Mylan’s Epinephrine Auto-Injectors

Important Facts Related to the EpiPen® (epinephrine injection, USP) Auto-Injector Discussion

The points that follow outline important facts related to Mylan, EpiPen® Auto-Injector and our mission of providing the world with access to high quality medicine. Additional detail and other resources are located on Mylan.com/EpiPenAccess.

- Mylan’s success since its founding in 1961 has been built on three principles: producing high quality medicine, significantly expanding access to those medicines, and helping to lower healthcare costs.

- While EpiPen® currently is dominating news about our company, Mylan is much more than one product. Globally, we have more than 2,700 products in our portfolio. In the U.S. alone, we offer 635 products, representing 21 billion doses. Our average price per dose for all prescriptions sold in the U.S., including EpiPen®, is about 25 cents.

- Over the last decade, Mylan’s products reduced total health expenses in the U.S. by about $180 billion.

- While Mylan is much more than any one product, all of our products are important, including EpiPen® Auto-Injector. Since we purchased the EpiPen® product in 2007, we’ve invested significantly to enhance the product and make it more widely available.
  - The epinephrine auto-injector we market today is very different than the one we acquired. For example, our “next-generation” EpiPen® launched in 2009, offered multiple new features, including a Never-See-Needle® to help protect against needle exposure, before and after use.
  - We are working on a formulation with a longer shelf life to extend the period between refills.
  - We’ve advocated for schools to have access to epinephrine auto-injectors without a prescription for a specific child, and 48 U.S. states now have that access. We’ve also donated more than 700,000 free EpiPen® Auto-Injectors to more than 66,000 schools (more than half of all public schools in the U.S.).

- There is a false impression out there that Mylan receives more than $600 for an EpiPen 2-Pak®. This is not the case, and we’re working hard to set the record straight. Of the $608 list price for each two pack, Mylan receives in revenues, on average, $274 after rebates and other fees per two-pack of EpiPen® Auto-Injectors. This amount is further reduced by the cost of goods ($69 per two pack) and other expenses for sales, marketing, regulatory compliance, and patient and school access programs.

- As recent concerns developed, we took immediate and unprecedented action to ensure that everyone who needs an EpiPen® Auto-Injector is able to get one.
  - This includes our announcement to offer the first-ever generic version of EpiPen® Auto-Injectors that will effectively cut the price in half from $608 to $300.
  - We also increased our My EpiPen Savings Card® program benefit from $100 to $300 and doubled the eligibility threshold of our Patient Assistance Program to $97,200 for a family of four.

- Because it’s in our DNA, we are going to do whatever we can to help address the issues that led to these pricing controversies. We understand and accept that Mylan and EpiPen® Auto-Injector are the focus today. But the pricing puzzle frustrating everyone in the U.S., goes far beyond EpiPen® Auto-Injector and Mylan.

- At Mylan, we are passionate about providing the world’s 7 billion people with access to high quality medicine. We always have been and always will be.

**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.

Please see additional Important Safety Information on next page.
Important Safety Information, continued

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 injected into the middle of your outer thigh (upper leg), through clothing if necessary. Do not inject into your veins, buttocks, fingers, toes, hands or feet. Hold the leg of young children firmly in place before and during injection to prevent injuries. In case of accidental injection, please seek immediate medical treatment.

Rarely, patients who have used EpiPen® or EpiPen Jr® may develop an infection at the injection site within a few days. Some of these infections can be serious. Call your healthcare professional right away if you have any of the following at an injection site: redness that does not go away, swelling, tenderness, or the area feels warm to the touch.

Tell your healthcare professional about all of your medical conditions, especially if you have asthma, a history of depression, thyroid problems, Parkinson’s disease, diabetes, high blood pressure or heart problems, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Be sure to also tell your healthcare professional all the medicines you take, especially medicines for asthma. If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you use EpiPen® or EpiPen Jr.®

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

Please see 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.
HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use EPIPEEN® and EPIPEEN Jr® safely and effectively. See full prescribing information for EPIPEEN® and EPIPEEN Jr®.

