EpiPen Auto-Injector

Newly designed for ease of use to help you
Stay prepared and confident

One-step, flip-top carrying case
Designed for single-handed opening.

Ergonomically designed grip
Allows for a firm grip and improves ease of handling.

Brightly colored orange tip
Aids in quick identification of needle end to reduce risk of accidental thumb puncture.

Blue safety-release cap
Designed to prevent unintentional activation.

Easy-to-read, illustrated instructions
Allows for rapid recognition of product usage instructions.

Built-in needle protection
The only epinephrine auto-injector that protects against needle exposure before and after use.

The #1 prescribed epinephrine auto-injector* offers the performance you can count on in an anaphylactic emergency.

Please see reverse side for Important Safety Information.
EpiPen 2-Pak Auto-Injector

Enhanced usability for emergency treatment†

If you or someone you are caring for shows signs of a severe allergic reaction, follow these steps:

1. After removing the EpiPen Auto-Injector from the plastic carrying case, pull off the blue safety-release cap. This must be done in order to unlock the EpiPen Auto-Injector.
2. Hold the orange tip near the outer thigh (always apply to thigh). Position the EpiPen Auto-Injector at a 90° angle.
3. Swing and firmly push the orange tip against the outer thigh until a click or popping sound is heard. Hold tightly pressed in place for 10 seconds. Remove the EpiPen Auto-Injector and massage the area for 10 more seconds.

Once the EpiPen Auto-Injector has been used, call 911 and get to the nearest emergency room as soon as possible. Take the used EpiPen Auto-Injector along with you to the hospital.

Indications
EpiPen and EpiPen Jr Auto-Injectors (0.3 and 0.15 mg epinephrine) are for the emergency treatment of severe allergic reactions (anaphylaxis) caused by allergens, exercise, or unknown triggers; and for patients who are at increased risk for these reactions. EpiPen and EpiPen Jr Auto-Injectors are designed for you to use immediately in an emergency, to treat an allergic reaction fast and give you time to get to a hospital or medical center. EpiPen and EpiPen Jr Auto-Injectors are not a substitute for emergency medical treatment.

Important Safety Information
Each EpiPen Auto-Injector contains a single dose of a medicine called epinephrine, which you inject into your outer thigh. DO NOT INJECT INTRAVENOUSLY. DO NOT INJECT INTO YOUR BUTTOCK, as this may not be effective for a severe allergic reaction. In case of accidental injection, please seek immediate medical treatment.

Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

Side effects may include an increase in heart rate, a stronger or irregular heartbeat, sweating, nausea and vomiting, difficulty breathing, paleness, dizziness, weakness or shakiness, headache, apprehension, nervousness, or anxiety. These side effects usually go away quickly, especially if you rest. If you have high blood pressure or an overactive thyroid, these side effects may be more severe or longer lasting. If you have heart disease, you could experience chest pain (angina). If you have diabetes, your blood sugar levels may increase after use. If you have Parkinson’s disease, your symptoms may temporarily get worse.

†The EpiPen Auto-Injector does not replace the need for emergency medical care.

Please see accompanying Patient Insert.
PATIENT INSERT

EpiPen® or EpiPen® Jr Auto-Injector right away and immediately go to your doctor or emergency room for more medical treatment.

It is important not to be afraid to use the EpiPen® or EpiPen® Jr Auto-Injector for emergency treatment of allergic reactions (anaphylaxis). For most people, injection of the EpiPen® or EpiPen® Jr Auto-Injector in the thigh does not hurt, and use of the EpiPen® or EpiPen® Jr Auto-Injector early at the start of such allergic reactions is important to help prevent the allergic reaction from becoming worse.

Inject EpiPen® or EpiPen® Jr Auto-Injector into the middle of the outer side of the thigh (upper leg).

Epinephrine, the active ingredient in EpiPen® and EpiPen® Jr Auto-Injectors is used to treat life-threatening allergic reactions (anaphylaxis). You should use this medication only if your doctor has prescribed it for allergic emergencies. Such emergencies may occur from insect stings or bites, foods, drugs, latex, other allergens, exercise induced anaphylaxis, or unknown causes.

Make sure to tell your doctor about all your medical conditions and allergies.

Always get medical treatment immediately after using EpiPen® or EpiPen® Jr Auto-Injector.

Since you cannot predict when a life-threatening allergic reaction may occur, carry the EpiPen® or EpiPen® Jr Auto-Injector with you at all times.

What is EpiPen® or EpiPen® Jr Auto-Injector?

