

PATIENT INFORMATION and INSTRUCTIONS FOR USE

Epinephrine Injection USP, 0.3 mg (Auto-Injector)

Epinephrine Injection USP, 0.3 mg = one dose of 0.3 mg epinephrine USP, 0.3 mg/0.3 mL

Epinephrine Injection USP, 0.15 mg (Auto-Injector)

Epinephrine Injection USP, 0.15 mg = 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 epinephrine injection, 0.3 mg (auto-injector) or epinephrine injection, 0.15 mg (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 epinephrine injection, 0.3 mg (auto-injector) or epinephrine injection, 0.15 mg (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 epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg?

1. Epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg contain 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 epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg 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 epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg 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 epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg right away.**
- **Get emergency medical help right away.** You may need further medical attention. You may need to use a second epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg 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 epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg?

- Epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg 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.
- Epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg 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 epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg.
- Epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg are for people who have been prescribed this medicine by their healthcare provider.
- The Epinephrine Injection, 0.3 mg (Auto-Injector) is for patients who weigh 66 pounds or more (30 kilograms or more).
- The Epinephrine Injection, 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, 0.3 mg and epinephrine injection, 0.15 mg are safe and effective in children who weigh less than 33 pounds (15 kilograms).

What should I tell my healthcare provider before using the epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg?

Before you use epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg, 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.

Epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg and other medicines may affect each other, causing side effects. Epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg may affect the way other medicines work, and other medicines may affect how epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg 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 epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg for treatment of anaphylaxis as prescribed by your healthcare provider, regardless of your medical conditions or the medicines you take.

How should I use epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg?

- Each epinephrine injection, 0.3 mg (auto-injector) or epinephrine injection, 0.15 mg (auto-injector) contains only 1 dose of medicine.
- Epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg 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 epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg.

- Your healthcare provider will show you how to safely use the epinephrine injection, 0.3 mg (auto-injector) or epinephrine injection, 0.15 mg (auto-injector).
- Use your epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg exactly as your healthcare provider tells you to use it. You may need to use a second epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg 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 epinephrine injection, 0.3 mg (auto-injector) and epinephrine injection, 0.15 mg (auto-injector) may come packaged with an Epinephrine Injection Trainer and separate Epinephrine Injection Trainer Instructions for Use. **The Epinephrine Injection Trainer has a grey color. The grey Epinephrine Injection Trainer contains no medicine and no needle.** Periodically practice with your Epinephrine Injection Trainer before an allergic emergency happens to make sure you are able to safely use the real epinephrine injection, 0.3 mg (auto-injector) and epinephrine injection, 0.15 mg (auto-injector) in an emergency. Always carry your real epinephrine injection, 0.3 mg (auto-injector) or epinephrine injection 0.15 mg (auto-injector) with you in case of an allergic emergency. Additional training resources are available at www.TevaEpinephrine.com.
- Do not drop the auto-injector. If the auto-injector is dropped, check for damage and leakage. Dispose of the auto-injector and replace if damage or leakage is noticed or suspected.

What are the possible side effects of epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg?

Epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg may cause serious side effects.

- **The epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg should only be injected into the middle of your outer thigh (upper leg). Do not** inject the epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg into your:
 - veins
 - buttocks
 - fingers, toes, hands, or feet

If you accidentally inject epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg 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 epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg 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, 0.3 mg or epinephrine injection, 0.15 mg, 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 epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg.** Talk to your healthcare provider about all your medical conditions.

Common side effects of epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg 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 epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg. 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, 0.3 mg and epinephrine injection, 0.15 mg?

- Store epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg 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 darker than slightly yellow) or if it contains a precipitate, replace the unit.
- Always protect your epinephrine injection, 0.3 mg (auto-injector) and epinephrine injection, 0.15 mg (auto-injector) from damage and water.
- The blue safety release helps to prevent accidental injection. Keep the blue safety release on until you need to use epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg.
- Your epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg has an expiration date. Replace it before the expiration date.