EPIPEEN® (epinephrine injection, USP), Auto-Injector 0.3 mg, EPIPEEN Jr® (epinephrine injection, USP) Auto-Injector 0.15 mg, for intramuscular or subcutaneous use

Indications and Usage
Epinephrine® and EpiPen Jr® contain epinephrine, a non-selective alpha and beta-adrenergic receptor agonist, indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis. (1)

DOSAGE AND ADMINISTRATION

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

Inject EpiPen® and EpiPen Jr® intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-use injection. (2)

DOSE FORMS AND STRENGTHS

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

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

• In conjunction with use, seek immediate medical or hospital care. (5.1)
• Do not inject intravenously, into buttck, or into digits, hands, or feet. (5.1)
• 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, heart palpitations, and arrhythmias. (5)

To report SUSPECTED ADVERSE REACTIONS, contact Mylan Specialty, L.P. at 1-877-4-INFO-RX or FDA at 1-800-FDA-1088 or contact Mylan Specialty, L.P. at 1-877-446-3679

DOSAGE AND ADMINISTRATION

1. INDICATIONS AND USAGE

EpiPen® and EpiPen Jr® are indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which includes bees, wasps, hornets, yellow jackets, and fire ants) and biting insects (e.g., triatomia, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast agents), and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis. EpiPen® and EpiPen Jr® are intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

Anaphylactic reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, tachypnea or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rash, urticaria or angioedema. EpiPen® and EpiPen Jr® are intended for immediate administration only and are not a substitute for immediate medical care.

2. DOSAGE AND ADMINISTRATION

Selection of the appropriate dosage strength (EpiPen® or EpiPen Jr®) is determined according to patient body weight.
• Patients greater than or equal to 30 kg (approximately 66 lbs): EpiPen® 0.3 mg
• Patients 15 to 30 kg (33 lbs to 66 lbs): EpiPen Jr® 0.15 mg

Inject EpiPen® or EpiPen Jr® intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-use injection. (2)

The epinephrine solution in the clear window of the EpiPen® and EpiPen Jr® contains sodium metabisulfite, a sulfite that may, in rare cases, cause an allergic reaction in some individuals. The preservative sodium metabisulfite at the concentration present in EpiPen® and EpiPen Jr® is not intended as a substitute for immediate medical care.

In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care. More than two sequential doses of epinephrine should only be administered under direct medical supervision [see Indications and Usage (1), Dosage and Administration (2) and Patient Counseling Information (17)].

5.1 Emergency Treatment

EpinePen® and EpiPen Jr® are intended 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.

5.2 Injection-Related Complications

Inadvertent administration should consist of vasodilation, increase in heart rate, and hypotension. Additionally, inadvertent injection into the buttock has been associated with Clostridial infections (gas gangrene). Cleansing with alcohol does not kill bacterial spores, and, therefore, does not lower this risk.

5.3 Serious Infections at the Injection Site

Rare cases of serious skin and soft tissue infections, including necrotizing fasciitis or gangrene, have been reported following epinephrine injection. Patients should be carefully instructed in regard to the circumstances under which infectious exposure and consist of flushing, apprehension, syncope, tachycardia, tachypnea or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rash, urticaria or angioedema. EpiPen® and EpiPen Jr® are intended for immediate administration only and are not a substitute for immediate medical care.

5.4 Drug Interactions

Inadvertent administration should consist of vasodilation, increase in heart rate, and hypotension. Additionally, inadvertent injection into the buttock has been associated with Clostridial infections (gas gangrene). Cleansing with alcohol does not kill bacterial spores, and, therefore, does not lower this risk.

5.5 Serum Reactions Associated with Sulfite

Some patients may be at greater risk for developing adverse reactions after epinephrine administration. Despite these concerns, they should be instructed that the presence of these conditions is not a contraindication to epinephrine administration in an acute, life-threatening situation. Therefore, patients with these conditions, and/or 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

3. DOSAGE FORMS AND STRENGTHS

• EpiPen® Injection, 0.3 mg/0.3 mL (0.3 mL, 1:1000) epinephrine injection, USP, pre-filled auto-injector
• EpiPen Jr® Injection, 0.15 mg/0.3 mL (0.3 mL, 1:2000) epinephrine injection, USP, pre-filled auto-injector

4. CONTRAINDICATIONS

None

5. WARNINGS AND PRECAUTIONS

5.1 Emergency Treatment

EpinePen® and EpiPen Jr® are intended 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 (17)].

5.2 Injection-Related Complications

Inadvertent administration should consist of vasodilation, increase in heart rate, and hypotension. Additionally, inadvertent injection into the buttock has been associated with Clostridial infections (gas gangrene). Cleansing with alcohol does not kill bacterial spores, and, therefore, does not lower this risk.

