

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**EpiPen / EpiPen Jr
Auto-Injector**

Active ingredients

EpiPen contains one dose of 0.3 mg epinephrine (0.3 mL) in a sterile solution (epinephrine 0.3 mg/0.3 mL)

EpiPen Jr: contains one dose of 0.15 mg epinephrine (0.3 mL) in a sterile solution (epinephrine 0.15 mg/0.3 mL)

Inactive ingredients and allergens: See section 6 'Additional information'.

Read the entire patient leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Read this leaflet carefully each time you purchase a new auto-injector. The leaflet may have new information. Make sure that you, your parents or caregiver understand the indications and the right way of using the auto-injector before a severe allergic reaction occurs – anaphylaxis.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

EpiPen and EpiPen Jr are indicated in the emergency treatment of severe allergic reactions (Type 1), including anaphylaxis to stinging insects (e.g., order Hymenoptera, which includes, bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, food, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as anaphylaxis due to an unknown cause (idiopathic) or exercise-induced anaphylaxis.

EpiPen and EpiPen Jr are intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

EpiPen and EpiPen Jr are intended for immediate administration as emergency supportive therapy only and are not a substitute for immediate medical care.

Therapeutic group: Epinephrine belongs to substances that act via adrenergic and dopaminergic receptors.

Anaphylactic shock can be life threatening and can happen within minutes. The symptoms that may develop during an anaphylactic reaction include:

Trouble breathing

Wheezing

Hoarseness (your voice sounds different)

Hives (raised reddened rash that may itch)

Severe itching

Swelling of your face, lips, mouth or throat

Skin rash, redness, or swelling

Palpitations

Weak pulse
Feeling very anxious
Confusion
Stomach pain
Losing control of urine or bowel movements
Diarrhea or stomach cramps
Dizziness, fainting

2. Before using this medicine

Take the EpiPen / EpiPen Jr auto-injector everywhere because you do not know when an anaphylactic episode will happen.

Talk to your doctor if you need additional packages to keep at work, school or other locations. Tell your family, your caregiver and others where your auto-injector is stored and how to use it. In the event of an anaphylactic episode, you may be unable to talk.

To prevent your condition from getting worse, if you were exposed to one of the factors described in the indication, or if you have signs and/or symptoms:

- **Use EpiPen or EpiPen Jr immediately upon onset of a severe allergic reaction.**
- **Immediately go to the closest hospital or the closest clinic for further treatment.**
Immediate injection is not a substitute for medical treatment, rather, only serves as first aid until you reach the doctor or closest hospital for further treatment. You may need to use a second EpiPen or EpiPen Jr if symptoms continue or recur. Only a doctor can give additional doses of epinephrine if you need more doses for a single episode.
- **If necessary, inject through your clothing.**

In life-threatening situations, there are no contraindications for EpiPen and EpiPen Jr.
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Special warnings about using this medicine

Tell the doctor before using EpiPen / EpiPen Jr about your medical condition, especially if:

- You have heart problems or high blood pressure
- You have diabetes
- You have thyroid problems
- You have asthma
- You have a history of depression
- You have Parkinson's disease
- You have any allergy
- You are elderly

Children and adolescents

It is not known if EpiPen and EpiPen Jr are safe and effective in children who weigh less than 15 kilograms.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Asthma therapy.

- Tricyclic medicines and monoamine oxidase inhibitors for depression, levothyroxine. The effect of epinephrine may increase when taken together.
- Certain antihistamines (antiallergics), particularly chlorpheniramine, triprolidine, diphenhydramine. The effect of epinephrine may increase when taken together.
- Adrenergic beta blockers such as propranolol, epinephrine's effects on the heart and dilation of the bronchi are reduced when taken together.
- Adrenergic alpha blockers, epinephrine's effects on constriction of the blood vessels and hypertension are reduced when taken together.
- Ergot derivatives for treatment of migraines. Taking them together may impair the effect of the epinephrine.
- Cardiac glycosides such as digitalis, quinidine, diuretics or medicines to control heart rhythm. Taking them together may lead to arrhythmias. These patients should be closely monitored.

