

PACKAGE LEAFLET: INFORMATION FOR THE USER

EpiPen 300 micrograms, solution for injection in pre-filled pen
Active substance: Adrenaline

Read the entire package leaflet carefully before you start using this medicine because it contains important information.

- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet.

What this leaflet contains:

1. What is EpiPen and what is it used for?
2. What should you consider before using EpiPen?
3. How to use EpiPen?
4. What are the possible side effects?
5. How to store EpiPen?
6. Contents of the pack and other information

1. WHAT IS EPIPEN AND WHAT IS IT USED FOR?

EpiPen is a sterile solution in a pre-filled pen for emergency injection into the muscle.

EpiPen is used for the emergency treatment of an anaphylactic shock or an allergic reaction to insect stings or bites, foods, or medicines.

Symptoms indicating an anaphylactic reaction include, among others: itching of the skin, blister-like rash (similar to hives), redness, swelling of the lips, throat, tongue, hands, and feet, wheezing, hoarseness, nausea, vomiting, abdominal cramps, and in some cases unconsciousness.

The active ingredient in the automatic injection syringe (pen) is adrenaline, an adrenergic substance.

Adrenaline acts directly on the cardiovascular (heart-circulatory) system and the respiratory tract (lungs), it rapidly constricts blood vessels, relaxes lung muscles, thus facilitating breathing, reduces swelling, and stimulates the heartbeat, counteracting the potentially fatal consequences of an anaphylactic shock.

2. WHAT SHOULD YOU CONSIDER BEFORE USING EPIPEN?

EpiPen must not be used

There is no known reason why EpiPen should not be used in an allergic emergency situation.

Warnings and precautions,

Please talk to your doctor or pharmacist before using EpiPen.

If you suffer from heart disease, hyperthyroidism, high blood pressure, or diabetes, please inform your doctor. Despite these precautions, adrenaline is vital for the treatment of an anaphylactic reaction. Patients with the aforementioned conditions, or individuals who may need to administer EpiPen to a patient experiencing an allergic reaction, should be thoroughly informed about the circumstances under which the product is to be used.

The instructions for use must be followed carefully to prevent accidental injection.

EpiPen should only be injected into the outer thigh. Due to the risk of accidental injection into a vein, it should not be injected into the buttocks.

Warnings: Accidental injection into the hands or fingers can lead to a loss of blood supply in the affected area, in which case please seek the emergency department of the nearest hospital immediately.

Use of EpiPen with other medicines

Please inform your doctor or pharmacist if you are taking/using or have recently taken/used other medicines, even if they are non-prescription medicines.

Especially important if you are taking the following:

Antidepressants (tricyclic antidepressants) or monoamine oxidase inhibitors (MAO inhibitors), as the effects of adrenaline could be enhanced.

Medicines that may lead to an irregular heartbeat (arrhythmias), such as digitalis, mercury diuretics, or quinidine.

Diabetics should carefully monitor their blood sugar levels after using EpiPen, as adrenaline can affect the amount of insulin produced by the body and thus increase blood sugar levels.

Use of EpiPen with food and drink

Food or drinks have no effect on the use of EpiPen.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, or if you suspect you are pregnant or intend to become pregnant, consult your doctor or pharmacist before using this medicine.

Consult your doctor or pharmacist before taking any medicines.

There is limited experience with the use of adrenaline during pregnancy. If you are pregnant, do not hesitate to use EpiPen in an emergency, as your life and that of your child could be in danger.

Talk to your doctor if you are pregnant.

Driving and using machines

Driving and using machines are not affected by an adrenaline injection. If you have an anaphylactic reaction, please do not drive a vehicle.

EpiPen contains sodium metabisulfite, which in rare cases can cause severe hypersensitivity reactions (allergies) or bronchial spasms (breathing difficulties).

3. HOW TO USE EPIPEN?

If your doctor prescribes EpiPen, you must be sure you understand the reason why you have been prescribed EpiPen. You should be sure that you are fully informed about its handling. Use EpiPen exactly as your doctor has told you.

If you are unsure about the handling, ask your doctor or pharmacist to explain the application to you again.

EpiPen is intended for use in individuals weighing over 30 kg.

Dosage

The dosage is determined by your doctor, who will tailor it individually for you.

The dose for emergency allergic treatment in adults is usually 300 micrograms of adrenaline into the muscle.

If you notice signs of an acute allergic reaction, use EpiPen immediately.

Each EpiPen auto-injector delivers a single dose of 0.3 ml of liquid, which corresponds to 300 micrograms of adrenaline. After use, a volume of 1.7 ml remains in the auto-injector, but it cannot be reused.

Sometimes a single dose of adrenaline is not sufficient to counteract an allergic reaction. For this reason, your doctor may prescribe more than one EpiPen. Repeat injections are possible. If your symptoms have not improved or have even worsened, you may need a second EpiPen within 5 - 15 minutes after the first injection. For this reason, it may be advisable to always have more than one EpiPen with you.

Method of administration

The EpiPen can be easily used by individuals without medical training. The EpiPen is simply jabbed firmly against the outer thigh from a distance of about 10 cm. Precise placement on the outer thigh is not necessary. When you jab the EpiPen firmly against your thigh, a spring-activated plunger is triggered, pushing the hidden needle into the thigh muscle and delivering a dose of adrenaline solution. If you are clothed, the EpiPen can also be injected through clothing.

The instructions for use of EpiPen must be followed carefully.

EpiPen must ONLY be injected into the outer thigh, not into the buttocks.

Instructions for use

Familiarize yourself carefully with the EpiPen, when and how it is to be used (see Figure 1).

Only follow the instructions when you are ready to use the EpiPen.

Hold the autoinjector firmly in the middle, never at the ends. To ensure proper administration, look at the illustrations and proceed as follows:

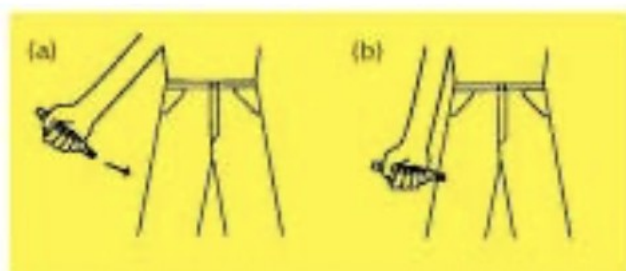
- Never place your thumb, fingers, or hand over the orange end.
- Never press the orange tip with your thumb, fingers, or hand.
- The needle comes out of the orange tip.
- Remove the blue safety cap ONLY when you are ready to use it.

Blue safety cap - Orange end



1. Take the EpiPen in your dominant hand (the hand you write with). The thumb should be on the blue cap. Make a fist around the EpiPen (orange end pointing down).
2. With the other hand, pull off the blue safety cap.
3. Hold the EpiPen about 10 cm away from the outer thigh, as shown in Figure 2a. The orange end should point towards the outer thigh.
4. Jab the EpiPen firmly into the outer thigh at a right angle (90°), as shown in Figure 2b (you will hear a click).
5. Hold the EpiPen firmly against the thigh for 10 seconds. The injection is now complete and the window on the auto-injector is obscured. Then remove the EpiPen (the orange needle cover automatically extends to cover the needle) and dispose of it safely.
6. Massage the area around the injection site for 10 seconds.

Abbildung 2



A small air bubble may sometimes be visible in the EpiPen autoinjector, which does not affect the effectiveness of the product.

Even though the majority of the liquid (about 90%) remains in the EpiPen after use, it cannot be reused. However, you have received the correct dose of the medication if the orange needle cover is extended and the window is obscured. Store the EpiPen safely in the designated yellow plastic container after use and take it with you to the doctor's office, hospital, or pharmacy next time.

Since the EpiPen is intended only as an emergency treatment, seek medical help immediately after using the EpiPen, go to the doctor or the nearest hospital. You must inform the attending physician that you have received an intramuscular injection of adrenaline, or show the autoinjector and/or the package leaflet.

If you have used more EpiPen than you should

In the event of an overdose or accidental injection of adrenaline, seek medical help immediately. If you have used too much EpiPen, contact your doctor, pharmacist, or poison control center immediately (070/245.245).

4. WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects that may occur include: irregular heartbeat, high blood pressure, sweating, nausea, vomiting, headache, dizziness, weakness, tremor, nervous restlessness, or anxiety.

Allergic reactions may occur in patients who are sensitive to sodium metabisulfite. In rare cases, heart muscle diseases have been observed in patients treated with adrenaline.

There are reports of accidental injection of the EpiPen into the hand or foot. This can lead to a loss of blood supply in the affected area. Seek medical help immediately in this case.

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet.

5. HOW TO STORE EPIPEN?

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Do not refrigerate or freeze.

Keep the autoinjector in the outer carton to protect the contents from light. If the active ingredient adrenaline is exposed to air or light, it spoils quickly and turns pink or brown. Please remember to occasionally check the contents of the glass cartridge in the EpiPen autoinjector to ensure the liquid is still clear and colorless. Replace the autoinjector by the expiry date or sooner if the solution has discolored or shows precipitates.

Do not dispose of medicines via wastewater or household waste. Ask your doctor or pharmacist how to dispose of medicines you no longer use. This helps protect the environment.

See also section 3 – Use of EpiPen.

7. CONTENTS OF THE PACKAGE AND FURTHER INFORMATION

What EpiPen contains

The active substance is adrenaline 300 micrograms per dose.

The other ingredients are sodium chloride, sodium metabisulfite, hydrochloric acid, water for injections.

What EpiPen looks like and contents of the package

EpiPen contains a clear and colorless solution in a ready-to-use pen (autoinjector).

The autoinjector (single dose) contains 2 ml of injection solution. Each autoinjector delivers a single dose (0.3 ml) of 300 micrograms of adrenaline.

2 x 1 Auto-Injector.

Packages:

1 Auto-Injector

2 x 1 Auto-Injector

Not all pack sizes are available.

Pharmaceutical entrepreneur and manufacturer

Pharmaceutical entrepreneur:

Meda Pharma s.a. - Chaussée de la Hulpe, 166 - 1170 Brussels - Belgium

Manufacturer:

MEDA Pharma GmbH & Co. KG - Benzstraße 1 - D-61352 Bad Homburg – Germany

This medicinal product is authorized in the Member States of the European Economic Area (EEA) under the following names:

Member State	Name of the medicinal product
Netherlands, Belgium, Iceland, Norway, Finland, Sweden, Denmark, Austria, Slovak Republic, Czech Republic, and Hungary	EpiPen
Poland	EpiPen Senior
Spain	ALTELLUS 0.3 adultos

MARKETING AUTHORIZATION NUMBER

BE193916

DELIVERY

prescription only

This package leaflet was last revised in 11/2012

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