

PATIENT INFORMATION

EPIPEN[®]

(epinephrine) Auto-Injector 0.3 mg

EpiPen[®] = one dose of 0.30 mg epinephrine (USP, 1:1000, 0.3 mL)

EPIPEN JR[®]

(epinephrine) 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 this Patient Information Leaflet carefully before using the EpiPen[®] Auto-Injector or EpiPen Jr[®] Auto-Injector (henceforth referred to as EpiPen or EpiPen Jr Auto-Injector), and each time you get a refill. There may be new information. You should know how to use the EpiPen or EpiPen Jr Auto-Injector 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 Auto-Injector?

1. EpiPen and EpiPen Jr Auto-Injectors 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)
- dizziness, fainting, or "passing out" (unconsciousness)

2. Always carry your EpiPen or EpiPen Jr Auto-Injector 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 and others where you keep your EpiPen or EpiPen Jr Auto-Injector 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 the EpiPen

or EpiPen Jr Auto-Injector right away. Get emergency medical help right away.

You may need further medical attention. You may need a second EpiPen or EpiPen Jr Auto-Injector should symptoms persist or recur. More than two sequential doses of epinephrine for a single episode should only be administered by a healthcare provider.

What are the EpiPen and EpiPen Jr Auto-Injectors?

- EpiPen and EpiPen Jr Auto-Injector are disposable, prefilled automatic injection devices used to treat life-threatening, allergic emergencies including anaphylaxis in people who are at risk for or have a history of serious allergic emergencies. They contain a single dose of epinephrine.
- EpiPen and EpiPen Jr Auto-Injector 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 the EpiPen and EpiPen Jr Auto-Injector.
- EpiPen and EpiPen Jr Auto-Injector are for people who have been prescribed this medication 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 Auto-Injectors 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 Auto-Injector?

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

- have heart problems or high blood pressure
- have diabetes
- have thyroid conditions
- 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 non-prescription medicines, vitamins, and herbal supplements. Inform your healthcare provider of all known allergies.

Especially tell your healthcare provider if you take certain asthma medications.

EpiPen or EpiPen Jr Auto-Injector and other medicines may affect each other, causing side effects. EpiPen or EpiPen Jr Auto-Injector may affect the way other medicines work, and other medicines may affect how the EpiPen or EpiPen Jr Auto-Injector 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 Auto-Injector for treatment of anaphylaxis as prescribed by your healthcare provider, regardless of medical conditions or medication.

How should I use the EpiPen and EpiPen Jr Auto-Injector?

- Each EpiPen or EpiPen Jr Auto-Injector contains only 1 dose of medicine.
- The EpiPen or EpiPen Jr Auto-Injector should be injected into the muscle of your outer thigh. 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 Auto-Injector.
- Use your EpiPen or EpiPen Jr Auto-Injector exactly as your healthcare provider tells you to use it.
- **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 occurs, 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 Auto-Injector Trainer and separate Trainer Instructions for Use. **The EpiPen Auto-Injector Trainer has a grey color. The grey EpiPen Auto-Injector Trainer contains no medicine and no needle.** Practice with your EpiPen Auto-Injector 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. Discard 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 Auto-Injector?

EpiPen and EpiPen Jr Auto-Injector may cause serious side effects.

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

- vein
- buttock
- fingers, toes, hands, or feet

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

If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you take the EpiPen or EpiPen Jr Auto-Injector. Talk to your healthcare provider about all your medical conditions.

Common side effects of the EpiPen and EpiPen Jr Auto-Injector include:

- fast, irregular or "pounding" heartbeat
- sweating
- headache
- weakness or shakiness
- paleness
- feelings of over excitement, nervousness or anxiety
- dizziness
- nausea and/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 Auto-Injector. 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 the EpiPen and EpiPen Jr Auto-Injector?

- Store at 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 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 of the device. Keep the blue safety release on until you need to use it.
- Your EpiPen or EpiPen Jr Auto-Injector has an expiration date. Replace it before the expiration date.

