

EPINEPHRINE INJECTION, USP AUTO-INJECTOR (ep-in-eph-rine)

## For allergic emergencies (anaphylaxis)

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

1. Epinephrine injection, USP auto-injector contains 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 other unknown causes. Symptoms of an anaphylaxis may include:

- ## What is epinephrine injection, USP auto-injector?

- Epinephrine injection, USP auto-injector is a disposable, prefilled automatic injection device (auto-injector) 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.
- Epinephrine injection, USP auto-injector is for immediate self (or caregiver) administration and does not take the place of emergency medical care. You should get emergency medical help right away after using epinephrine injection, USP auto-injector.
- Epinephrine injection, USP auto-injector is for people who have been prescribed this medicine by their healthcare provider.
- The epinephrine injection, USP auto-injector 0.3 mg auto-injector is for patients who weigh 66 pounds or more (30 kilograms or more).
- The epinephrine injection, USP auto-injector 0.15 mg auto-injector is for patients who weigh about 33 to 66 pounds (15 to 30 kilograms).
- It is not known if epinephrine injection, USP auto-injector is safe and effective in children who weigh less than 33 pounds (15 kilograms).

**Before you use epinephrine injection, USP auto-injector, tell your healthcare provider about all your 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.

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

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 epinephrine injection, USP auto-injector for treatment of anaphylaxis as prescribed by your healthcare provider, regardless of your medical conditions or the medicine you take.

- Each epinephrine injection, USP auto-injector contains only 1 dose of medicine.
- Epinephrine injection, USP auto-injector should only be injected into the middle of the outer thigh (upper leg). It can be injected through clothing, if needed.
- Read the Instructions for Use at the end of this Patient Information Leaflet for information about the right way to use epinephrine injection, USP auto-injector.
- Your healthcare provider will show you how to safely use the epinephrine injection, USP auto-injector.
- Use epinephrine injection, USP auto-injector exactly as your healthcare provider tells you to use it. You may need to use a second epinephrine injection, USP auto-injector 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 red tip. Never press or push the red tip with your thumb, fingers, or hand.** The needle comes out of the red tip. Accidental injection into finger, hands, or feet may cause a loss of blood flow to those 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 epinephrine injection, USP auto-injector comes packaged in a carton containing 1 or 2 epinephrine injection, USP auto-injectors.
- You may request a separate Trainer, that comes packaged with instructions. Additional video instructions on the use of epinephrine injection, USP auto-injector are available from [www.epinephrineautoinject.com](http://www.epinephrineautoinject.com). **The epinephrine injection, USP auto-injector Trainer has a beige color. The beige epinephrine injection, USP auto-injector Trainer contains no medicine and no needle.** Practice with your epinephrine injection, USP auto-injector Trainer before an allergic emergency happens to make sure you are able to safely use the real epinephrine injection, USP auto-injector in an emergency. Always carry your real epinephrine injection, USP auto-injector with you in case of an allergic emergency.
- Do not drop the carrying case or epinephrine injection, USP auto-injector. If the carrying case or epinephrine injection, USP auto-injector is dropped, check for damage and leakage. Dispose of the auto-injector and carrying case, and replace if damage or leakage is noticed or suspected.

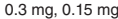
## What are the possible side effects of epinephrine injection, USP auto-injector?

**Epinephrine injection, USP auto-injector may cause serious side effects.**

- **Epinephrine injection, USP auto-injector should only be injected into the middle of your outer thigh (upper leg). Do not** inject epinephrine injection, USP auto-injector into your:
  - veins
  - buttocks
  - fingers, toes, hands or feet.

If you accidentally inject epinephrine injection, USP auto-injector 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 use epinephrine injection, USP auto-injector 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 epinephrine injection, USP auto-injector, 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 an injection.
- **If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have more or longer lasting side effects when you use epinephrine injection, USP auto-injector.** Talk to your healthcare provider about all your medical conditions.

Common side effects of epinephrine injection, USP auto-injector include:

- faster, 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 epinephrine injection, USP 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 epinephrine injection, USP auto-injector?**

- Store epinephrine injection, USP auto-injector at room temperature between 68° to 77° F (20° to 25° C).
- Protect from light.
- **Do not** expose to extreme heat or cold. 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 viewing window of your auto-injector periodically. The solution should be clear. If the solution is discolored (pinkish or brown), cloudy or contains solid particles, replace the unit.
- Always keep your epinephrine injection, USP auto-injector in the carrying case to protect it from damage; however, the carrying case is not waterproof.
- The two blue end caps help to prevent accidental injection. Do not remove the blue end caps until you are ready to use epinephrine injection, USP auto-injector.
- Your epinephrine injection, USP auto-injector has an expiration date. Replace it before the expiration date.

**Keep epinephrine injection, USP auto-injector and all medicines out of the reach of children.**

**General information about the safe and effective use of epinephrine injection, USP auto-injector:**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use epinephrine injection, USP auto-injector for a condition for which it was not prescribed. Do not give epinephrine injection, USP auto-injector to other people.

This Patient Information Leaflet summarizes the most important information about epinephrine injection, USP auto-injector. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about epinephrine injection, USP auto-injector that is written for health professionals.

For more information and video instructions on the use of epinephrine injection, USP auto-injector, go to [www.epinephrineautoinject.com](http://www.epinephrineautoinject.com) or call 1-800-934-6729.

