HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use EPINEPHRINE INJECTION, 0.3 mg and EPINEPHRINE INJECTION, 0.15 mg safely and effectively. See full prescribing information for EPINEPHRINE INJECTION, 0.3 mg and EPINEPHRINE INJECTION, 0.15 mg.

PROFESSIONAL GUIDELINES: EPINEPHRINE INJECTION, 0.3 mg and EPINEPHRINE INJECTION, 0.15 mg contain epinephrine, a non-selective agonist and beta-adrenergic receptor agonist, indicated in the emergency treatment of anaphylactic reactions (type I) due to allergic mechanisms. Epinephrine is a potent vasoconstrictor and induces vomiting. (e.g., severe anaphylaxis, including anaphylactic shock (type I) due to allergic mechanisms, including anaphylactic shock (type I) due to allergic mechanisms), angioedema, anaphylactic shock, and therefore, does not lower this risk. (5.4)

ADMINISTRATION
Injection, 0.15 mg should only be administered under direct medical supervision.

5 WARNINGS AND PRECAUTIONS

8.1 Pregnancy
Do not inject intravenously.

8.4 Pediatric Use
Do not inject into digits, hands or feet.

8.5 Geriatric Use
FDA approved patient labeling.

Epinephrine Injection, 0.3 mg intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Each dose is a single-use injection. (2)

ADVERSE REACTIONS

ADVERSE REACTIONS

CONTRAINDICATIONS

• Beta-adrenergic blocking drugs: antagonize cardiostimulating effects of epinephrine. (7)

Antihistamines: potentiate effects of epinephrine. (7)

• Administer with caution in patients with heart disease; may aggravate angina pectoris or produce ventricular arrhythmias. (5.5)

• Do not inject into digits, hands or feet. (5.4)

DOSE FORMS AND STRENGTHS

EPINEPHRINE injection, 0.3 mg (Auto-Injector), pre-filled auto-injector (3)

Use in Specific Populations

• Do not inject intravenously, large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. Rapidly acting vasodilators can counteract the rapid rise in blood pressure caused by epinephrine. (5.3)

• Do not inject into digits, hands or feet. (5.4)

• Do not inject into buttock, injection into the buttock may cause intense local anesthetic action. (5.3)

• Do not inject immediately after a meal. (5.3)

• Do not inject into fatty tissue. (5.3)

• Do not inject intravenously. Large doses or accidental intravenous injection of epinephrine may be harmful. 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. (5.1)

• Do not inject immediately after a meal. (5.3)

• Do not inject into fatty tissue. (5.3)

• Do not inject intravenously. Large doses or accidental intravenous injection of epinephrine may be harmful. (5.3)

• Do not inject immediately after a meal. (5.3)

• Do not inject into fatty tissue. (5.3)

• Do not inject intravenously. Large doses or accidental intravenous injection of epinephrine may be harmful. In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care. (5.1)

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• Do not inject intravenously. Large doses or accidental intravenous injection of epinephrine may be harmful. (5.3)

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• Do not inject intravenously. Large doses or accidental intravenous injection of epinephrine may be harmful. In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care. (5.1)

• Do not inject immediately after a meal. (5.3)

• Do not inject into fatty tissue. (5.3)
Ergot alkaloids may also reverse the pressor effects of epinephrine, which are antagonized by beta-adrenergic blocking agents. See Warnings and Precautions (5.5) should be observed carefully for the development of gangrene or any other signs of peripheral vascular disease or those receiving certain drugs (see Warnings and Precautions (5.5)). See Warnings and Precautions (5.5) for the potential for epinephrine to impair fertility has not been evaluated. See Warnings and Precautions (5.3) for serious infections at the injection site. See Warnings and Precautions (5.5) for the development of angina in patients with coronary artery disease or those receiving certain drugs (see Warnings and Precautions (5.5)). See Warnings and Precautions (5.5) for the presence of a sulfite in this product should not prevent the use of epinephrine under the conditions ruled under subsection and chapter 17. Protect from light. Keep out of the reach of children.
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/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/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 will use this product should read this information on the back of this Patient Information Leaflet about the 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 and can happen within minutes, and can be caused by sting/ing and biting insects, allergies, 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)
• swelling of your face, lips, mouth, or tongue
• skin rash, redness, or swelling
• fast heartbeat
• weak pulse
• feeling very anxious
• confusion
• stomach pain
• loss of 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 who may be in a position to administer 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. If you do not use it right away, you may need more medical attention.
• Get emergency medical help right away. 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 you epinephrine injection 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 contain epinephrine hydrochloride. Each epinephrine injection, 0.3 mg (auto-injector) or epinephrine injection, 0.15 mg contains 1 dose of epinephrine for emergency use. Each device contains a single dose of epinephrine.
• 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 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 disposable prefilled automatic injection devises (auto-injectors) used to treat life-threatening, allergic emergencies including anaphylaxis in people who are at risk or have a history of serious allergic emergencies. Each device contains a single dose of epinephrine.
• 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 about 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.
Epinephrine Injection USP, 0.15 mg (Auto-Injector)

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

Inactive Ingredients:

• Only inject into the middle of the outer thigh (upper leg). Never inject into any other part of the body.
• Your auto-injector is designed to work through clothing.
• 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

Yellow Cap

Orange Tip

• 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

Green Cap

Orange Tip

• 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.

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 (open 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 auto-injector or 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

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

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 1-888-638-2872 or visit www.TevaEpinephrine.com

www.TevaEpinephrine.com
epinephrine injection, 0.15 mg go to www.TevaEpinephrine.com or call 1-888-838-2872.
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.

Your grey colored Trainer:

Grey Cap (do not remove until ready for use)

Orange Tip (do not remove until ready for use)

Blue Safety Release

• 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)

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

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.

Manufactured For:
Teva Pharmaceuticals USA, Inc.
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Iss. 6/2018