EpiPen® Jr. Expiry Date Alert Form

EpiPen Alert Service, Mylan Products Limited, Building 4, Trident Place, Mosquito Way, Hatfield, Herts, AL10 9UL

you when you need to replace your EpiPen Jr. Please fill in the form below and return it to:

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

Keep in container in 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.

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).

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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 December 2018.

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

EpiPen® Jr. Auto-Injector 0.15 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 symptoms 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 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.

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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)
– if you have severe kidney problems
– if you have a tumour in your prostrate
– if you have high calcium levels in your blood
– if you have Parkinson’s disease
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 that 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® 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 (50 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 portion of the thigh from a distance of approximately 10 cm (4 inches).

There is no need for precise placement in the outer thigh. When you jab the EpiPen® Jr. 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® Jr. can be injected through the clothes.

The instructions for use of the EpiPen® Jr. given below must be carefully followed.

EpiPen® Jr. 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® Jr. when and how it should be used (refer to diagram 1). Follow these directions only when ready to use.

Hold the EpiPen® Jr. 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

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 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 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 pins 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.