



March 23, 2020

### Important Prescribing Information

**Subject: Important Safety Information on the EpiPen® and EpiPen Jr® Auto-Injectors and their authorized generic versions:**

- **Risk of device failure due to spontaneous activation.**
- **Difficulty removing the device from the carrier tube may also occur.**
- **Use errors.**

**These issues could delay or prevent emergency treatment when needed.**

Dear Healthcare Provider,

The purpose of this letter is to inform you that the administration of EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors and the authorized generic versions (referenced collectively as EpiPen in the remainder of this letter) may be delayed or prevented during an emergency due to:

1. Device failure from spontaneous activation caused by using a sideways force to remove the blue safety release.
2. Device failure from inadvertent or spontaneous activation due to a raised blue safety release
3. Difficulty removing the device from the carrier tube.
4. Certain identified use errors.

Additional detail around the identified issues is provided below.

Since EpiPen is administered for severe and potentially life-threatening allergic reactions, anything that prevents or delays the administration of the intended dose of epinephrine could result in a high risk to the patient, including the risk of death.

Your patients should continue to carry their EpiPen or EpiPen Jr or authorized generic version at all times, and we encourage you to review the information below with your patients and their caregivers to ensure its appropriate use. Per the instructions for use, we recommend that patients always carry two EpiPen or EpiPen Jr auto-injectors or the authorized generic version at all times. Please refer to the important training reminders enclosed in this letter and precautionary handling instructions for healthcare providers and patients/caregivers, including pictures of the auto-injector, included in Appendix 1. This letter is being issued with the knowledge of the FDA.

#### **1. Device Failure from Spontaneous Activation Caused by Using a Sideways Force to Remove the Blue Safety Release**

- Removing the blue safety release using sideways forces has been shown to activate the EpiPen prematurely. If spontaneous activation occurs, the device cannot be used to inject epinephrine; a new device must be obtained.
  - This can occur if a user tries to hold the EpiPen with only one hand and tries to remove the blue safety release with their thumb using a lateral force. As an example, **parents who are administering EpiPen to their children should first restrain their child, then use both**

**hands to hold the EpiPen and remove the blue safety release with the other hand straight up without bending, twisting or applying horizontal force.**

- **To prevent this premature activation, patients and their caregivers should be advised of the following:**
  - Do NOT flip the blue safety release off using a thumb or by pulling it sideways or bending and twisting. This may cause the device to spontaneously activate: a “click” is heard, the orange needle tip is extended, and the window is blocked. An activated device cannot be used for a patient. If this occurs, obtain a new EpiPen.
  - **Use both hands to remove the blue safety release.** Hold the EpiPen auto-injector in one fist with the orange end pointing down, while removing the blue safety release with the other hand straight up without bending, twisting or applying horizontal force.
  - **Healthcare providers should instruct parents who are administering EpiPen to their children to first restrain the child and then use both hands to remove the blue safety release.**

## **2. Device Failure from Inadvertent or Spontaneous Activation Due to a Raised Blue Safety Release**

- In a very limited number of cases, EpiPen devices may have a blue safety release that is slightly raised.
- The function of the blue safety release is to ensure the device does not activate prior to its intended use.
- If the blue safety release is raised (see Appendix 1), the device may activate prematurely, which could potentially delay or prevent emergency treatment when needed.
- **To prevent this spontaneous activation, pharmacists, patients, and their caregivers should be advised of the following:**
  - When dispensing or receiving an EpiPen or EpiPen Jr Auto-Injector or authorized generic, and prior to using the device, visually inspect the auto-injectors to confirm the blue safety release is not raised (see Appendix 1, Steps 1 through 5 for more details including pictures).
  - If the blue safety release is raised, the auto-injector should NOT be dispensed or used since premature activation may occur. Contact Mylan Customer Relations at 1-800-796-9526 to obtain a replacement device(s) at no additional cost.