During an anaphylactic episode, use EpiPen/EpiPen Jr for treatment as prescribed by your doctor, regardless of your medical condition or the medicines you are taking.

Pregnancy and breastfeeding

Use EpiPen during pregnancy and breastfeeding according to the same considerations - treatment of choice in case of anaphylactic shock.

If you are pregnant or are planning a pregnancy, consult the doctor about what to do in case of need. It is not known if epinephrine will harm your unborn baby.

If you are breastfeeding, or planning to breastfeed, consult your doctor before using epinephrine. It is not known if epinephrine passes into your breast milk.

3. How to use this medicine?

EpiPen / EpiPen Jr are disposable, pre-filled auto-injectors for immediate self-injection into the muscle.

EpiPen / EpiPen Jr is **intended for immediate** self-administration or given by family/a caregiver.

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

You should understand why the medicine has been prescribed for you and be sure that you understand how and when to use it. It is recommended that a family member/caregiver/teacher also be trained on how to use the medicine.

If you are stung by an insect, try to remove the stinger with your fingers. Make sure not to press, pinch or push the stinger into the skin. If possible, place ice on the area which was stung. Maintain your body temperature, and avoid physical activity.

For an allergic reaction caused by food, make sure to take all remnants out of the mouth immediately.

Only your doctor will determine your dose and how you should take this medicine. The recommended dosage unless otherwise instructed by the doctor:

One EpiPen injection provides one dose of 0.3 mg (0.3 mL) epinephrine, which is appropriate for patients who weigh 30 kilograms or more.

One EpiPen Jr injection provides one dose of 0.15 mg (0.3 mL) epinephrine, which is appropriate for children who weigh 15-30 kilograms.

Do not exceed the recommended dose unless the symptoms of anaphylactic shock continue or recur. In this case, you may need to use an additional auto-injector.

Sometimes, one injection is not sufficient to relieve you of the anaphylactic episode symptoms. For this reason, the doctor may give you a prescription for more than one auto-injector. If the symptoms have not improved, or if they worsen within 5-15 minutes of the first injection, you, or someone who is with you, must inject the second injection.

For this reason, you must always carry more than one auto-injector with you.

If you need more than two auto-injectors in a single anaphylactic episode, only your doctor will decide whether additional epinephrine doses are essential.

Note:

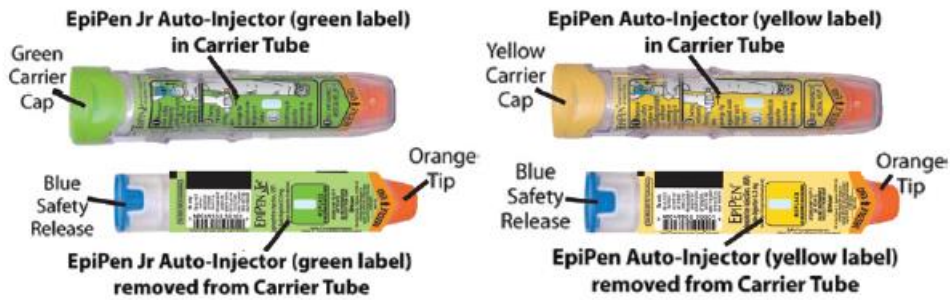
- EpiPen / EpiPen Jr are intended for injection into the middle of your outer thigh only.
- **Do not inject** into a vein or into the buttocks, fingers, toes, hands or feet.
- **If you accidentally injected into another place in the body, go immediately to the nearest emergency room. Show the doctor where you accidentally injected the injection.**
- It is not known if EpiPen / EpiPen Jr are safe and effective in children who weigh less than 15 kilograms.
- Each auto-injector contains one dose of epinephrine.
- EpiPen / EpiPen Jr are intended for immediate self-injection (by yourself or a caregiver/family member).

