle of the outer thigh (through clothing, if necessary). Each EpiPen® or EpiPen Jr® contains a fixed, non-variable dose of epinephrine. Lacerations, bent needles, and embedded needles have been reported when EpiPen® and EpiPen Jr® have been injected into the thigh of children who are uncooperative and kick or irritate during an injection [see Warnings and Precautions (5.2)].

Complete patient information, including dosage, directions for proper administration and precautions can be found inside each EpiPen® or EpiPen Jr® carton. A printed label on the surface of EpiPen® shows instructions for use and a diagram depicting the injection process.

Instruct patients and/or caregivers to use and practice with
the Trainer device to familiarize themselves with the use of EpiPen® in an allergic emergency. The Trainer may be used multiple times. A Trainer device is provided in 2-Pak cartons. Adverse Reactions Epinephrine may produce symptoms and signs that include an increase in heart rate and blood pressure, pain or pressure in the chest, 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 adverse 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 (5.3)].

Accidental Injection Advise patients to seek immediate medical care in the case of accidental injection. Since epinephrine is a strong vasconstrictor 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 Rare cases of serious skin and soft tissue infections, including necrotizing fasciitis and myonecrosis caused by Clostridia (gas gangrene), have been reported at the injection site following epinephrine injection for anaphylaxis. Advise patients to seek medical care if they develop signs or symptoms of infection, such as persistent redness, warmth, swelling, or tenderness, at the epinephrine injection site [see Warnings and Precautions (5.3)].

Storage and Handling Instruct patients to inspect the epinephrine solution visually through the clear window of the auto-injector periodically. Replace EpiPen® or 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 directions for vaccinations can be found inside each EpiPen® Auto-Injector carton. Manufactured for Mylan Specialty L.P., Morgantown, WV 26505, U.S.A. by Meridian Medical Technologies, Inc., Columbia, MD 21046, U.S.A., a Pfizer company. EpiPen® and EpiPen Jr® are registered trademarks of Mylan Inc. licensed exclusively to its wholly-owned affiliate, Mylan Specialty L.P. of Morgantown, WV 26505, U.S.A. Copyright © 2016 Meridian Medical Technologies. All rights reserved.

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PATIENT INFORMATION and 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

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 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. The information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about the EpiPen® and EpiPen Jr®?

1. EpiPen® and EpiPen Jr® contain epinephrine, a medicine used to treat allergic emergencies (anaphylaxis). Anaphylaxis can be life threatening, can happen within minutes, and can cause breathing and biting insects, allergy injections, foods, medicines, exercise, or unknown causes. Symptoms of anaphylaxis may include:
   • trouble breathing
   • wheezing
   • hoarseness (changes in the way your voice sounds)
   • hives (raised reddened rash that may itch)
   • severe itching
   • swelling of your face, lips, mouth, or tongue
   • skin rash, redness, or swelling
   • fast heartbeat
   • weak pulse
   • feeling very anxious
   • confusion
   • stomach pain
   • losing control of urine or bowel movements (incontinence)
   • dizziness or stomach cramps
   • dizziness, fainting, or “passing out” (unconsciousness)

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

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

3. When you have an allergic emergency (anaphylaxis)
   • Use EpiPen® or EpiPen Jr® right away.
   • Get emergency medical help right away. You may need further medical attention. You may need to use a second EpiPen® or EpiPen Jr® if symptoms continue or recur. Only a healthcare provider should give additional doses of epinephrine if you need more than 2 injections for a single anaphylaxis episode.

What are EpiPen® and EpiPen Jr®?

• EpiPen® and EpiPen Jr® are disposable, prefilled automatic injectors. Each EpiPen® or EpiPen Jr® Auto-Injector contains epinephrine 0.3 mg or 0.15 mg (1:1000 or 1:2000), respectively, in an anesthetic solution for use in the treatment of anaphylaxis. Epinephrine is ready to use. There is no mixing, dilution, or preparation necessary. Epinephrine is light sensitive and should be stored in the carrier tube provided to protect it from light.

• EpiPen® and EpiPen Jr® are for immediate self (or caregiver) administration and do not need to be refrigerated. Instructions for Use 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 healthcare provider where on your body you injected EpiPen® or EpiPen Jr®.

• Rarely, patients who have used EpiPen® or EpiPen Jr® may develop infections at the injection site within a few days of an injection. Some of these infections can be serious. Call your healthcare provider right away if you have any of the following at an injection site:
   • redness that does not go away
   • swelling
   • tenderness
   • the area feels warm to the touch
   • cuts on the skin, bent needles, and needles that remain in the skin after the injection, have happened in young children who do not cooperate and kick or move during an injection. If you inject a young child with EpiPen® or EpiPen Jr®, hold their leg firmly in place before and during the injection to prevent injuries. Ask your healthcare provider to show you how to properly hold the leg of a young child during injection.