5.3 Serious Infections at the Injection Site

Rare cases of serious skin and soft tissue infections, including necrotizing fasciitis or gangrene, have been reported following epinephrine injection. Patients should be carefully instructed in regard to the circumstances under which
which epinephrine should be used.

- Avoid accidental injection.

Epinephrine should be administered with caution to patients who have heart disease, including patients with cardiac arrhythmias, coronary heart disease, myocardial infarction, unstable angina, conduction disturbances, or heart failure. When epinephrine is used to treat anaphylaxis, the potential for epinephrine to impair fertility has not been evaluated.

16.2 Storage and Handling

Epinephrine should be stored at controlled room temperature 15°C-30°C (59°F-86°F) when the container is not exposed to direct sunlight. Each EpiPen Jr Auto-Injector contains 0.15 mg. 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)]. Angina may occur in patients with coronary artery disease [see Warnings and Precautions (5.5)].

17 PATIENT COUNSELING INFORMATION

- Avoid accidental injection.

17.1 General

If sensitization to the contents of the auto-injector occurs, treatment consists of rapidly acting vasodilators or alpha-adrenergic blocking drugs and/or respiratory support. Epinephrine overdosage can also cause transient bradycardia followed by tachycardia, and these may be accompanied by potentially fatal cardiac arrhythmias. Premature ventricular contractions may appear within 1 minute after injection resulting from a rapid ventricular tachycardia (pre fibrillation rhythm). Subsidence of the ventricular effects may be followed by atrial tachycardia and occasionally by atrioventricular block. Treatment of arrhythmias consists of administration of a beta-adrenergic blocking drug such as propranolol. Overdosage sometimes results in extreme pallor and coldness of the skin, metabolic acidosis, and kidney failure. Suitable corrective measures must be taken in such situations.

17.2 Administration

Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin. Replace Epinephrine and EpPen Jr if the epinephrine solution appears discolored (pink, brown, or black), or if it smells. Thoroughly review the patient instructions and operation of EpPen® or EpPen Jr with patients and caregivers prior to using the Patient Counseling Information (17).

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Epinephrine acts on alpha-, beta- and alpha-beta-receptors.

12.2 Pharmacodynamics

Through its action on alpha-adrenergic receptors, epinephrine lessens the vasodilator and increases vascular permeability that occurs during anaphylaxis, which can lead to loss of intravascular fluid volume and hypotension. Through its action on beta receptors, epinephrine causes bronchial smooth muscle relaxation and helps alleviate bronchospasm, wheezing and dyspnea that may occur with anaphylaxis.

Epinephrine also alleviates pruritus, urticaria, and angioedema and may relieve gastrointestinal and genitourinary symptoms associated with anaphylaxis because of its relaxant effects on the smooth muscle of the stomach, intestine, uterus and urinary bladder. When given subcutaneously or intramuscularly, epinephrine has a rapid onset and short duration of action.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies to evaluate the carcinogenic potential of epinephrine have not been performed.

Epinephrine and other catecholamines have been shown to have mutagenic potential in vitro and to be an oxidative mutagen in a V79 bacterial test system. Epinephrine was positive in the DNA Repair test with B. subtilis (REC) assay, but was not mutagenic in the Salmonella bacterial reverse mutation assay.

The potential for epinephrine to impair fertility has not been evaluated. This does not prevent the use of epinephrine under the conditions noted under Indications and Usage (7).

16 HOW SUPPLIED/STORAGE AND HANDLING

EpPen® Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 mL) are available as EpiPen 2-Pak®, NDC 49002-500-02, a pack that contains two EpiPen® Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 mL) and one EpiPen® Auto-Injector trainer device. EpPen Jr® Auto-Injectors (epinephrine injections, USP, 1:2000, 0.3 mL) are available as EpiPen Jr 2-Pak®, NDC 49002-501-02, 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 container tube provided to protect it from light. Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP, Controlled Room Temperature]. Do not refrigerate. Before using, check to make sure the solution in the auto-injector is clear and colorless. Replace the auto-injector if the solution is discolored (pinkish or brown color), cloudy, or contains particles.

17 PATIENT COUNSELING INFORMATION

[See FDA-Approved Patient Labeling (Patient information and instructions for use) for a healthcare provider should review the patient instructions and operation of EpPen® and EpPen 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 EpPen Jr®. EpPen 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 EpPen®.