## **3. Difficulty Removing the Device from the Carrier Tube**

- In some (approximately 0.0002% or 2 parts per million units based on the internal manufacturing process occurrence rate) cases, EpiPen devices may not slide out of their carrier tube easily or potentially at all, which could potentially delay or prevent emergency treatment.
- This issue is related to a slight deformation on the open rim of the plastic carrier tube that may be present but may not be visually obvious to patients/caregivers.
- The probability of an auto-injector that may have a deformity that could cause a delay in release from the carrier tube is very low.
- This issue may affect any EpiPen auto-injector lot currently on the market in the U.S. with the labeled expiry on the device and carton prior to September 2020.



- **To ensure the device can be used when needed, pharmacists, patients, and their caregivers should be advised of the following:**
  - When dispensing or receiving an EpiPen or EpiPen Jr Auto-Injector or authorized generic, and prior to using the device: remove both carrier tubes from the S-clip, flip open the caps of the carrier tubes, and tip each carrier tube to verify that each auto-injector readily slides out of the tube (see Appendix 1, Steps 2, 3 and 4 for more details including pictures).
  - If the auto-injectors do not readily slide from the carrier tubes, they should NOT be dispensed or used. Contact Mylan Customer Relations at 1-800-796-9526 to obtain a replacement device(s) at no additional cost.

#### 4. Certain Identified Use Errors

Through a study examining use by intended users in expected use environments as well as a thorough review of post marketing information, Pfizer, whose subsidiary Meridian Medical Technologies manufactures EpiPen, identified that certain use errors have occurred.

Use Errors	Correct Administration/Important Reminders
✗ Failing to remove the device from the carrier tube prior to use.	✓ EpiPen must be removed from the carrier tube it is provided in prior to use.
✗ Failing to remove the blue safety release prior to use.	✓ EpiPen will not activate with the blue safety release in place.
✗ Activating the auto-injector upside down, resulting in hand injections.	✓ The needle exits from the orange end of the EpiPen which should be in contact with the outer thigh (upper leg) at a right angle (perpendicular) to the thigh prior to, and during activation. The orange needle tip will extend to cover the needle after activation. If the needle is still visible, do not attempt to reuse it.
✗ Failing to apply sufficient force to activate EpiPen.	✓ EpiPen should be administered by swinging and pushing firmly against the outer thigh until it “clicks.” The click signals that injection has started. The correct dose has been administered if the orange needle tip is extended and the window is blocked.
✗ Administering at a site other than the outer thigh.	✓ Administer EpiPen in the outer thigh only.
✗ Failing to hold the auto-injector in place for a full three seconds.	✓ Hold EpiPen in place for at minimum 3 seconds following activation (count slowly 1, 2, 3).



### Risk

These use errors could potentially delay or prevent emergency treatment of epinephrine. Since EpiPen is administered for severe and potentially life-threatening allergic reactions, anything that prevents or delays the administration of the intended dose of epinephrine could result in a high risk to the patient, including the risk of death. Additionally, failure to hold EpiPen in the correct orientation could result in inadvertent puncture of the hand, which could lead to infection, anaphylactic shock, or death. Failure to administer EpiPen in the outer thigh could result in incomplete treatment or a bone strike. Incomplete treatment could lead to worsened patient outcomes, including possibly death. Bone strike could lead to infection or nerve injury.

### Important Training Reminders

- It is important that you review the Patient Information and Instructions for Use with your patients and caregivers at the time of prescribing and dispensing of EpiPen, as well as during your regular patient interactions.
- It is important that you demonstrate use of the EpiPen with your patients and caregivers. During this review and demonstration reinforce the correct administration associated with the use errors in the above chart.
- In addition, encourage patients and their caregivers to regularly read and to ensure they understand the Patient Information and Instructions for Use.
- Please refer to Appendix 2 of this letter for the Patient Information and Instructions For Use.
- The complete Prescribing Information can be found at <https://www.epipen.com/>.
- Patients and caregivers should periodically practice using the EpiPen trainer, a needle-less, non-drug containing device, referred to as the Trainer in this letter, and included in the EpiPen carton.
- Healthcare providers and consumers should review training resources on EpiPen's Instructions For Use on a regular basis, which can be found on the product website at <https://www.epipen.com/about-epipen-and-generic/how-to-use-epipen>, as well as the official EpiPen YouTube channel at <https://www.youtube.com/user/EpiPenOfficial>.