The EpiPen® and EpiPen® Jr Auto-Injectors are products used for the emergency injection of epinephrine. Epinephrine is a medicine used for life-threatening allergic reactions such as severe swelling, breathing problems, or loss of blood pressure. Allergic reactions can be caused by stinging and biting insects, allergies, insect poisons, foods, medicines, exercise, or unknown causes.

Life-threatening allergic reactions may show up as closing of your breathing airways, wheezing, sneezing, hoarseness, hives, itching, swelling, skin rashness, fast heartbeat, weak pulse, feeling very anxious, confusion, stomach pain, loss of control of urine or bowel movements (incontinence), faintness, or “passing out” (unconsciousness).

The EpiPen® Auto-Injector (0.3 mg) is generally intended for patients who weigh 66 pounds or more (30 kilograms or more).

The EpiPen® Jr Auto-Injector (0.15 mg) is generally intended for patients weighing approximately 33 to 66 pounds (15 to 30 kilograms).

Who should not use EpiPen® or EpiPen® Jr Auto-Injector?

There are no absolute contraindications to the use of EpiPen® or EpiPen® Jr Auto-Injector in a life-threatening allergic reaction. People with certain medical conditions have a higher chance of having serious side effects from EpiPen® or EpiPen® Jr Auto-Injector.

Tell your doctor and pharmacist about all your medical conditions, but especially if you:

- Have heart disease or high blood pressure
- Have diabetes
- Have thyroid conditions
- Are pregnant

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Inform your doctor of all known allergies. Some medicines may cause serious side effects if taken while you use EpiPen® or EpiPen® Jr Auto-Injector. Some medicines may affect how EpiPen® or EpiPen® Jr Auto-Injector works.

Importantly, EpiPen® or EpiPen® Jr Auto-Injector may affect how your other medicines work.

What should I avoid while using EpiPen® or EpiPen® Jr Auto-Injector?

Never put thumbs, fingers or hand over orange tip. Never press or push orange tip with thumbs, fingers or hand. The needle comes out of orange tip. Accidental injection into finger, hands or feet may result in loss of blood flow to these areas. If this happens, go immediately to the nearest emergency room.

Do not inject EpiPen® or EpiPen® Jr Auto-Injector into the buttock or any other part of the body, other than the middle of the outer side of your thigh (upper leg).

Do not drop carrier tube or auto-injector. If carrier tube or auto-injector is dropped, inspect for damage and leakage. Discard auto-injector and carrier tube, and replace if damage or leakage is noticed or suspected.

What are the possible side effects of EpiPen® or EpiPen® Jr Auto-Injector?

Too much epinephrine can cause dangerous high blood pressure or stroke.

If you take certain medicines, you may develop serious life-threatening side effects from the epinephrine in EpiPen® or EpiPen® Jr Auto-Injector. Be sure to tell your doctor all the medicines you take, especially medicines for asthma.

Patients with certain medical conditions, or who take certain medicines for asthma, allergies, depression, low thyroid, high blood pressure, and heart disease. Patients with heart disease may feel chest pain (angina).

EpiPen® or EpiPen® Jr Auto-Injector (epinephrine) can cause the following reactions. Some reactions can be serious. They usually go away with rest. Please notify your doctor if you experience any of these:

Common side effects of EpiPen® or EpiPen® Jr Auto-Injector include:

- Faster, irregular (wrong) or “bounding” heartbeat
- Sweating
- Nausea and vomiting
- Breathing problems
- Paleness
- Dizziness
- Weakness or shakiness
- Headache
- Feelings of over excitement, nervousness or anxiety

Those are not the only possible side effects of EpiPen® or EpiPen® Jr Auto-Injector. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088.

How should I store EpiPen® or EpiPen® Jr Auto-Injector?

Keep the EpiPen® and EpiPen® Jr Auto-Injector nearly and ready for use at all times.

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) (See USP Controlled Room Temperature). Contains no latex. Protect from light.

Do NOT store in refrigerator.

Do NOT expose to extreme cold or heat. For example, do NOT store in your vehicle’s glove box.

Examine contents in clear window of auto-injector periodically. If the solution is discolored or contains solid particles (precipitate), replace the unit. Solution should be clear.

Always keep your EpiPen® or EpiPen® Jr Auto-Injector in the carrier tube with the blue safety release on until you need to use it.

Your auto-injector has an expiration date

Example: DG 08 (8 December 2008)

Replace it before the expiration date.

See OTHER SIDE FOR "DIRECTIONS FOR USE" AND FOR EPIPen® CENTER FOR ANAPHYLACTIC SUPPORT™ FREE ENROLLMENT FORM.

