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, 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.

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: Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishop’s Stortford, CM22 6PU

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 Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishop’s Stortford, CM22 6PU, United Kingdom.
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 for the adrenaline not reaching the muscle tissue resulting in a suboptimal effect. 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 make the heart sensitive to uneven beats (arythmias), such as digitals, 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 3 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.

Viewing window
Blue safety cap Orange tip

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:

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.