

EPIPEN[®]

EPIPEN[®] Junior

(adrenaline) Auto-Injectors 300/150mcg

THE FACTS ABOUT ANAPHYLAXIS



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1

WHAT IS ANAPHYLAXIS?

Anaphylaxis is serious and can be a potentially life-threatening type of allergic reaction. Symptoms can start within seconds or minutes of exposure to the substance you are allergic to, called an allergy trigger or allergen.

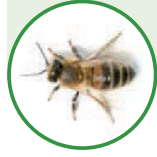
Anaphylaxis is the result of your body's immune system overreacting to a harmless substance, such as certain types of food. The body reacts and releases chemicals to protect itself. This reaction can produce life-threatening symptoms.

a) Common triggers for an anaphylactic reaction



Food

e.g. peanuts, hazelnuts, pecan, egg, soya, fish, shellfish, wheat, milk



Insect venom

e.g. bee, wasp, hornet, bumblebee



Medicine

e.g. antibiotics, anaesthetics, analgesics



Latex

e.g. gloves, plasters, condoms



Physical stress (e.g. exercise)

Very seldom, tentatively in combination with other factors



Idiopathic causes

Unknown trigger



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b) Recognise the symptoms

Normally an anaphylactic reaction is clearly indicated when serious physical discomfort occurs. These symptoms appear within minutes, therefore it is of particular importance to treat yourself immediately. Severe allergic reactions are indicated by the following symptoms:

- Difficulty/noisy breathing
- Swelling of tongue
- Swelling/tightness in throat
- Swelling of face/lips/eyelids
- Difficulty talking and/or hoarse voice
- Wheeze or persistent cough
- Loss of consciousness and/or collapse
- Pale and floppy (young children)

This is not a full list of symptoms. Always speak to your doctor about what you should watch out for.

c) How to treat anaphylaxis

Know what triggers your allergy and avoid these at all times. It is very important that you know the signs and symptoms of anaphylaxis. However, if it comes to an anaphylactic reaction an intramuscular adrenaline injection is the first-line treatment option to circumvent the progression of your symptoms and then call an ambulance. Adrenaline should be administered as soon as symptoms occur before they evolve into anaphylaxis (see chapter 1b). Adrenaline causes vasoconstriction, thereby raising the blood pressure and maintaining the circulation and reducing the swelling. Furthermore adrenaline leads to the relaxation of the bronchia and relieving breathing difficulty.



2 WHAT IS THE EPIPEN®/ EPIPEN® JUNIOR ADRENALINE AUTO-INJECTOR?

The EpiPen®/EpiPen® Junior is a disposable, pre-filled automatic injection device that administers adrenaline in the event of a severe allergic reaction. The EpiPen®/EpiPen® Junior auto-injector is designed to be used by the patient for the injection of a standardised adrenaline dosage in the thigh, when it comes to a life-threatening anaphylactic reaction. Each EpiPen®/EpiPen® Junior can only be used once.

a) Characteristics of the device

Blue safety cap

Prevents unintentional activation of the EpiPen®.

Instructions

Comprehensive step-by-step guidance direct on the device – enabling a quick administration in the case of an emergency.

Viewing window

Check regularly to make sure the solution is clear and colourless. If the solution becomes discoloured contact your physician for a replacement of the EpiPen®.

Orange needle protection cover

This keeps the needle covered both before and after use.



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Hard flip-top carry case
To ensure the safe transport and quick access of the EpiPen®

Check the viewing window of your EpiPen® regularly to make sure the solution is clear and colourless.

Needle cover

Before Use After Use



Viewing window

Before Use After Use



b) How to use the EpiPen®/EpiPen® Junior

Remove the EpiPen®/EpiPen® Junior from the carry case. Lie down with your legs slightly elevated to keep your blood flowing or sit up if breathing is difficult.