PATIENT INSERT

Pharmacist - Please Dispense this Leaflet with Product

IMPORTANT INFORMATION

The patient and caregiver should read this information carefully before using EpiPen® or EpiPen® Jr Auto-Injector. Please be prepared: Read the entire insert before an emergency occurs! EpiPen® and EpiPen® Jr Auto-Injectors are disposable, prefilled automatic injector devices for use during allergic emergencies. They contain a single dose of epinephrine which you inject into your outer thigh. EpiPen® and EpiPen® Jr Auto-Injectors contain no latex. The EpiPen® and EpiPen® Jr Auto-Injectors are intended for people who have been prescribed this medication by their physician.

It’s important that you have this emergency medicine with you at all times. If you need additional units to keep at work, school, etc., please talk to your doctor. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about EpiPen® or EpiPen® Jr Auto-Injector?

When you have allergic reaction (anaphylaxis) use the
DIRECTIONS FOR USE

TO REMOVE AUTO-INJECTOR FROM CARRIER TUBE BEFORE USE.

• REMOVE AUTO-INJECTOR FROM CARRIER TUBE BEFORE USE.
• NEVER PUT THUMB, FINGERS OR HAND OVER ORANGE TIP.
• NEVER PRESS OR PUSH ORANGE TIP WITH THUMB, FINGERS OR HAND.
• THE NEEDLE COMES OUT OF ORANGE TIP.
• DO NOT REMOVE BLUE SAFETY RELEASE UNTIL READY TO USE.
• DO NOT USE IF SOLUTION IS DISCOLORS.
• DO NOT PLACE PATIENT INSERT OR ANY OTHER FOREIGN OBJECTS IN CARRIER WITH AUTO-INJECTOR, AS THIS MAY PREVENT YOU FROM REMOVING THE AUTO-INJECTOR FOR USE.

TO USE AUTO-INJECTOR:

1. Grasp unit with the orange tip pointing downward.
2. Form fist around the unit (orange tip down).
3. With your other hand, pull off the blue safety release.
4. Hold orange tip near outer thigh.
5. Swing and firmly push against outer thigh until it clicks so that unit is perpendicular (at 90° angle) to the thigh.
6. Hold firmly against thigh for approximately 10 seconds to deliver drug. (The injection is now complete. The window on auto-injector will be obscured.)
7. Remove unit from thigh (the orange needle cover will extend to cover needle) and massage injection area for 10 seconds.
8. Call 911 and seek immediate medical attention.
9. Take the used auto-injector with you to the hospital emergency room.

Note: Most of the liquid (about 85%) stays in the auto-injector and cannot be reused. However, you have received the correct dose of the medication if the orange needle tip is extended and the window is obscured. Too much medication is not harmful. Have the label checked by a pharmacist. Blue background labeled trainer contains no needle and no drug.

WARNING!

• NEVER put thumb, fingers or hand over orange tip. NEVER press or push orange tip with thumb, fingers or hand. The needle comes out of orange tip. Accidental injection into hands or feet may result in loss of blood flow to these areas. If this happens, go immediately to the nearest emergency room.
• EpiPen® and EpiPen Jr Auto-injector should be injected only into the outer thigh size "Directions for Use" DO NOT INJECT INTO BUTTOCK.
• Do NOT remove blue safety release until ready to use.

IMMEDIATELY AFTER USE

• Go immediately to the nearest hospital emergency room or call 911. You may need further medical attention.
• Take your used auto-injector with you.
• Tell the doctor that you have received an injection of epinephrine in your thigh.
• Give your used EpiPen®/EpiPen Jr Auto-injector to the doctor for inspection and proper disposal.

To dispose of expired units

• Expired auto-injectors must be disposed of properly.
• To dispose of an expired auto-injector and carrier tube, take them to your doctor’s office or to a hospital for proper disposal.
• Used auto-injector with extended needle cover will not fit in carrier tube.

Join the Free EpiPen® Center for Anaphylaxis Support™ Today!

Because it’s important that you always have an up-to-date EpiPen® and EpiPen Jr Auto-Injector with you at all times, we started an expiration reminder program as part of the EpiPen® Center for Anaphylaxis Support™. Every time you purchase a new EpiPen® Auto-Injector, be sure to register it with us, so we’ll send you reminders so you can have an up-to-date EpiPen® Auto-Injector. This important program is a FREE service!

Join the Center for Anaphylaxis Support at www.epiPen.com

OR

Please fill in the information at right.

To ensure accuracy, please PRINT neatly in uppercase letters in dark or black-blue ink.

Mail to:

EpiPen® Center for Anaphylaxis Support™
DEY
P.O. Box 2000
Napa, CA 94559-9956

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Proof A

Product Information

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Size: 9.575X1.0
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RGR: NA

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Date: 03/6/09

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