General information about the safe and effective use of the EpiPen and EpiPen Jr Auto-Injector:

Do not use the EpiPen or EpiPen Jr Auto-Injector for a condition for which it was not prescribed. Do not give your EpiPen or EpiPen Jr Auto-Injector to other people.

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

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

What are the ingredients in EpiPen and EpiPen Jr Auto-Injector?

Active Ingredients: Epinephrine

Inactive Ingredients: sodium chloride, sodium metabisulfite, hydrochloric acid, and water. The EpiPen and EpiPen Jr Auto-Injector contain **no latex**.

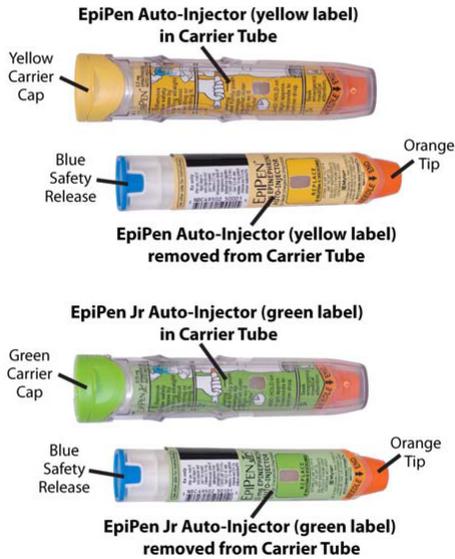
Important Information

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

Instructions for Use

Carefully read these Instructions for Use before you need to use your EpiPen or EpiPen Jr Auto-Injector. Before you use your EpiPen or EpiPen Jr Auto-Injector, make sure your healthcare provider shows you the right way to use it. If you have any questions, ask your healthcare provider.

Your EpiPen and EpiPen Jr Auto-Injector



3-Step Easy To Follow Instructions:

1. **Prepare** the EpiPen or EpiPen Jr Auto-Injector For Injection
2. **Administer** the EpiPen or EpiPen Jr Auto-Injector
3. **Finalize** the Injection Process
(See detailed instructions below)

1. Prepare the EpiPen or EpiPen Jr Auto-Injector For Injection

Remove the auto-injector from the clear carrier tube.



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



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



Grasp the auto-injector in your fist with the orange tip pointing downward.

With your other hand, **remove the blue safety release by pulling straight up without bending or twisting it.**

Note:

- The needle comes out of the orange tip.
 - Never put your thumb, fingers or hand over the orange tip.
2. **Administer** the EpiPen or EpiPen Jr Auto-Injector

Hold the auto-injector with orange tip near the outer thigh.



Swing and firmly push the orange tip against the outer thigh until it 'clicks'. Keep the auto-injector firmly pushed against the thigh at a 90° angle (perpendicular) to the thigh.



Hold firmly against the thigh for approximately 10 seconds to deliver the drug. The injection is now complete.

3. Finalize the Injection Process



Remove the auto-injector from the thigh. The orange tip will extend to cover the needle.



Massage the injection area for 10 seconds.

Get emergency medical help right away. You may need further medical attention. You may need a second EpiPen or EpiPen Jr Auto-Injector should symptoms persist or recur.

Note:

- Take your used auto-injector with you when you go to see the 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 a healthcare provider for inspection and proper disposal.
- Ask for a refill, if needed.
- The used auto-injector with extended needle cover will not fit in the carrier tube.
- Most of the liquid medicine stays in the auto-injector and cannot be reused. You have received the correct dose of the medicine 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 Auto-Injector Trainer and separate Trainer Instructions for Use. **The EpiPen Trainer**

has a grey color. The grey EpiPen Trainer contains no medicine and no needle. Practice with your EpiPen Trainer, but always carry your real EpiPen or EpiPen Jr Auto-Injector in case of an allergic emergency.

- Do not attempt 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., Basking Ridge, NJ 07920, USA
by Meridian Medical Technologies, Inc.,
Columbia, MD 21046, USA, 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, visit www.epipen.com.