

Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Epinephrine Injection Mylan 0.3 mg
Epinephrine Injection Mylan Jr 0.15 mg
Solution for injection in an auto-injector

Active ingredient

Epinephrine Injection Mylan 0.3 mg contains one dose of epinephrine 0.3 mg/0.3 ml (1 mg/ml) in a sterile solution.

Epinephrine Injection Mylan Jr 0.15 mg contains one dose of epinephrine 0.15 mg/0.3 ml (0.5 mg/ml) in a sterile solution.

Inactive ingredients and allergens in the medicine: see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. Anyone who may give you the medicine should know how to use it before you have an acute allergic reaction (anaphylaxis).

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

1. What is the medicine intended for?

Epinephrine Injection Mylan 0.3 mg / Epinephrine Injection Mylan Jr 0.15 mg are intended for emergency treatment of severe allergic reactions (type 1), including anaphylaxis to stinging insects (e.g., the order Hymenoptera, including bees, wasps, oriental hornets, yellow jackets and fire ants) and to biting insects (e.g., triatoma, mosquitoes), to allergen immunotherapy, food, medicines, diagnostic testing substances (e.g., contrast agents in radiography tests) and other allergens, as well as for treatment of anaphylaxis due to an unknown cause (idiopathic) or exercise-induced anaphylaxis.

Epinephrine Injection Mylan 0.3 mg / Epinephrine Injection Mylan Jr 0.15 mg are for immediate administration in patients who have been determined to be at increased risk of anaphylaxis, including people with a history of anaphylactic reactions.

Epinephrine Injection Mylan 0.3 mg / Epinephrine Injection Mylan Jr 0.15 mg are for immediate administration as emergency supportive treatment only and are not a substitute for immediate medical treatment.

Therapeutic group: epinephrine belongs to substances that work via adrenergic and dopaminergic receptors.

Anaphylaxis may occur within minutes and can be life-threatening. If not treated, anaphylaxis can lead to death. Symptoms of anaphylaxis can include:

- Difficulty breathing
- wheezing
- hoarseness (the voice sounds different)
- hives (red raised rash that may itch)
- severe itching
- swelling of the face, lips, mouth or throat
- skin rash, redness or swelling
- fast heartbeat
- weak heartbeat
- feeling of acute anxiety

- confusion
- abdominal pain
- loss of control of urination or bowel movements
- diarrhea or abdominal cramps
- dizziness, fainting or loss of consciousness.

2. Before using the medicine

Always carry 2 epinephrine injectors with you, because sometimes one dose of epinephrine is not enough to treat a severe allergic reaction, before seeking medical assistance. You should also always carry 2 epinephrine injectors with you in case the first auto-injector is activated before administering the dose. An injector that has been accidentally activated cannot be used in an allergic emergency (anaphylaxis).

You may not know when an anaphylactic event may occur. Talk to the doctor if you need additional packages to keep at work, school or other locations. If you have used one injector to treat a severe allergic reaction, replace it so that you always carry 2 epinephrine injectors with you.

Tell your family, your caregiver and others where the injectors are stored. Make sure that they know how to use the injector before you need it. In case of an anaphylactic event, you may be in a condition in which you are unable to speak.

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

- **Use Epinephrine Injection Mylan immediately upon onset of a severe allergic reaction (anaphylaxis).**
- **Immediately seek emergency medical treatment, even if you have used an epinephrine injector.**

You can use a second **Epinephrine Injection Mylan** if the symptoms persist or recur, or if the first auto-injector was activated before administering the dose. For this reason, you should carry 2 injectors with you at all times. If you need more than 2 doses for the same allergy episode, only a doctor can administer additional doses of epinephrine.

- **If necessary, inject through clothing.**

In life-threatening situations, there are no contraindications for the use of **Epinephrine Injection Mylan**.

Special warnings regarding the use of the medicine

Before using Epinephrine Injection Mylan, inform the doctor about your medical condition. The doctor may give you additional instructions on when and how to use the medicine if you have:

- **Heart problems or high blood pressure**
- **Diabetes**
- **Thyroid problems**
- **Asthma**
- **A history of depression**
- **Parkinson's disease**
- **If you are elderly**

Children and adolescents

It is not known whether **Epinephrine Injection Mylan 0.3 mg / Epinephrine Injection Mylan Jr 0.15 mg** are safe and effective in children who weigh less than 15 kg.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Asthma treatment
- Tricyclic medicines and monoamine oxidase inhibitors for depression, levothyroxine. The effect of epinephrine may increase when taken at the same time.
- Certain antihistamines (for allergy), particularly chlorpheniramine, tripelemamine, diphenhydramine. The effect of epinephrine may increase when taken at the same time.
- Adrenergic beta blockers, such as propranolol, the effects of epinephrine on cardiac stimulation and bronchodilation are suppressed when taken at the same time.
- Adrenergic alpha blockers, such as phentolamine, the effects of epinephrine on blood vessel constriction and hypertension are suppressed when taken at the same time.
- Ergot derivatives for treatment of migraine, taking them at the same time may compromise the effect of epinephrine.
- Cardiac glycosides such as digitalis, diuretics or medicines to regulate the heart rhythm, taking them at the same time may cause arrhythmias. These patients should be closely monitored.

