



Package leaflet: Information for the user

EpiPen® Jr. Adrenaline Auto-Injector 0.15 mg

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® Jr. is and what it is used for
2. What you need to know before you use EpiPen® Jr.
3. How to use EpiPen® Jr.
4. Possible side effects
5. How to store EpiPen® Jr.
6. Contents of the pack and other information

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

EpiPen® Jr. contains a sterile solution of adrenaline for emergency injection into the outer part of the thigh muscle (intramuscular injection). 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 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® 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.

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

Do not use EpiPen® Jr. There is no known reason why anyone should 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)

also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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. 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® Jr. 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® 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 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 13 mm for EpiPen® Jr.

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
This leaflet was last revised in October 2024. 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

- What to do in an emergency:**
- **Use your adrenaline auto-injector immediately if you have any signs of anaphylaxis. If in doubt use. Don't delay.**
 - **Dial 999 – say anaphylaxis (“ana-fill-axis”) – straight after using your auto-injector.**
 - **Lie down and raise your legs.**
 - **Sit up if you are struggling to breathe but don't change position suddenly.**
 - **Lie down again as soon as you can.**
 - **Stay lying down even if you are feeling better.**
 - **You must not stand up even if someone encourages you to.**
 - **Use your second auto-injector if you haven't improved after 5 minutes.**
 - **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.**
 - **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.**

Be prepared:

- **Carry two adrenaline auto-injectors with you at all times.**
- **You must use your auto-injector as soon as you notice any signs of anaphylaxis.**
- **Make sure you know beforehand what the signs are so you can act swiftly.**
- **Make sure you know how to use your auto-injector before you need to. Get familiar with it. Get a trainer auto-injector from the manufacturer. Practise. If you change brand, get familiar with the new one. Each one is used differently.**

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 correct 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.

Rare (may affect up to 1 in 1,000 people) Cardiomyopathy has been seen in patients treated with adrenaline.

Not known (frequency cannot be estimated from the available data): Usual side effects include: irregular heartbeat, palpitations, severe rapid heartbeats, severe chest pains, high blood pressure, reduced blood flow to limbs, sweating, nausea, vomiting, difficulty breathing, paleness, headache, dizziness, weakness, tremor and apprehension, nervousness or anxiety, injection site infection, injection site bruising, bleeding, discoloration, redness of the skin and skeletal injury.

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

EpiPen® Jr. Expiry Date Alert Service

It is important that your EpiPen® Jr. should be replaced before the expiry date marked on the label. For your safety and convenience, Meda offers all patients prescribed EpiPen Jr. an expiry date alert service. We will contact you to remind you when you need to replace your EpiPen Jr. Please fill in the form below and return it to: EpiPen Alert Service, Mylan Products Limited, Building 4, Trident Place, Mosquito Way, Hatfield, Herts, AL10 9UL

EpiPen® Jr. Expiry Date Alert Form

Please print clearly in capital letters.

Lot No.: _____
(see label)

Your Full Name: _____

Your Mailing Address: _____

Postal Code: _____

Please remember to inform us if you change address.

Expiry Date: _____
(see label)

Your Doctor's Name: _____

Your Doctor's Address: _____

Postal Code: _____

Tel No.: _____



Description				EpiPen Junior 0.15mg 1/2		Date: 08/Oct/24		Time: 12:50	
Component Type	Leaflet	Site Barcode/ DataMatrix	14633 (2D)	No. of colours	4		Page Count	2 of 2	
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TrackWise/GLAMS Job No.	ART-919-04	Artwork Proof No.	1	Non-Print Colours					
MA No.	PL 46302/0172	Client Market	United Kingdom	Equate CMYK with	<div>Pantone 376 52/0/100/5</div> <div>Pantone 186 0/100/81/4</div>				
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Superseded Supplier Code	P090820014341			Keyline/Drawing No.		ARTW-00021-202-V01.pdf			
Packing Site/Printer Sign-offs	Sharp Packaging Solutions (Heerenveen - NL)								
				V3 MAY 2023					



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