

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. Before you 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 30 kg (4 stone 9lbs) as there is a greater risk of getting side effects. 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.

Warning

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.

Taking other medicines

When being prescribed EpiPen®, please tell your doctor or pharmacist if you are taking, or have recently taken, 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.

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 your 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.

Important information about some of the ingredients of EpiPen®

EpiPen® contains sodium metabisulphite, 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.

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 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.

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 30Kg. For persons weighing less than 30 kg (4 stone 9lbs), 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 the 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 an allergic reaction. For this reason, your doctor may prescribe more than one EpiPen® for you. Repeated injections may be administered after 5-15 minutes if the symptoms are still there and the doctor has told you that you can do this. For this reason it may be a good idea to 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 buttock (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:

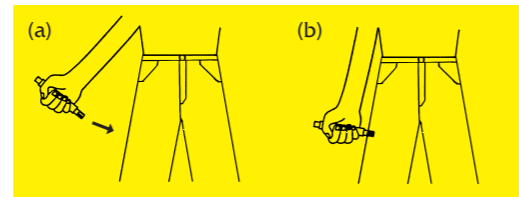
- Never put thumb, fingers or hand over the black tip.
- Do **not** remove grey safety cap until ready to use.

Diagram 1



1. Grasp EpiPen® in dominant hand (the hand you use to write), with thumb nearest grey cap and form fist around unit (black tip down).
2. With other hand pull off grey safety cap.
3. Hold the EpiPen® at a distance of approximately 10 cm (4 inches) away from the outer thigh, as shown in diagram 2a. The black tip should point towards the outer thigh.
4. Jab the EpiPen® **firmly** into outer thigh at a right angle (90 degree angle) as shown in diagram 2b. (listen for click)
5. Hold firmly in thigh for 10 seconds. EpiPen® should be removed and safely discarded.
6. Massage the injection area for 10 seconds.

Diagram 2



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

As the EpiPen® is designed as emergency treatment only, you should always seek medical help immediately after using EpiPen®, by reporting to your doctor, nearest hospital or by calling an ambulance. 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.

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.

4. Possible side effects

Like all medicines EpiPen® can cause side effects, although not everybody gets them.

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

Accidental injection of the pens in hands or fingers have been reported and may result in lack of blood supply to these areas. In case of accidental injection, always seek immediate medical help.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE EpiPen®

Keep out of the reach and sight of children.

Do not use EpiPen® after the expiry date which is stated on the label.

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

Medicines should not be disposed of via drains or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment. See also section 3 - Directions for use.

6. FURTHER INFORMATION

What EpiPen® contains

The active substance is adrenaline 0.3 mg (300 microgram). The other ingredients are: Sodium Chloride, Sodium Metabisulphite, 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.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder: ALK-Abelló A/S Bøge Allé 6-8, 2970 Hørsholm, Denmark. Manufacturer: Meridian Medical Techn. Inc., St. Louis, USA Distributor: ALK-Abelló Ltd., 1 Tealgate, Hungerford, Berkshire RG17 0YT

This leaflet was last approved on

For information in large print, tape, CD or Braille, telephone 01488 686016

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Patient Information Leaflet

EpiPen® Auto-Injector 0.3 mg Adrenaline

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What EpiPen® is and what it is used for
2. Before you use EpiPen®
3. How to use EpiPen®
4. Possible side effects
5. How to store EpiPen®
6. Further information

1. What EpiPen® is and what it is used for

EpiPen® contains a sterile solution for emergency injection into the 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.

EpiPen® Expiry Date Alert Service

It is important that your EpiPen® should be replaced before the expiry date marked on the label. For your safety and convenience, ALK-Abelló offers all patients prescribed EpiPen® an Expiry Date Alert Service. We will contact you by mail to remind you when you need to replace your EpiPen®. Please fill in the form below and return it to:
ALK-Abelló Ltd. - Freepost (RG3630) - Hungerford, Berkshire, RG17 0YT

EpiPen® Expiry Date Alert Form
Please print clearly in capital letters.

Lot No.: _____
(see label)

Expiry Date: _____
(see label)

Your Full Name: _____
Your Mailing Address: _____

Your Doctor's Name: _____
Your Doctor's Address: _____

Postal Code: _____

Postal Code: _____

Please remember to inform us if you change address.

Tel No.: _____