

Package leaflet: Information for the user

EpiPen® Auto-Injector 0.3 mg 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® contains a sterile solution of adrenaline for emergency injection into the outer part of the thigh muscle (intramuscular injection). EpiPen® is to be used for the emergency treatment of sudden life threatening allergic reactions (anaphylactic shock) to insect stings or bites, foods or drugs or exercise. The reaction is the result of the body trying to protect itself from the allergen (the foreign substance that causes the allergy) by releasing chemicals into the blood stream. Sometimes the cause of the allergic reaction is not known.

Symptoms that signal the onset of an anaphylactic shock occur within minutes of exposure to the allergen and include: itching of the skin; raised rash (like a nettle rash); flushing; swelling of the lips, throat, tongue, hands and feet; wheezing; hoarseness; shortness of breath; nausea; vomiting; stomach 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, to stop the possible fatal effects of anaphylactic shock by very quickly making the blood vessels smaller, relaxing muscles in the lungs to improve breathing, reducing swelling and stimulating heartbeat.

The EpiPen® is intended for immediate self administration by a person with a history or recognised risk of going into anaphylactic shock. If you are at risk, you should always keep your EpiPen® with you. It is designed as an emergency rescue therapy but you must get medical attention as soon as possible after its use.

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.

Take special care with EpiPen®

Adrenaline is essential for the treatment of anaphylaxis.

However, take special care with EpiPen®:

- particularly if you have heart disease as it may affect the medicines that you are taking and may bring on an attack of chest pain (angina)
- if you have an overactive thyroid

- if you have high blood pressure
- if you have diabetes
- if you are elderly, pregnant or the child weighs less than 25 kg (3 stone 13 lbs) as there is a greater risk of getting side effects.
- if you have increased pressure in your eye(s) (glaucoma)
- if you have severe kidney problems
- if you have a tumour in your prostate
- if you have high calcium levels or a low potassium level in your blood
- if you have Parkinson's disease

Make sure you have discussed this with your doctor if any of these apply to you.

Patients with these conditions, or anyone who may be in the position to administer EpiPen® to a patient having an allergic reaction, should be properly instructed on how and when to give it.

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 and precautions

If you have asthma you may be at increased risk of 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.

Accidental injection into the hands or fingers may result in reduced blood supply to these areas. 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-subcutaneous fat layer, there is a risk of the adrenaline not reaching the muscle tissue resulting in a suboptimal effect. In such individuals there may be a higher likelihood of needing a second injection with an additional EpiPen. Therefore you should ensure you carry two auto-injectors with you at all times.

In case of injection performed by a caregiver, immobilization of the patient's leg should be ensured during injection to minimize the risk of injection site laceration.

The needle should never be reinserted after use.

Other medicines and EpiPen®

When being prescribed EpiPen®, please tell your doctor or pharmacist if you are taking, have recently taken or might take, any other medicines, including medicines obtained without a prescription as they may affect how the adrenaline works.

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 that may make the heart sensitive to uneven beats (arrhythmias), such as digitalis, mercurial diuretics or quinidine.

- Medicines for the treatment of Parkinson's disease such as catechol-O-methyl transferase inhibitors (COMT inhibitors) and levodopa since the effect of adrenaline may be increased
- Beta-blocking medicines for heart disease or medicines to treat disorders of the nervous system as they can reduce the effect of adrenaline
- Medicines for thyroid disease
- Medicines that make you breathe more easily; used for asthma (theophylline)
- Medicines 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 reduce the amount of insulin made by the body, thus increasing the blood glucose level.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

There is limited experience of the use of adrenaline during pregnancy. If you are pregnant, do not hesitate to use EpiPen® in an emergency, since you and your baby's lives may be in danger.

Discuss this with your doctor if you are pregnant.

Driving and using machines

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

EpiPen® contains

EpiPen® contains sodium metabisulphite (E223), which may rarely cause severe allergic reactions (hypersensitivity) or breathing difficulty (bronchospasm). However, you should still use the EpiPen® as there are no satisfactory alternatives.