During an anaphylactic event, use Epinephrine Injection Mylan for treatment as prescribed by the doctor, regardless of your medical condition or the medicines you are using.

Pregnancy and breastfeeding

Use **Epinephrine Injection Mylan 0.3 mg** during pregnancy and breastfeeding according to the same considerations – the treatment of choice in case of an anaphylactic shock.

If you are pregnant or planning a pregnancy, consult the doctor about what you should do in case of need. It is not known whether epinephrine is harmful to the fetus.

If you are breastfeeding or planning to breastfeed, consult the doctor before using epinephrine. It is unknown whether epinephrine passes into breastmilk.

Important information about some of the ingredients of the medicine

This medicine contains sodium metabisulfite, which in rare cases may cause severe hypersensitivity reactions and bronchospasm.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say, it is essentially "sodium-free".

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

Epinephrine Injection Mylan 0.3 mg / Epinephrine Injection Mylan Jr 0.15 mg are single-use auto-injectors, ready for immediate self injection into the muscle. Epinephrine Injection Mylan 0.3 mg / Epinephrine Injection Mylan Jr 0.15 mg are intended for immediate self use or immediate use by family/caregiver.

You should understand the reason why you have been prescribed the medicine, 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 that was stung. Maintain your body temperature and avoid physical activity.

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

The dosage and manner of treatment will be determined by the doctor only, standard dosage when no other instruction from the doctor is given:

One injection of **Epinephrine Injection Mylan 0.3 mg** provides a dose of 0.3 mg epinephrine (0.3 ml), which is suitable for patients who weigh 30 kg and more.

One injection of **Epinephrine Injection Mylan Jr 0.15 mg** provides a dose of 0.15 mg epinephrine (0.3 ml), which is suitable for children who weigh 15-30 kg.

Do not exceed the recommended dose unless the anaphylactic shock symptoms persist or recur. In this case, you may need to use an additional injector. Sometimes, one injection is not sufficient to relieve you of the symptoms of the anaphylactic event. For this reason, the doctor may give you a prescription for more than one injector. If the symptoms have not improved or if they worsen within 5-15 minutes after the first injection, you, or someone who is with you, should administer a second injection. For this reason, you should carry more than one injector with you at all times.

If you need more than two injectors in a single anaphylactic event, only the doctor will decide whether additional epinephrine doses are essential.

Note:

- **Epinephrine Injection Mylan 0.3 mg / Epinephrine Injection Mylan Jr 0.15 mg** are intended for injection into the middle of the outer thigh only.
- **Do not inject** into a vein or into the buttocks, fingers, toes, hands or feet.
- **If you accidentally inject into another area of the body, go immediately to the nearest emergency room. Show the doctor where in the body you have accidentally injected the injection.**
- It is not known whether **Epinephrine Injection Mylan 0.3 mg / Epinephrine Injection Mylan Jr 0.15 mg** are safe and effective in children who weigh less than 15 kg.
- Each injector contains one dose of epinephrine.
- **Epinephrine Injection Mylan 0.3 mg / Epinephrine Injection Mylan Jr 0.15 mg** are intended for immediate self injection (alone or by a caregiver/family member).

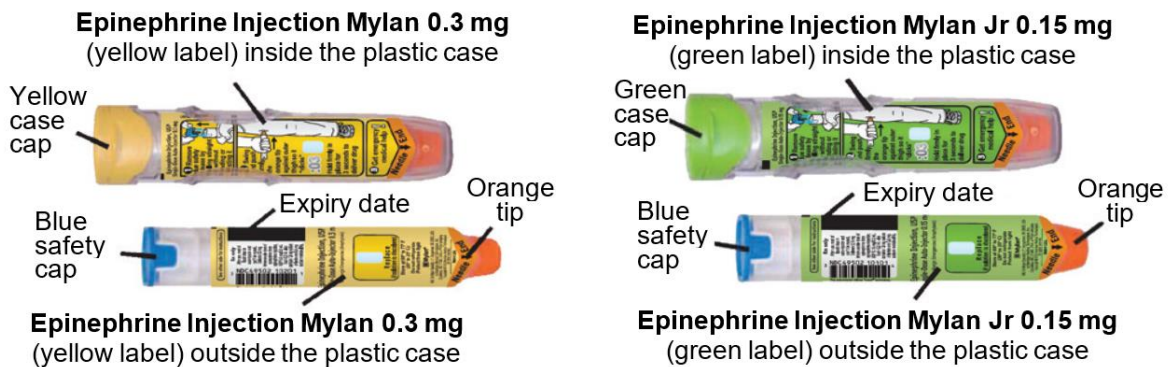
In case of an anaphylactic event

- Use the injector immediately. The injector can also be used through clothing.