### **AFFECTED PRODUCT**

- EpiPen® 0.3 mg (EpiPen® NDC 49502-500-02) (Authorized Generic NDC 49502-102-02)
- EpiPen Jr® 0.15 mg (EpiPen Jr® NDC 49502-501-02) (Authorized Generic NDC 49502-101-02)

### **CONTACT AND REPORTING INFORMATION**

Please contact Mylan Customer Relations at 1-800-796-9526 (Monday-Friday 8 a.m. - 5 p.m. ET) for any questions you may have regarding this notification.

To report adverse reactions or quality issues, contact Mylan at 1-877-4-INFO-RX (1-877-446-3679).

Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, phone, or by fax:

- Complete and submit the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular mail, phone, or Fax: download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178)



This letter is not intended as a complete description of the benefits and risks related to the use of EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors, and the authorized generic versions of these strengths. Full Prescribing Information is available at <https://www.epipen.com/>.

We understand the challenge and inconvenience that the additional actions requested in this letter and in Appendix 1 may pose. Thank you for your attention to these important reminders and continued training to patients and caregivers to ensure proper use and reporting of any potential concerns or questions regarding their EpiPen.

Sincerely,

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Edward G.M. Power, Ph.D., M.B.A.  
VP North America Medical Affairs, Hospital Business  
Pfizer, Inc.

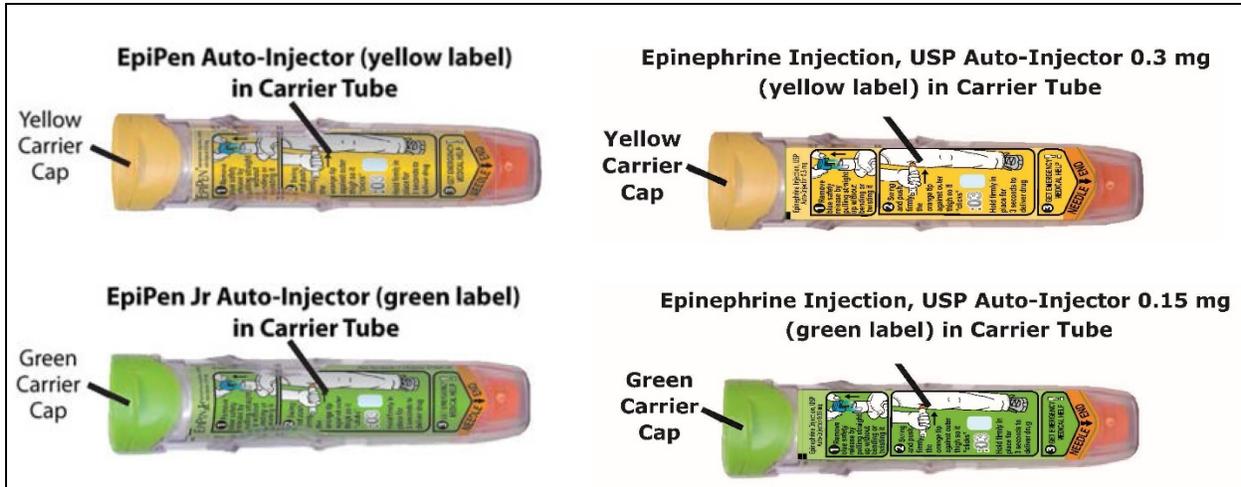
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Rafael Muniz, M.D.  
Head of Global Medical Affairs  
Mylan, Inc.