**What are the ingredients in epinephrine injection, USP auto-injector?**

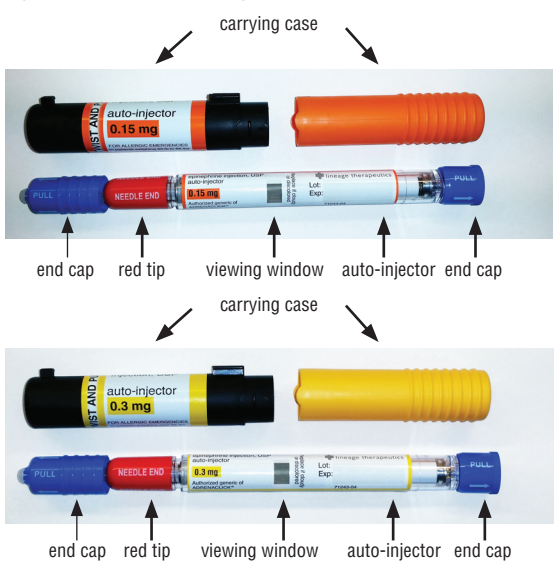
**Active Ingredient:** epinephrine

**Inactive Ingredients:** sodium chloride, chlorobutanol, sodium bisulfite, hydrochloric acid and sodium hydroxide, and water.

**Important Information**

- **The epinephrine injection, USP auto-injector 0.3 mg auto-injector has a yellow colored label.**
- **The epinephrine injection, USP auto-injector 0.15 mg auto-injector has an orange colored label.**
- **The epinephrine injection, USP auto-injector Trainer has a beige color, and contains no medicine and no needle.**
- **Your auto-injector is designed to work through clothing.**
- **The two blue end caps on the epinephrine injection, USP auto-injector help to prevent accidental injection of the device. Do not remove the blue end caps 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 red tip. The needle comes out of the red tip.**
- **If an accidental injection happens, get medical help right away.**
- **Do not place patient information or any other foreign objects in carrier with the auto-injector, as this may prevent you from removing the auto-injector for use.**

**Your epinephrine injection, USP auto-injector**

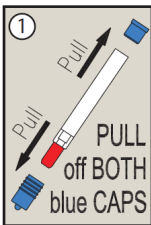


**STEP 1. Prepare epinephrine injection, USP auto-injector for injection**

- Remove epinephrine injection, USP auto-injector from its protective carrying case.
- **Pull off blue end caps;** you will now see a red tip. Grasp the auto-injector in your fist with the red tip pointing downward. **See Figure A.**

**Note:**

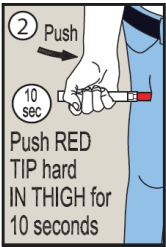
- The needle comes out of the red tip.
- To avoid an accidental injection, never put your thumb, fingers, or hand over the red tip. If an accidental injection happens, get medical help right away.



**Figure A**

**STEP 2. Administer epinephrine injection, USP auto-injector**

- If you are administering epinephrine injection, USP auto-injector to a young child, hold the leg firmly in place and limit movement prior to and while administering an injection.
- **Put the red tip against the middle of the outer thigh** (upper leg) at a 90° angle (perpendicular) to the thigh.
- **Press down hard and hold firmly against the thigh for approximately 10 seconds** to deliver the medicine. **See Figure B.**



**Figure B**

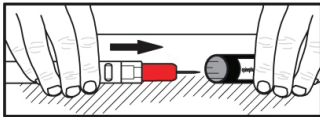
- Only inject into the middle of the outer thigh. **Do not** inject into any other part of the body.
- **Remove epinephrine injection, USP auto-injector from the thigh.**
- Massage the area for 10 seconds.
- **Check the red tip.** The injection is complete and you have received the correct dose of the medicine if you see the needle sticking out of the **red** tip. **If you do not see the needle repeat Step 2.**

**STEP 3. Get emergency medical help right away.** You may need further medical attention. You may need to use a second epinephrine injection, USP auto-injector if symptoms continue or recur.

**STEP 4. After use / Disposal**

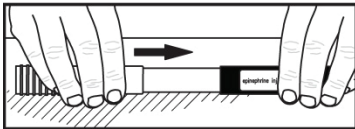
**Carefully cover the needle with the carrying case.**

- Lay the labeled half of the carrying case cover down on a flat surface. Use one hand to carefully slide the end of the auto-injector, needle first, into the labeled carrying case cover. **See Figure C.**



**Figure C**

- After the needle is inside the labeled cover, push the unlabeled half of the carrying case cover firmly over the non-needle end of the auto-injector. **See Figure D.**



**Figure D**

- Take your used epinephrine injection, USP 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 epinephrine injection, USP auto-injector to the healthcare provider for inspection and proper disposal.
- Ask for a refill, if needed.

**Note:**

- Epinephrine injection, USP auto-injector is a single-use injectable device that delivers a fixed dose of epinephrine. The auto-injector cannot be reused. Do not attempt to reuse epinephrine injection, USP auto-injector 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 you see the needle sticking out of the **red** tip.
- A separate epinephrine injection, USP auto-injector Trainer is available. The epinephrine injection, USP auto-injector Trainer has a beige color. The beige epinephrine injection, USP auto-injector Trainer contains no medicine and no needle. Practice with your epinephrine injection, USP auto-injector Trainer, but always carry your real epinephrine injection, USP auto-injector in case of an allergic emergency.
- If you will be administering epinephrine injection, USP auto-injector 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 epinephrine injection, USP auto-injector apart.

For more information and video instructions on the use of epinephrine injection, USP auto-injector, go to [www.epinephrineautoinject.com](http://www.epinephrineautoinject.com) or call 1-800-934-6729.

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

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**Instructions for Use**

EPINEPHRINE INJECTION, USP AUTO-INJECTOR (ep-in-eph-rine)

For allergic emergencies (anaphylaxis)

Read these Instructions for Use carefully before you use epinephrine injection, USP auto-injector. Before you need to use your epinephrine injection, USP auto-injector, 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 epinephrine injection, USP auto-injector should also understand how to use it well. If you have any questions, ask your healthcare provider.