Patent Information Leaflet

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

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 contains 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 15 mm for EpiPen.

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder: Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK
Manufacturer: MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg, Germany

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If this leaflet is difficult to see or read and you would like it in a different format, please contact Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK.
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), as the effects of adrenaline may be increased.
- Medicines that may make the heart sensitive to uneven beats (arrhythmias) such as digitals, mercurial diuretics or quinidine.
- 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 13 lbs), 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.

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.

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