**Appendix 1: Precautionary Handling Instructions for Healthcare Providers and Consumers  
Verifying EpiPen® Auto-Injectors for Ease of Removal from Carrier Tube and No Raised Blue  
Safety Release**

EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors, and the authorized generic versions of these strengths, inside the carrier tubes are shown below in Figure 1.

**Figure 1. Auto-Injectors in the Carrier Tubes**



1. Before dispensing or administering EpiPen 0.3 mg and EpiPen Jr 0.15 mg Auto-Injectors, and the authorized generic versions of these strengths, open the carton and remove both carrier tubes containing auto-injectors from the carton. Leave all other contents inside the carton (i.e., package inserts and auto-injector trainer).

2. Remove both carrier tubes from the S-clip.

3. Per the Instructions for Use, flip open the caps of the carrier tubes. The carrier tube caps are:

- a. yellow for EpiPen or Epinephrine 0.3 mg, and
- b. green for EpiPen Jr or Epinephrine 0.15 mg.



4. Tip each carrier tube and verify that each auto-injector readily slides out of the tube.



5. Visually inspect both auto-injectors to confirm the blue safety release is not raised: (Note: Quarter is included for thickness reference only.)



**Call Mylan to obtain a replacement unit(s) at no additional cost.**



**OK to dispense or use.**

If the blue safety release is raised, return EpiPen to the carrier tube, close the carrier tube lid and return the unit. Do *NOT* attempt to push the blue safety release back down.

The blue safety release should be kept on the auto-injector until the time of use. Do *NOT* remove the blue safety release from the auto-injector unless you are ready to use the auto-injector.

6. If both auto-injectors readily slide from the carrier tube *AND* the blue safety release is not raised:
  - a. place both auto-injectors back into the carrier tubes,
  - b. close both carrier tube caps,
  - c. connect both carrier tubes to the S-clip, and
  - d. place both auto-injectors back into the carton.

Ensure all contents (both carrier tubes each containing an auto-injector, S-clip connecting the carrier tubes, package inserts and auto-injector trainer) are placed back inside the carton and close the carton. These auto-injectors are ready to be dispensed or used.

7. If an auto-injector does not readily slide out of the carrier tube *OR* if the blue safety release is raised, the auto-injector should *NOT* be dispensed or used. Contact Mylan Customer Relations at 1-800-796-9526 to obtain a replacement unit(s) at no additional cost.



## **Appendix 2: Patient Information and Instructions for Use**

## PATIENT INFORMATION and INSTRUCTIONS FOR USE

### EPIPEN<sup>®</sup>

(epinephrine injection, USP) Auto-Injector 0.3 mg  
EpiPen<sup>®</sup> = one dose of 0.3 mg epinephrine, USP 0.3 mg/0.3 mL

### EPIPEN JR<sup>®</sup>

(epinephrine injection, USP) Auto-Injector 0.15 mg  
EpiPen Jr<sup>®</sup> = one dose of 0.15 mg epinephrine, USP 0.15 mg/0.3 mL

For allergic emergencies (anaphylaxis)

### Patient Information

Read this Patient Information Leaflet carefully before using the EpiPen<sup>®</sup> or EpiPen Jr<sup>®</sup> Auto-Injector and each time you get a refill. There may be new information. You, your parent, caregiver, or others who may be in a position to administer EpiPen or EpiPen Jr Auto-Injector, should know how to use it before you have an allergic emergency.

This information does not take the place of talking with your 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 be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or unknown causes.