This medicine contains less than 23 mg sodium per dose, i.e. 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 and when to use it.

Always use EpiPen® exactly as your doctor or pharmacist 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.

If you have been stung by an insect, try to remove the stinger with your fingernails – do not squeeze, pinch or push it deeper into the skin. If possible, put an ice pack on the area of the sting. Keep warm and avoid exercise.

For allergic reactions caused by foods make sure you remove any remaining food from the mouth immediately.

EpiPen® is intended to be used by people with a body weight above 25 kg (3 stone 13 lbs). For persons weighing less than 25 kg (3 stone 13lbs). EpiPen® Jr. may be more appropriate for use.

Dosage

The dose will be decided by your doctor, who will adjust it individually for you. The usual adult dose for allergic emergencies is 0.3 mg adrenaline for injection into muscle (intramuscular use).

If you notice the signs of an acute allergic reaction, use EpiPen® immediately, through your clothing if necessary.

Each EpiPen® Auto-injector delivers one single dose of 0.3 ml liquid which is equal to 0.3 mg

(300 micrograms) adrenaline. After use a volume of 1.7 ml 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.

Method of administration

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 (4 inches). 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® given below must be carefully followed.

EpiPen® should only be injected into the outer thigh.

It should not be injected into the buttocks (your bottom).

Directions for use

Before you ever need to use it, fully familiarise yourself with the EpiPen®, when and how it should be used (refer to diagram 1).

Follow these directions only when ready to use.

Hold the EpiPen® 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.
- Do **not** remove blue safety cap until ready to use.

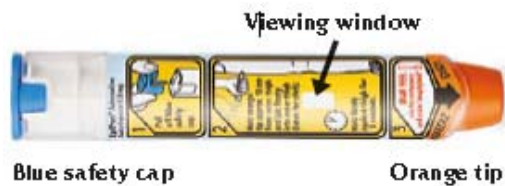


Diagram 1



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. With other hand pull off blue safety cap.



3. Hold the EpiPen at 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 window on the auto-injector is obscured.

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

7. Dial 999, ask for ambulance, and state anaphylaxis.

As the EpiPen® is designed as emergency treatment only, you should always seek medical help immediately after using EpiPen®, by dialling 999, ask for 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.

Make sure that you inform the healthcare professional that you have received an intramuscular injection of adrenaline or show them the container and/or leaflet.

A small air bubble may be present in the EpiPen® Auto-injector. It does not affect the way the product works.

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 window is obscured.

After use, place the EpiPen® safely in the tube provided and bring it with you when you visit your doctor, hospital or pharmacy

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. Your blood pressure may rise sharply and it will need to be monitored. If you have any further questions on the use of this medicine; ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them. Seek urgent medical advice immediately in case of accidental injection. Accidental injection of the pens in hands or fingers have been reported and may result in lack of blood supply to these areas. Tell your doctor or pharmacist if any of the following side effects occur or worsen.

Not known (frequency cannot be estimated from the available data):

Usual side effects include: irregular heartbeat (including palpitations and rapid heartbeats), high blood pressure, sweating, nausea, vomiting, difficulty breathing, paleness, headache, hypertension, dizziness, weakness, tremor and apprehension, nervousness or anxiety.

Rare (may affect up to 1 in 1,000 people)

Cardiomyopathy has been seen in patients treated with adrenaline.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. 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 label and carton. The expiry date refers to the last day of that month.

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

Keep 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. Do not use this medicine if you notice that the liquid is unclear, coloured or contains solid particles.

Replace the Auto-injector by the expiry date or earlier if the solution is discoloured or contains a precipitate (solid particles).

Do not throw away 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.

See also section 3 – Directions for use.

6. Contents of the Pack and Other Information

What EpiPen® contains

The active substance is adrenaline 0.3 mg (300 microgram).

The other ingredients are: Sodium Chloride, Sodium Metabisulphite (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 (single-dose) contains 2 ml solution for injection. Each auto-injector delivers one single dose (0.3 ml) of adrenaline.

The exposed needle length is approximately 16 mm for EpiPen.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

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