- Seek emergency medical treatment immediately. You may need further medical supervision.

Instructions for maintaining the injector

- Familiarize yourself with the parts of the injector (see the illustration included).
- Keep the injector ready for use and accessible at all times.
- Do not disassemble the parts of the injector.
- Avoid exposure to light and high heat (see in section 5 “Storage conditions”).
- Do not remove the blue safety cap, except before use.
- You should periodically examine the solution’s color in the window. Do not use an injector whose solution is discolored or has developed a precipitate.

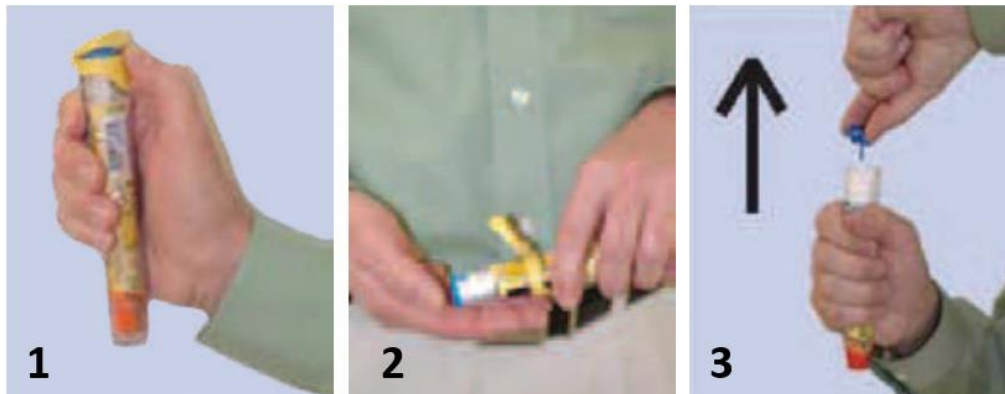


Injection instructions

Injecting the preparation requires three steps: preparing the injector, injecting, seeking medical assistance.

Step 1: taking the injector out of the plastic case

1. Open the yellow cap of the plastic case of **Epinephrine Injection Mylan 0.3 mg** or the green cap of the plastic case of **Epinephrine Injection Mylan Jr 0.15 mg**. (Figure 1)
2. Take the injector out by tilting and sliding the injector out of the plastic case. (Figure 2)
3. Hold the injector in your hand (the hand should be wrapped around the injector like a fist) with the orange tip facing downwards. With your other hand, pull the blue safety cap straight up and release it without bending or twisting it. (Figure 3)



Note:

- Do not remove the blue safety cap using your thumb or by pulling it to the sides. Do not bend or twist the blue safety cap. If the blue safety cap is not removed properly (straight up), accidental activation may occur. An injector that has been accidentally activated cannot be used in an emergency. If this happens, replace it with a new injector.
- The needle comes out of the orange tip.
- Do not place your fingers or hand above the orange tip, to prevent accidental injection. **If you accidentally inject yourself, refer to a hospital immediately for assistance.**

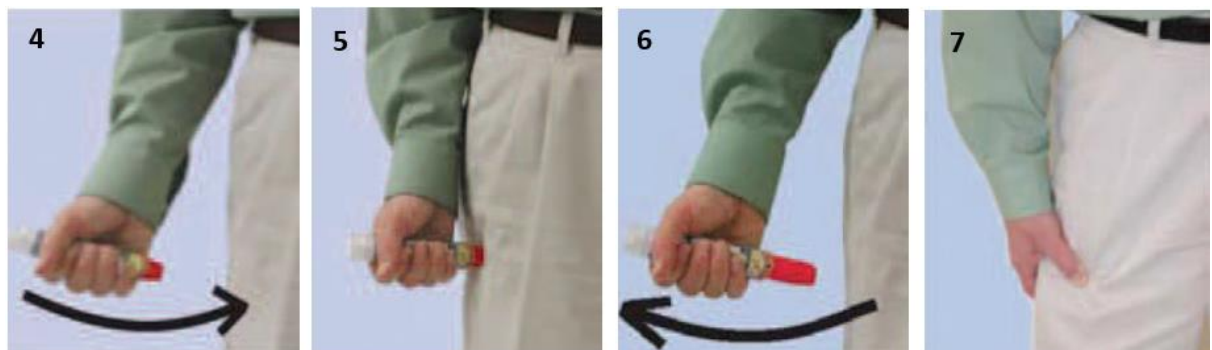
Step 2: injecting

If you are injecting a young child, hold his leg firmly so that the leg does not move while injecting, in order to prevent injuries during injection.