Symptoms of anaphylaxis may include:

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

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

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 injection devices (auto-injectors) used to treat life-threatening, allergic emergencies including anaphylaxis in people who are at risk for or have a history of serious allergic emergencies. Each device contains a single dose of epinephrine.
- EpiPen and EpiPen Jr are for immediate self (or caregiver) administration and do not take the place of emergency medical care. You should get emergency help right away after using EpiPen and EpiPen Jr.
- EpiPen and EpiPen Jr are for people who have been prescribed this medicine by their 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 of all known 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 grey color. The grey EpiPen Trainer contains no medicine and no needle.** Periodically practice with your EpiPen Trainer before an allergic emergency happens to make sure you are able to safely use the real EpiPen and EpiPen Jr Auto-Injector in an emergency. Always carry your real EpiPen or EpiPen Jr Auto-Injector with you in case of an allergic emergency. Additional training resources are available at [www.epipen.com](http://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.

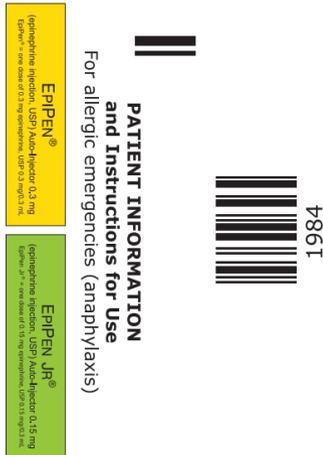
### What are the possible side effects of the EpiPen and EpiPen Jr?

**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 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
- paleness
- 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](http://www.epipen.com) or call 1-800-395-3376.

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

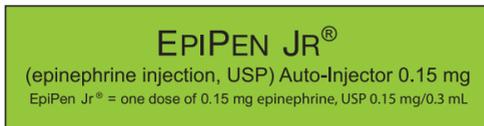
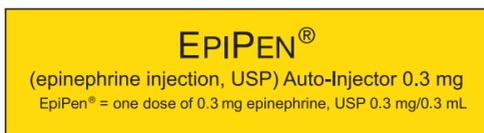
**Active Ingredients:** Epinephrine

**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.**

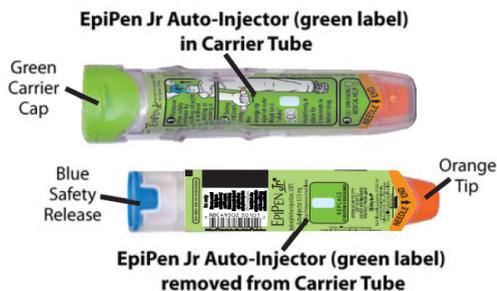
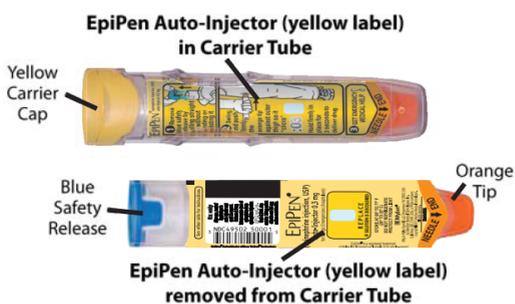
## Instructions for Use



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.

### Your EpiPen and EpiPen Jr Auto-Injector



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

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

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



Flip open the yellow cap of your EpiPen or the green cap of your EpiPen Jr carrier tube.



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



**Grasp the auto-injector in your fist with the orange tip (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 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.

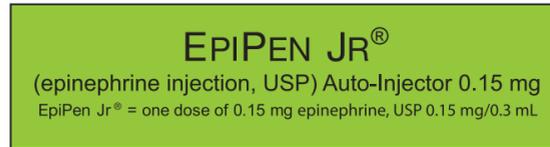
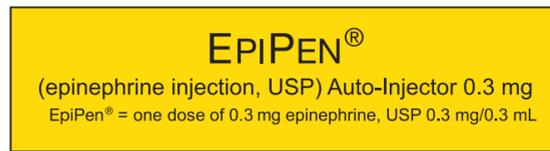
This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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

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Register your EpiPen or EpiPen Jr Auto-Injector at **MyEpiPen.com** and find out more about:

- Free EpiPen Auto-Injector **Refill Reminder Program**. It is important to keep your auto-injector up-to-date.

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](http://www.epipen.com).