   If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you use your EpiPen® or EpiPen Jr®, talk to your healthcare provider about all your medical conditions.

   Common side effects of EpiPen® and EpiPen Jr® include:
   • fast, irregular or “pounding” heartbeat
   • sweating
   • headache
   • weakness
   • shakiness
   • palpitations
   • feelings of over excitement, nervousness or anxiety
   • dizziness
   • nausea or vomiting
   • breathing problems
These side effects may go away with rest. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

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

How should I store EpiPen® and EpiPen Jr®?

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

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

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

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

This Patient Information Leaflet summarizes the most important information about EpiPen® and EpiPen Jr®. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about EpiPen® and EpiPen Jr® that is written for health professionals.

For more information and video instructions on the use of EpiPen® and EpiPen Jr®, go to www.epipen.com or call 1-800-395-3376.

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

Active Ingredients: Epinephrine

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

Important Information

• The EpiPen® Auto-Injector has a yellow colored label.
• The EpiPen Jr® Auto-Injector has a green colored label.
• The EpiPen® Trainer has a grey color and contains no medicine and no needle.
• Your auto-injector is designed to work through clothing.
• The blue safety release on the EpiPen® and EpiPen Jr® Auto-Injector helps to prevent accidental injection of the device. Do not remove the blue safety release until you are ready to use it.
• Only inject into the middle of the outer thigh (upper leg). Never inject into any other part of the body.
• Never put your thumb, fingers, or your hand over the orange tip. The needle comes out of the orange tip.
• If an accidental injection happens, get medical help right away.
• Do not place patient information or any other foreign objects in the carrier tube with the Auto-Injector, as this may prevent you from removing the Auto-Injector for use.

INSTRUCTIONS FOR USE

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

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

For allergic emergencies (anaphylaxis)

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

Step 1. Prepare EpiPen® or EpiPen Jr® for injection

Remove the EpiPen® or EpiPen Jr® from the clear carrier tube.

Tip and slide the auto-injector out of the carrier tube.

Grasp the auto-injector in your fist with the orange tip (needle end) 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®

If you are administering EpiPen® or EpiPen Jr® to a young child, hold the leg firmly in place while administering an injection.

Place the orange tip against the middle of the outer thigh (upper leg) at a right angle (perpendicular) to the thigh. Swing and push the auto-injector firmly until it ‘clicks’. The click signals that the injection has started.

Hold firmly in place for 3 seconds (count slowly 1,2,3). The injection is now complete.

Remove the auto-injector from the thigh. The orange tip will extend to cover the needle. If the needle is still visible, do not attempt to reuse it.

Massage the injection area for 10 seconds.

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 any healthcare provider.
• Tell the healthcare provider that you have received an injection of epinephrine. Show the healthcare provider where you received the injection.
• Give your used EpiPen® or EpiPen Jr® Auto-Injector to the healthcare provider for inspection and proper disposal.
• Ask for a refill, if needed.

Note:

• The used auto-injector with extended needle cover will not fit in the carrier tube.
• EpiPen® and EpiPen Jr® are single-use injectable devices that deliver a fixed dose of epinephrine. The auto-injector cannot be reused. Do not attempt to reuse EpiPen® after the device has been activated. It is normal for most of the medicine to remain in the auto-injector after the dose is injected. The correct dose has been administered if the orange needle tip is extended and the window is blocked.
• Your EpiPen® and EpiPen Jr® Auto-Injector may come packaged with an EpiPen® Trainer and separate Trainer instructions for Use. The EpiPen® Trainer has a grey color. The grey EpiPen® Trainer contains no medicine and no needle. Practice with your EpiPen® Trainer, but always carry your real EpiPen® or EpiPen Jr® Auto-Injector in case of an allergic emergency.
• If you will be administering EpiPen® or EpiPen Jr® to a young child, ask your healthcare provider to show you how to properly hold the leg in place while administering a dose.
• Do not try to take the EpiPen® or EpiPen Jr® Auto-Injector apart.

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 21045, U.S.A., a Pfizer company EpiPen® and EpiPen Jr® are registered trademarks of Mylan Inc. licensed exclusively to its wholly-owned affiliate, Mylan Specialty L.P. of, Morgantown, WV 26505, U.S.A. Copyright © 2016 Meridian Medical Technologies. All rights reserved. Revised: May 2016

MyEpiPen.com

MyEpiPen.com and find out more about:

• Free EpiPen® Auto-Injector Refill Reminder Program. It is important to keep your auto-injector up-to-date. Register up to 6 EpiPen® or EpiPen Jr® Auto-Injectors and receive automatic Refill Reminder Alerts.
• Receive periodic information related to allergies and allergens.
• Instructional Video
For more information about EpiPen® or EpiPen Jr® Auto-Injectors and proper use of the product, call Mylan at 1-877-446-3679 or visit www.epipen.com.