1. Place the orange tip of the injector against the middle of the thigh, on the outer side of the thigh, at a right angle (perpendicular to the thigh)
2. Swing and push the injector firmly against the outer thigh until it makes a “click” sound; the “click” signals that the injection has started. (Figure 4)
3. Hold the injector steadily on the thigh **for 3 seconds** (slowly count 1,2,3); the injection is complete. (Figure 5)

Note: if you do not hold the injector in place long enough, the injector may not provide the correct dose of the medicine.

4. Remove the injector from the thigh. The orange cover of the injector will extend and cover the needle. If the needle is still exposed, do not try to use the injector again. (Figure 6)
5. Massage the injection site for 10 seconds. (Figure 7)

**Step 3: go immediately to the nearest hospital**

- You may require additional medical treatment. You may need to use the second injector if the symptoms persist or recur.
- Take the injector(s) that you have used to the hospital and inform the doctor that you have received an injection of epinephrine into the thigh. Show him the injection site.
- Give the used injector to the doctor for inspection and proper destruction of the injector.

Note:

- The used injector with the covered needle is longer after use and will no longer fit into the plastic package.
- The auto-injector releases a measured dose of epinephrine and cannot be used again. Do not try to use an injector that has been used.

- Most of the injection liquid remains in the injector and cannot be reused. However, the injection provides you with the required dose if the orange cover is extended and covers the needle, and the window is hidden.

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

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Epinephrine Injection Mylan** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Cardiovascular side effects

- Arrhythmias (fast, irregular heartbeat, palpitations), including ventricular fibrillation that causes death, especially in patients with pre-existing heart disease or those receiving certain medicines.
- Rapid increases in blood pressure have led to intracerebral hemorrhage, especially in elderly patients with cardiovascular diseases.
- Angina pectoris 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 injections can include rise in heart rate, local reactions including pallor, sensation of coldness and decreased sensitivity at the injection site, or injury at the injection site that causes bruising, bleeding, skin discoloration, erythema (skin redness) or skeletal injury.
- Injection into the buttock has caused cases of gas gangrene.
- Cuts on the skin, bent needles and needles that remain in the skin after the injection can happen when children kick or move during the injection.

Infections of the skin and soft tissues

Rarely, patients who have used **Epinephrine Injection Mylan 0.3 mg / Epinephrine Injection Mylan Jr 0.15 mg** have developed an infection at the injection site within a few days after the injection. Some of these infections may be serious.

Refer to the doctor immediately if you develop any of the following effects at the injection site:

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

Common side effects (effects that occur in 1-10 users out of 100):

- Sweating • headache • weakness • tremor • pallor • overexcitement, nervousness, anxiety, restlessness • dizziness • nausea or vomiting • difficulty in breathing

The side effects may go away at rest.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning.
- Do not use the medicine after the expiry date (EXP) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C. Do not store in the refrigerator. Protect from light. Always keep the injector in the plastic case, to protect the injector. Please note, the case is not waterproof.
- Examine the solution's color in the clear window of the injector periodically. The solution should be clear. If the solution is discolored (pink or brown) or contains a precipitate, do not use the injector. Replace it.
- The safety cap of the injector prevents accidental injection, do not remove it except before use.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Sodium chloride, sodium metabisulfite, hydrochloric acid, water for injection.

What the medicine looks like and what the package contains:

Epinephrine Injection Mylan 0.3 mg / Epinephrine Injection Mylan Jr 0.15 mg are auto-injectors, for self injection. Each injector is in a plastic case.

Epinephrine Injection Mylan 0.3 mg: an injector with a yellow label stored in a plastic case and in a single package. In addition, there is a double package that contains two injectors, each in a plastic case, with a clasp that connects the two cases, and in addition contains a gray trainer syringe.

Epinephrine Injection Mylan Jr 0.15 mg: an injector with a green label stored in a plastic case and in a single package. In addition, there is a double package that contains two injectors, each in a plastic case, with a clasp that connects the two cases, and in addition contains a gray trainer syringe.

Not all package sizes may be marketed.

Revised in June 2025 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

Epinephrine Injection Mylan 0.3 mg: 161-59-35821-00

Epinephrine Injection Mylan Jr 0.15 mg: 161-58-35820-00

Manufacturer and registration holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel