

Package leaflet: Information for the user

EpiPen 300 micrograms, solution for injection in pre-filled pen

Adrenaline

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What EpiPen is and what it is used for
2. What you need to know before you use EpiPen
3. How to use EpiPen
4. Possible side effects
5. How to store EpiPen
6. Contents of the pack and other information

1. What EpiPen is and what it is used for

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

EpiPen (adrenaline) Auto-Injectors are to be used in the emergency treatment of severe allergic reactions (anaphylaxis) caused by allergens in e.g. foods, drugs, insect stings or bites as well as triggered by exercise or by unknown causes.

EpiPen Auto-Injectors 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.

Symptoms that signal the onset of an anaphylactic reaction include: itching of the skin; raised rash (like a nettle rash); flushing; swelling of the lips, throat, tongue, hands and feet; wheezing; hoarseness; nausea; vomiting; abdominal cramps and in some cases, loss of consciousness.

The medicine in the Auto-Injector (the pen) is adrenaline which is an adrenergic drug.

It works directly on the cardiovascular (heart and circulation) system and respiratory (lung) system, countering the potentially fatal effects of anaphylaxis by rapidly constricting the blood vessels, relaxing muscles in the lungs to improve breathing, reducing swelling and stimulating heartbeat.

2. What you need to know before you use EpiPen

Do Not Use EpiPen

There is no known reason why anyone should not use EpiPen during an allergic emergency.

Warnings and precautions

If you have asthma you may be at increased risk of a severe allergic reaction.

Anyone who has an episode of anaphylaxis should see their doctor about testing for substances they may be allergic to, so these can be strictly avoided in future. It is important to be aware that an allergy to one substance can lead to allergies to a number of related substances.

If you have food allergies it is important to check the ingredients in everything you ingest (including medicines) as even small amounts can cause severe reactions.

Tell your doctor if you have

- heart disease
- an overactive thyroid
- high blood pressure
- diabetes
- increased pressure in your eye (glaucoma)
- severe kidney problems
- a tumor in your prostate
- high calcium levels or low potassium level in your blood
- Parkinson's disease

Despite these concerns, adrenaline is essential for the treatment of anaphylaxis. Patients with these conditions, or anyone who may be in the position to give EpiPen to a patient experiencing an allergic reaction, should be properly instructed as to the situations in which it should be given.

The instructions for use must be carefully followed in order to avoid accidental injection.

EpiPen should only be injected into the outer thigh. It should not be injected into the buttock due to the risk of accidental injection into a vein.

Warnings: Accidental injection into the hands or fingers may result in loss of blood supply to the affected area. If there is an accidental injection into these areas, you should go immediately to the nearest hospital casualty department for treatment.

If you have a thick sub-cutaneous fat layer, there is a risk that a single dose of EpiPen may not be sufficient. A second injection may be needed. Carefully follow the instructions for use given in section 3.

Children and adolescents

Children between 15 kg and 30 kg in weight:

For children with a body weight between 15 kg and 30 kg EpiPen Jr. Auto-Injector containing 150 micrograms adrenaline per dose is available.

Children below 15 kg in weight:

The suitability of EpiPen Jr. (150 micrograms) has to be judged individually by the doctor.

The use in children weighing less than 7.5 kg is not recommended unless in a life-threatening situation and under medical advice.

Other medicines and EpiPen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important if you take any of the following:

- Antidepressants such as tricyclic antidepressants or monoamine oxidase inhibitors (MAO inhibitors), since the effects of adrenaline may be increased
- Medicines for treatment of Parkinson's disease such as catechol-O-methyl transferase inhibitors (COMT inhibitors), and levodopa since the effect of adrenaline may be increased
- Medicines that may make the heart sensitive to uneven beats (arrhythmias), such as digitalis and quinidine
- Medicines for heart disease or medicines to treat disorders of the nervous system called alpha- or beta-blocking medicines, as they can reduce the effect of adrenaline
- Medicines for thyroid disease

- Medicine that makes you breathe more easily, used for asthma (theophylline)
- Medicine used in labour (oxytocin)
- Medicines used to treat allergies such as diphenhydramine or chlorpheniramine (antihistamines)
- Medicines that act on the nervous system (parasympatholytics)

Diabetic patients should carefully monitor their glucose levels after use of EpiPen as adrenaline can affect the amount of insulin made by the body, thus increasing the blood glucose level.

EpiPen with food, drink and alcohol

Food or drink has no influence on the use of EpiPen.

Tell your doctor if you are taking alcohol since the effect of adrenaline can be increased.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

In an acute life-threatening situation, do not hesitate to use EpiPen, since your and your child's lives may be in danger. There is limited experience of the use of adrenaline during pregnancy.

Breast-feeding

EpiPen would not be expected to have any effect on the nursing infant.

Driving and using machines

The ability to drive and use machines will not be affected by the administration of an adrenaline injection, but may be affected by an anaphylactic reaction. If affected, do not drive.

EpiPen contains sodium metabisulfite (E223)

Sodium metabisulfite may rarely cause severe allergic reactions or breathing difficulty (bronchospasm).

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

3. How to use EpiPen

When your doctor prescribes EpiPen, you must make sure you understand the reason it has been prescribed for you. You should be confident that you know exactly how to use the device. Always use EpiPen exactly as your doctor has told you. If you are at all unsure about how to use it, ask to have the instructions repeated by your doctor, nurse or pharmacist.

It is recommended that your family members, carers or teachers are also instructed in the correct use of EpiPen.

In case the injection is performed by a caregiver, ensure that the patient's leg is immobilized during injection to minimize the risk of leg laceration, bent needle or other injuries.

The product is for single use only. Do not reuse the used pen.

For training and demonstration purposes, an EpiPen training device (without drug, without needle) is available. The training device and the active EpiPen Auto-Injector should not be routinely carried together in order to avoid confusion in an emergency situation.

EpiPen is intended to be used by people with a body weight above 30 kg.

For children weighing less than 30 kg see section "Children and adolescents" above.

Dosage

The dose will be decided by your doctor, who will adjust it individually for you. The usual adult dose for allergic emergencies is 300 micrograms adrenaline for intramuscular use.

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

Each EpiPen Auto-Injector delivers one single dose of 0.3 ml liquid which is equal to 300 micrograms adrenaline. After use a small volume will remain in the Auto-Injector but this cannot be reused.

Sometimes a single dose of adrenaline may not be sufficient to completely reverse the effects of a serious allergic reaction. For this reason, your doctor is likely to prescribe more than one EpiPen for you. If your symptoms have not improved or have deteriorated within 5-15 minutes after the first injection, either you or the person with you should give a second injection. **For this reason, you should carry more than one EpiPen with you at all times.**

How EpiPen is given

The EpiPen is designed to be used easily by people without medical training. EpiPen should simply be jabbed firmly against the **outer portion of the thigh** from a distance of approximately 10 cm. There is no need for precise placement in the outer portion of the thigh. When you jab the EpiPen firmly into your thigh, a spring activated plunger will be released, which pushes the hidden needle into the thigh muscle and administers a dose of adrenaline. If you are wearing clothes the EpiPen can be injected through the clothes.

The instructions for use of the EpiPen must be carefully followed. It is recommended that your family members, carers or teachers are also instructed in the correct use of EpiPen.

EpiPen should ONLY be injected into the outer thigh. **It should not be injected into the buttock.**

Directions for use

Fully familiarise yourself with the EpiPen, when and how it should be used.



Follow these directions only when ready to use.

Hold the Auto-Injector by the middle, never by the ends. For proper administration, look at the diagrams and follow these steps:

- Never put thumb, fingers or hand over the orange tip. Never press or push the orange tip with thumb, fingers or hand.
- The needle comes out of orange tip.
- Do NOT remove blue safety cap until ready to use.