In case of an anaphylactic episode

- Use the auto-injector immediately. It can be used through clothing.
- Get emergency medical attention. You may need additional monitoring.

Instructions for maintaining the auto-injector

- Familiarize yourself with the parts of the auto-injector (see enclosed figure).
- Keep the auto-injector ready for use and accessible at all times.
- Do not disassemble the auto-injector.
- Avoid exposure to light and extreme heat (see section 5 'Storage instructions').
- Do not remove the blue safety release until you are ready to use it.
- You should periodically examine the solution's color in the window. Do not use an auto-injector whose solution is discolored or contains a sediment.



Injection instructions

Injection of the medicine involves three stages: preparing the auto-injector, injection and getting medical help

Step 1: Taking the auto-injector out of the plastic carrier tube

1. Open the yellow cap of the plastic EpiPen carrier tube or the green cap of the plastic EpiPen Jr carrier tube (Figure no. 1).
2. Take out the auto-injector by tipping and sliding it out of the plastic carrier tube (Figure no. 2).
3. Grasp the auto-injector in the palm of your hand (form a fist around the auto-injector), with the orange tip pointing downward. With your other hand, remove the blue safety release by pulling straight up, without bending or twisting it. (Figure no. 3).



Note:

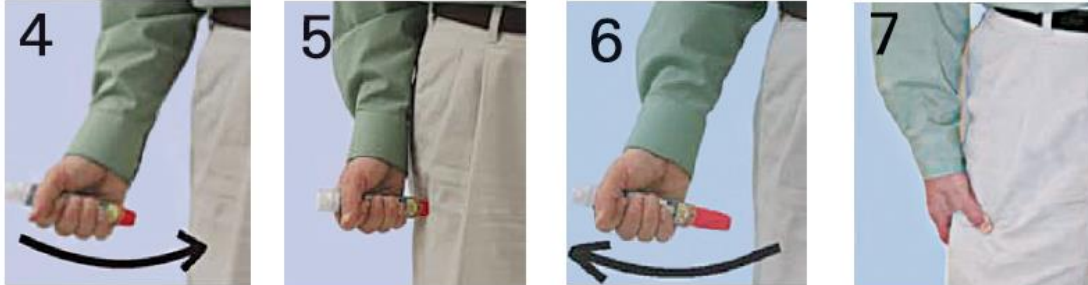
- The needle comes out of the orange tip.
- To avoid accidental injection, do not put your fingers or hand over the orange tip. **If you accidentally inject yourself, go to a hospital for help right away.**

Step 2: Injection

If you are injecting a young child, hold the leg firmly, so that the leg will not move, to avoid injuries while administering an injection.

1. Place the orange tip of the auto-injector against the middle of the outer thigh at a right angle (perpendicular to the thigh)
2. Swing and push the auto-injector firmly against the outer thigh until you hear a “click”; the “click” signals that the injection has started. (Figure no. 4)

3. Hold the auto-injector firmly against the thigh for 3 seconds (count slowly 1, 2, 3); the injection is complete. (Figure no. 5)
4. Remove the auto-injector from the thigh. The orange tip will extend and cover the needle. If the needle is still exposed, do not attempt to reuse the auto-injector. (Figure no. 6)
5. Massage the injection area for 10 seconds (Figure no. 7)



Step 3: Proceed immediately to the nearest hospital

- You may require further medical treatment. You may need to use a second auto-injector if the symptoms continue or recur.
- Take your used auto-injector(s) to the hospital, and tell the doctor that you have received an injection of epinephrine in the thigh. Show the doctor the injection site.
- Give your used auto-injector to the doctor for inspection and proper disposal.

Note:

- The used auto-injector with the needle cover is longer after use and will not fit in the plastic carrier tube.
- The auto-injector releases a metered dose of epinephrine and it cannot be reused. Do not attempt to reuse an auto-injector that has been used.
- Most of the injection liquid remains in the auto-injector and cannot be reused. However, the injection provides you with the required dose if the orange tip is extended and covers the needle and the window is blocked.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using this medicine may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Cardiovascular side effects

- Arrhythmias (fast, irregular or pounding heartbeat), including atrial fibrillation that causes death, particularly in patients with basic heart disease or those receiving certain medicines.
- Rapid increases in blood pressure led to intracerebral hemorrhage, particularly in elderly patients with cardiovascular disease.
- Angina may occur in patients with coronary artery disease.
- A heart muscle disease due to severe psychological stress (“broken heart syndrome”) in patients who have been treated with epinephrine (rare).

Side effects due to accidental injection or improper injection technique

- Accidental injection into the fingers, hands or feet may cause a loss of blood flow to the affected area.
- Negative reactions that appear due to accidental injection may increase an increase in heart rate, local reactions that include pallor, feeling cold and reduced sensitivity at the injection site, or injury at the injection site leading to bruising, bleeding, discoloration of the skin, redness or skeletal injury.
- Injection into the buttocks has caused cases of gas gangrene.
- Cuts on the skin, bent needles, and needles that remain in the skin after the injection have happened in children who did not cooperate, kicked or moved during the injection.

Infections of the skin and soft tissues

Rarely, patients who have used EpiPen / EpiPen Jr have developed infections at the injection site within a few days of an injection. Some of these infections can be serious.

Call your doctor right away if you develop any of the following at an injection site:

- Redness that does not disappear
- Swelling
- Tenderness
- The area feels warm to the touch

Common side effects (affect more than 1-10 in 100 users)

Sweating

Headache

Weakness

Shakiness

Paleness

Overexcitement, nervousness or anxiety, agitation

Dizziness

Nausea or vomiting

Breathing problems

The side effects may go away with rest.

If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>.

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package and label. The expiry date refers to the last day of that month.

Storage conditions

- To protect the auto-injector, always store it in the plastic carrier tube. Note that the carrier tube is not waterproof.
- Store EpiPen / EpiPen Jr at a temperature below 25°C.
- Protect from light.
- Do not store in the refrigerator.
- Examine the color of the solution in the clear window of your auto-injector periodically. The solution should be clear. If the solution is discolored (pink or brown) or contains sediment, do not use the auto-injector. Replace it.
- The safety release of the auto-injector prevents accidental injection; do not take it off unless you are about to use it.

6. Additional information

In addition to the active ingredients, this medicine also contains:

sodium chloride, sodium metabisulfite, hydrochloric acid to adjust pH, water for injection.

What the medicine looks like and contents of the pack:

EpiPen / EpiPen Jr are automatic injectors for self-injection. Each auto injector is in a plastic carrier tube.

EpiPen: An auto-injector with a yellow label, stored in a plastic carrier tube and in a single package. In addition, there is a double package that contains two auto-injectors, each in a plastic carrier tube, with a clasp that connects the two auto-injectors, and in addition, contains a grey training auto-injector.

EpiPen Jr: An auto-injector with a green label, stored in a plastic carrier tube and in a single package. In addition, there is a double package that contains two auto-injectors, each in a plastic carrier tube, with a clasp that connects the two auto-injectors, and in addition, contains a gray training auto-injector.

Not all pack sizes may be marketed.

Registration holder's name and address: Trupharm Marketing 1985 Ltd., P.O.B. 8105,
Netanya

Manufacturer's name and address:

Manufactured for Mylan Specialty L.P., Morgantown, WV 26505, U.S.A. by Meridian Medical Technologies, Inc., Columbia, MD 21046, U.S.A

Revised in November 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

EpiPen: 0193724854, EpiPen Jr: 0193824853

PL-1002 06-07.22