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

EpiPen® Jr. is a sterile solution of adrenaline for emergency injection to the outer part of the thigh muscle (intramuscular injection). It contains adrenaline which is an adrenergic drug. EpiPen® Jr. 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 by very quickly making the blood vessels smaller, relaxing muscles in the lungs to improve breathing, reducing swelling and stimulating heartbeat.

The EpiPen® Jr. 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® Jr. available at all times.

2. What you need to know before you use EpiPen® Jr.

Do not use EpiPen® Jr. during an allergic emergency.

Take special care with EpiPen® Jr.

Adrenaline is essential for the treatment of anaphylaxis. However, take special care with EpiPen® Jr.:

- 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 administering EpiPen® Jr. to patients who weigh less than 7.5 kg (1 stone 3 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 prostrate;
- if you have high calcium levels or a low potassium level in your blood;
- if you have Parkinson’s disease.

3. How to use EpiPen® Jr.

You should use EpiPen® Jr. during an allergic emergency. If you have any further questions, ask your doctor, pharmacist or nurse.

4. Possible side effects

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.

5. How to Store EpiPen® Jr.

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.

6. Contents of the Pack and Other Information

What EpiPen® Jr. contains

The active substance is adrenaline 0.15 mg (150 microgram).

The other ingredients are: Sodium Chloride, Sodium Metabisulphite (E223), Hydrochloric Acid, Water for Injections.

What EpiPen® Jr. looks like and contents of the pack

Clear and colourless solution in a pre-filled pen (Auto-injector).

The exposed needle length is approximately 13 mm for EpiPen Jr.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder: Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK

Manufacturers: 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.

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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 by very quickly making the blood vessels smaller, relaxing muscles in the lungs to improve breathing, reducing swelling and stimulating heartbeat.

The EpiPen® Jr. 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® Jr. with you. It is designed as an emergency rescue therapy but you must get medical attention as soon as possible after its use.
This medicine contains less than 23 mg sodium per dose, i.e. essentially 'sodium-free'.

3. How to use EpiPen Jr.

When your doctor prescribes EpiPen Jr., you must make sure you understand the reason it has been prescribed for you. You should be confident you know exactly how and when to use it. Always use EpiPen Jr. 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 Jr.

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 Jr. is intended to be used by children with a body weight between 7.5 - 25 kg (1 stone 3 lbs - 3 stone 13 lbs). For persons weighing more 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 dose for children is 0.15 mg or 0.3 mg adrenaline for intramuscular injection depending on the body weight of the patient (0.01 mg/kg body weight). If you notice the signs of an acute allergic reaction, use EpiPen Jr. immediately, through your clothing if necessary.

Each EpiPen Jr. Auto-injector delivers one single dose of 0.3 ml liquid which is equal to 0.15 mg (150 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 Jr. 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 Jr. with you at all times.

Method of administration

The EpiPen Jr. is designed to be used easily by people without medical training. EpiPen Jr. should simply be jabbed firmly against the outer thigh.

As the EpiPen Jr. is designed as emergency treatment only, you should always seek medical help immediately after using EpiPen Jr., 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 Jr. Auto-injector. It does not affect the way the product works.

Even though most of the liquid (about 90%) remains in the EpiPen Jr. after use, it cannot be reused. However, you have received the appropriate dose of the medication if the orange needle tip is extended and the window is obscured. After use, place the EpiPen Jr. safely in the tube provided and bring it with you when you visit your doctor, hospital or pharmacy.

If you use more EpiPen Jr. 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:

- Do not remove blue safety cap until ready to use.

Viewing window

- Never put thumb, fingers or hand over the needle cover.
- Always use EpiPen Jr. in the dominant hand (the hand you use to write), with thumb nearest blue cap and finger flat against unit (orange tip down)
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