1. Grasp EpiPen in dominant hand (the hand you use to write), with thumb nearest blue cap and form fist around unit (orange tip down).

2. Remove the blue safety cap by pulling it straight up with the other hand.



3. Hold the EpiPen in a distance of approximately 10 cm away from the outer thigh. The orange tip should point towards the outer thigh.



4. Jab the EpiPen **firmly** into outer thigh at a right angle (90-degree angle). (listen for click).

5. Hold firmly against thigh for 3 seconds. The injection is now complete and the viewing window on the Auto-Injector is obscured.



6. EpiPen should be removed (the orange needle cover will extend to cover needle) and safely discarded.

Gently massage the injection area for 10 seconds. Dial 112, ask for ambulance, state anaphylaxis.

A small bubble may be present in the EpiPen Auto-Injector. It has no influence on the product's effectiveness.

Even though most 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 tip is extended and the viewing window is obscured. Discard EpiPen safely after use in the tube provided and bring it with you when you visit your doctor, hospital or pharmacy.

EpiPen is designed as emergency treatment. You should always get medical help immediately after using EpiPen. Dial 112, ask for an ambulance and state "anaphylaxis" **even if symptoms appear to be improving**. You will need to go to hospital for observation and further treatment as required. This is because the reaction may happen again at some time later.

While waiting for the ambulance you should lie down with your feet raised unless this makes you breathless in which case you should sit up. Ask someone to stay with you until the ambulance arrives in case you feel unwell again.

Unconscious patients should be placed on their side in the recovery position.

If you use more EpiPen than you should

In case of overdose or accidental injection of the adrenaline, you should always seek immediate medical help.

4. Possible side effects

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

Rare cases of serious skin and soft tissue infections (injection site infection) have been reported. In case of signs of injection site infection such as swelling, redness, heat or pain always seek immediate medical help.

Accidental injection of the pens in hands or feet have been reported, which may result in loss of blood supply to the affected area, causing paleness, coldness or numbness. In case of accidental injection always seek immediate medical help.

Allergic reactions can appear in patients sensitized to sodium metabisulfite. In rare cases (may affect up to 1 in 1.000 people) damage to the heart muscle (stress cardiomyopathy) has been seen in patients treated with adrenaline.

Not known: (frequency cannot be estimated from the available data): Fast or irregular heartbeat, sometimes severe, irregular and uncoordinated contractions to the lower chamber of the heart (ventricular fibrillation), severe pain in the chest, high blood pressure, difficulties in breathing, paleness, sweating, nausea, vomiting, headache, dizziness, weakness, tremor and nervousness or anxiety, injury at the injection site such as bruising, bleeding, redness of the skin, and skeletal injury.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in the leaflet. You can also report side effects directly via **the national reporting system listed in Appendix V** [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store EpiPen

Keep this medicine out of the sight and 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.

Do not store above 25 °C. Do not refrigerate or freeze.

Keep the container in the outer carton in order to protect from light. When exposed to air or light, adrenaline deteriorates rapidly and will become pink or brown. **Please remember to check the contents of the glass cartridge in the EpiPen Auto-Injector from time to time to make sure the liquid is still clear and colourless. Replace the Auto-Injector by the expiry date or earlier if the solution is discoloured or contains a precipitate (solid matter).**

Do not away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What EpiPen contains

The active substance is adrenaline. Each dose contains 300 micrograms adrenaline.
The other ingredients are sodium chloride, sodium metabisulfite (E223), hydrochloric acid, water for injections.

What EpiPen looks like and contents of the pack

Clear and colourless solution in a pre-filled pen (Auto-Injector).
The Auto-Injector contains 2 ml solution for injection. Each Auto-Injector delivers one single dose (0.3 ml) of 0.3 mg adrenaline.
Exposed and protected needle length approx. 15 mm.

Pack sizes:

1 Auto-Injector.

2 x 1 Auto-Injector.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

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

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of Member State	Name of 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

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