Keep epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg and all medicines out of the reach of children.

General information about the safe and effective use of epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use the epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg for a condition for which it was not prescribed. Do not give your epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg to other people.

This Patient Information Leaflet summarizes the most important information about epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg that is written for health professionals.

For more information and video instructions on the use of epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg go to www.TevaEpinephrine.com or call 1-888-838-2872.

What are the ingredients in epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg?

Active Ingredients: Epinephrine

Inactive Ingredients: sodium chloride, sodium metabisulfite, sodium tartrate (dihydrate), hydrochloric acid, and water.

Important Information

- **The Epinephrine Injection, 0.3 mg (Auto-Injector) has a yellow colored label.**
- **The Epinephrine Injection, 0.15 mg (Auto-Injector) has a green colored label.**
- **The Epinephrine Injection 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 Epinephrine Injection, 0.3 mg (Auto-Injector) and Epinephrine Injection, 0.15 mg (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.**

Instructions for Use

Epinephrine Injection USP, 0.3 mg (Auto-Injector)

Epinephrine Injection USP, 0.3 mg = one dose of 0.3 mg epinephrine USP, 0.3 mg/0.3 mL

Epinephrine Injection USP, 0.15 mg (Auto-Injector)

Epinephrine Injection USP, 0.15 mg = one dose of 0.15 mg epinephrine USP, 0.15 mg/0.3 mL

For allergic emergencies (anaphylaxis)

Read these Instructions for Use carefully before you use epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg. Before you need to use your epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg, 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, 0.3 mg (auto-injector) or epinephrine injection, 0.15 mg (auto-injector) should also understand how to use it as well. If you have any questions, ask your healthcare provider.

Your Epinephrine Injection, 0.3 mg (Auto-Injector) and Epinephrine Injection, 0.15 mg (Auto-Injector)

- A CARRYING TUBE IS NOT PROVIDED AS SEEN WITH OTHER PRODUCTS.
- **Epinephrine Injection, 0.3 mg Auto-Injector (yellow label) with Yellow Cap**



Blue Safety Release



- **Epinephrine Injection, 0.3 mg Auto-Injector (yellow label) with Yellow Cap Removed**
- **Epinephrine Injection, 0.15 mg Auto-Injector (green label) with Green Cap**



Blue Safety Release



- **Epinephrine Injection, 0.15 mg Auto-Injector (green label) with Green Cap Removed**

A dose of epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg requires 3 simple steps: Prepare, Administer and Get emergency medical help

Step 1. Prepare epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg for injection



Quickly twist the yellow cap off the epinephrine injection, 0.3 mg auto-injector or the green cap off the epinephrine injection, 0.15 mg auto-injector in the direction of the “twist arrow” to remove it.

Grasp the auto-injector in your fist with the orange tip (needle end) pointing downward. With your other hand, pull off the blue safety release.

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 epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg

If you are administering epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg 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 epinephrine injection, 0.3 mg auto-injector or epinephrine injection, 0.15 mg 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 epinephrine injection, 0.3 mg auto-injector or epinephrine injection, 0.15 mg auto-injector to the healthcare provider for inspection and proper disposal.
- Ask for a refill, if needed.

Note:

- A carrying tube is not provided as seen with other products.
- Epinephrine injection, 0.3 mg and epinephrine injection, 0.15 mg are single-use injectable devices that deliver a fixed dose of epinephrine. The auto-injector cannot be reused. Do not attempt to reuse epinephrine injection 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 epinephrine injection, 0.3 mg auto-injector and epinephrine injection, 0.15 mg auto-injector may come packaged with an Epinephrine Injection Trainer and separate Epinephrine Injection Trainer Instructions for Use. The Epinephrine Injection Trainer has a grey color. The grey Epinephrine Injection Trainer contains no medicine and no

needle. Practice with your Epinephrine Injection Trainer, but always carry your real epinephrine injection, 0.3 mg auto-injector or epinephrine injection, 0.15 mg auto-injector in case of an allergic emergency.

- If you are administering epinephrine injection, 0.3 mg or epinephrine injection, 0.15 mg 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, 0.3 mg auto-injector or epinephrine injection, 0.15 mg auto-injector apart.

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

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured For:

Teva Pharmaceuticals USA, Inc.

North Wales, PA 19454

Iss. 6/2018

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Epinephrine Injection USP, 0.3 mg = one dose of 0.3 mg epinephrine USP, 0.3 mg/0.3 mL

Epinephrine Injection USP, 0.15 mg (Auto-Injector)

Epinephrine Injection USP, 0.15 mg = one dose of 0.15 mg epinephrine USP, 0.15 mg/0.3 mL

TevaEpinephrine.com

Register your Epinephrine Injection 0.3 mg Auto-Injector or Epinephrine Injection 0.15 mg Auto-Injector at **www.TevaEpinephrine.com** and find out more about:

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

Register up to 6 Epinephrine Injection 0.3 mg Auto-Injectors or Epinephrine Injection 0.15 mg Auto-Injectors and receive automatic **Refill Reminder Alerts**.

- Receive periodic information related to allergies and allergens.
- Instructional Video

For more information about Epinephrine Injection 0.3 mg Auto-Injector or Epinephrine Injection 0.15 mg Auto-Injector and proper use of the products, call Teva at 1-888-838-2872 or visit www.TevaEpinephrine.com.

Epinephrine Injection Trainer Instructions for Use

In an emergency: Do not use the grey Trainer. Use your real yellow Epinephrine Injection 0.3 mg Auto-Injector or green Epinephrine Injection 0.15 mg Auto-Injector.

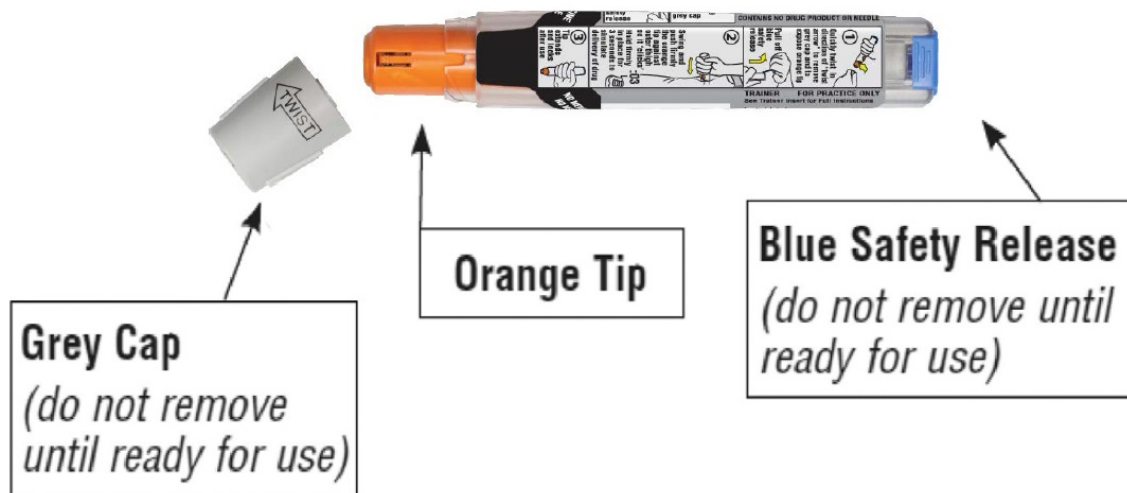
Important Information

- **The Trainer label has a grey color.**
- **The Trainer contains no medicine and no needle.**
- Periodically practice with the grey colored Trainer before an allergic emergency (anaphylaxis) happens to make sure you are able to safely use the real yellow epinephrine injection 0.3 mg auto-injector or green epinephrine injection 0.15 mg auto-injector in case of an emergency.
- Always carry your real yellow epinephrine injection 0.3 mg auto-injector or green epinephrine injection 0.15 mg auto-injector in case of an allergic emergency.

The Epinephrine Injection Trainer

Familiarize yourself with this grey Trainer. Practice until you are comfortable using it.

Your grey colored Trainer:



- Never put your thumb, other fingers, or hand over the Orange Tip (below grey safety cap).
- The Orange Tip is where the needle comes out of your epinephrine injection 0.3 mg auto-injector or epinephrine injection 0.15 mg auto-injector.

Practice Instructions



1 Prepare the Trainer for Simulated Injection

- **Grasp the grey Trainer in your fist with the orange tip pointing downward** and twist off Grey Cap in the direction of “twist arrow”.
- With your other hand, **pull off blue safety release**.
- Removing the blue safety release unlocks the Trainer.

2 Administer the Trainer Simulation

- **If practicing with a young child, hold the leg firmly in place while using the Epinephrine Trainer.**

Ask your healthcare provider to show you how to properly hold the leg to practice so that you will be prepared before an allergic emergency happens.



- 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 trainer firmly** until it ‘clicks’. The click signals that the injection has started.
- **Hold firmly in place for 3 seconds (count slowly 1,2,3).**
- **Remove the Trainer from the thigh** and massage the injection area for 10 seconds. The orange tip automatically extends out after use.

Note:

- In an actual emergency, you would need to seek medical help right away
- The actual auto-injector is made to work through clothing
- Do not inject into any other part of the body

3 To reset the Trainer

- Put the blue safety release back on the Trainer
- Replace Grey Cap

NOTE: With the real yellow Epinephrine Injection 0.3 mg Auto-Injector or green Epinephrine Injection 0.15 mg Auto-Injector, the orange tip covers the needle after self-injection to help protect you from accidentally sticking yourself or others.

Practice Session Information

In case of an allergic emergency, use the real yellow Epinephrine Injection 0.3 mg Auto-Injector or green Epinephrine Injection 0.15 mg Auto-Injector and not the grey Trainer.

Follow instructions above. Repeat as often as needed until you are able to self-inject quickly and correctly.

Reread:

- These Trainer Instructions for Use
- The “Patient Information” that comes with your Epinephrine Injection 0.3 mg Auto-Injector or Epinephrine Injection 0.15 mg Auto-Injector




Train others who could help you in an emergency:

- Your parents, caregivers, and others who may be in a position to administer epinephrine injection 0.3 mg or epinephrine injection 0.15 mg should know how to help you during an allergic emergency (anaphylaxis). Before an emergency occurs, have them:
 - Practice activating the Trainer
 - Read these Trainer Instructions and the “Patient Information”

For more information about the Epinephrine Injection 0.3 mg Auto-Injector and Epinephrine Injection 0.15 mg Auto-Injector and the proper use of the products, go to www.TevaEpinephrine.com.

Caution:

Important differences between the Trainer and your real yellow Epinephrine Injection 0.3 mg (Auto-Injector) or green Epinephrine Injection 0.15 mg (Auto-Injector)

			
	TRAINER (Grey)	Epinephrine Injection 0.3 mg (Yellow)	Epinephrine Injection 0.15 mg (Green)
Contains medication?	NO	YES	YES
Has needle?	NO	YES	YES
Comes in Carrier Tube?	NO	NO	NO
Color of label	Grey	Yellow	Green
Has expiration date?	YES	YES	YES
Can be reused?	YES	NO (use only once)	NO (use only once)
Okay to remove and replace cap and/or safety release?	YES	NO (remove just once before use)	NO (remove just once before use)
Pressure needed to hold against thigh?	Moderate	Strong	Strong

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

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

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