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 Jr has 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 EpPen® or EpPen 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
EpiPen® and EpiPen Jr®

What are EpiPen® and EpiPen Jr®?

EpiPen® and EpiPen Jr® are disposable, prefilled automatic injection devices (auto-injectors) used to treat life-threatening, allergic emergencies including anaphylaxis in people who are at risk for or have a history of serious allergic emergencies. Each device contains a single dose of epinephrine.

EpiPen® and EpiPen Jr® are for immediate self (or caregiver) administration and do not take the place of medical care. EpiPen Jr® is for patients weighing 33 to 66 pounds.

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

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 your all 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 of all your 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® works.

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 gray color. The EpiPen® Trainer contains medicine and no needle. Periodically practice with your EpiPen® Trainer before an allergic emergency happens to make sure you are able to safely use the real EpiPen® and EpiPen Jr® Auto-Injector in an emergency. Always carry your real EpiPen® or EpiPen Jr® Auto-Injector with you in case of an allergic emergency. Additional training resources are available at www.epipen.com.

Do not drop the carrier tube or auto-injector. If the carrier tube or auto-injector is dropped, check for damage and leakage. Dispose of the auto-injector and carrier tube, and replace if damage or leakage is noticed or suspected.

What are the possible side effects of the EpiPen® and EpiPen Jr®?

EpiPen® and EpiPen Jr® may cause serious side effects.

The EpiPen® or EpiPen Jr® should only be injected into the middle of your outer thigh (upper leg). Do not use the EpiPen® or EpiPen Jr® Auto-injector to:

• veins
• buttocks
• fingers, toes, hands, or feet

If you accidentally inject EpiPen® or EpiPen Jr® into any other part of your body, go to the nearest emergency room right away. Tell the healthcare provider where on your body you received the accidental injection.

Rarely, patients who have used EpiPen® or EpiPen Jr® may develop infections at the injection site within a few days of an injection. Some of these infections can be serious. Call your healthcare provider right away if you have any of the following at an injection site:

• redness that does not go away
• swelling
• tenderness
• the area feels warm to the touch
• Cuts on the skin, bent needles, and needles that remain in the skin after the injection, have happened in young children who do not 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®. Common side effects of EpiPen® and EpiPen Jr® include:

• fast, irregular or pounding heartbeat
• dizziness
• feeling very anxious
• fast heartbeat
• sweating
• shaking
• paleness
• dizziness
• nausea or vomiting
• breathing problems

The EpiPen® or EpiPen Jr® should be stored in the carrier tube provided to protect it from light.

Contains particles. Epinephrine is light sensitive and should not be stored in the carrier tube provided to protect it from light. EpiPen® and EpiPen Jr® Auto-Injectors are prefilled disposable devices.

EpiPen® and EpiPen Jr® should be used or properly disposed of 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.


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.

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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 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 refill. There may be new information. You, your parent, caregiver, or other who may be in a position to administer EpiPen® or EpiPen Jr® Auto-Injector, should know how to use it before you have an allergic emergency. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

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

EpiPen® and EpiPen Jr® contain epinephrine, a medicine used to treat an allergic emergency. The EpiPen® and EpiPen Jr® should be used repeatedly. A Trained Caregiver or 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.

The Trained Caretaker or 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 an allergic emergency. The EpiPen® and EpiPen Jr® should be used repeatedly. Your Trained Caretaker or 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 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 medical conditions, 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 of all your 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.
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 1-800-386-3376.

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

Active Ingredients: Epinephrine
Inactive Ingredients: sodium chloride, sodium metabsulfi te, 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 0.3 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)

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.

A dose of EpiPen® or EpiPen Jr® requires 3 simple steps: Prepare, Administer and Get emergency medical help

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

Remove the EpiPen® or EpiPen Jr® from the clear carrier tube.
Flip open the yellow cap of your EpiPen® or the green cap of your EpiPen Jr® carrier tube.
Tip and slide the auto-injector out of the carrier tube.

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 see a 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 21046, U.S.A. a Pfizer company EpiPen® and EpiPen Jr® are registered trademarks of Mylan Inc. licensed exclusively to its wholly-owned affiliate, Mylan Specialty L.P. of Morgantown, WV 26505, U.S.A. Copyright © 2016 Meridian Medical Technologies. All rights reserved. Revised: May 2016

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Register your EpiPen® or EpiPen Jr® Auto-Injector at

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

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.