If you are wearing clothes EpiPen®/EpiPen® Junior can be injected through the clothes. EpiPen®/EpiPen® Junior should **ONLY** be injected into the outer thigh. It should not be injected into the buttocks.

In case of injection performed by a caregiver, immobilization of the patient's leg should be ensured during injection to minimize the risk of leg laceration. In no case reinsert the used needle.



- 1) Grasp EpiPen®/EpiPen® Junior 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®/EpiPen® Junior at a distance of approximately 10cm away from the outer thigh. The orange tip should point towards the outer thigh.



- 4) Jab the EpiPen®/EpiPen® Junior firmly into outer thigh at a right angle (90° angle) (listen for click).
- 5) Hold firmly against thigh for 3 seconds. The injection is now complete and the viewing window on the auto-injector is obscured.



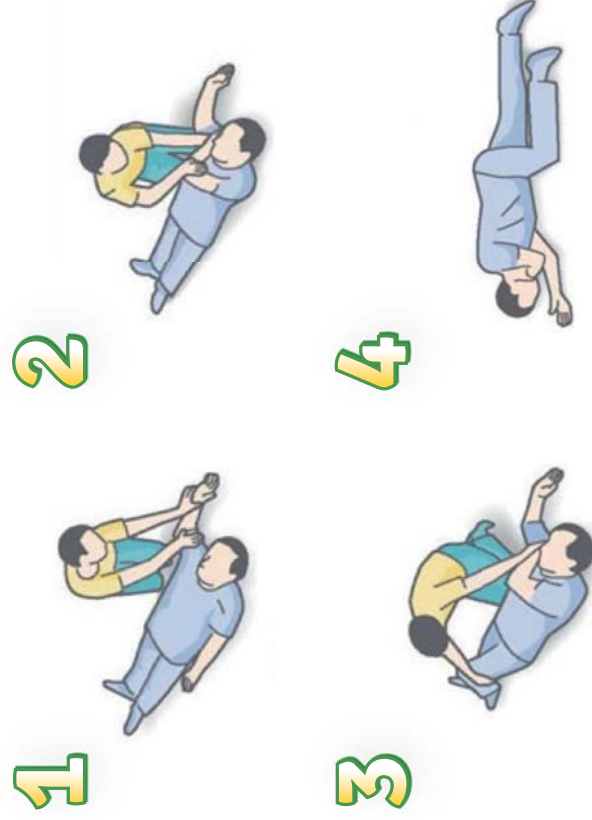
- 6) EpiPen®/EpiPen® Junior should be removed (the orange needle cover will extend to cover needle) and safely discarded.
Gently massage the injection area for 10 seconds. Dial 112, ask for ambulance and state 'anaphylaxis', even if symptoms appear to be improving.



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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 in the recovery position.



You can learn more by visiting www.epipen.ie and watching the “How to use the EpiPen®/EpiPen® Junior” video.

Always carry two EpiPen®/EpiPen® Junior with you at all times — in case symptoms do not improve within 5–15 minutes and a second dosage is needed. Each EpiPen®/EpiPen® Junior can only be used once.

Explain to others that you are at risk for an anaphylactic reaction and about your trigger. Make family, friends, teachers and colleagues aware how to recognize symptoms of anaphylaxis and what to do in the event of a reaction. Make sure they know where you keep your EpiPen®/EpiPen® Junior and how to administer it.

If using an EpiPen® trainer, please ensure to store the active device and the trainer device separately in order to avoid confusion in an emergency situation.

3 EPIPEN®/EPIPEN® JUNIOR FAQS

Q: What is the difference between EpiPen® and EpiPen® Junior?

A: They both contain adrenaline, but in different amounts. If you weigh more than 30kg, you will need EpiPen®, if you weigh between 15 and 30kg, you will need EpiPen® Junior. Your GP will decide which is right for you.

Q: How will I know that my EpiPen®/EpiPen® Junior has worked and that I have received the adrenaline I need?

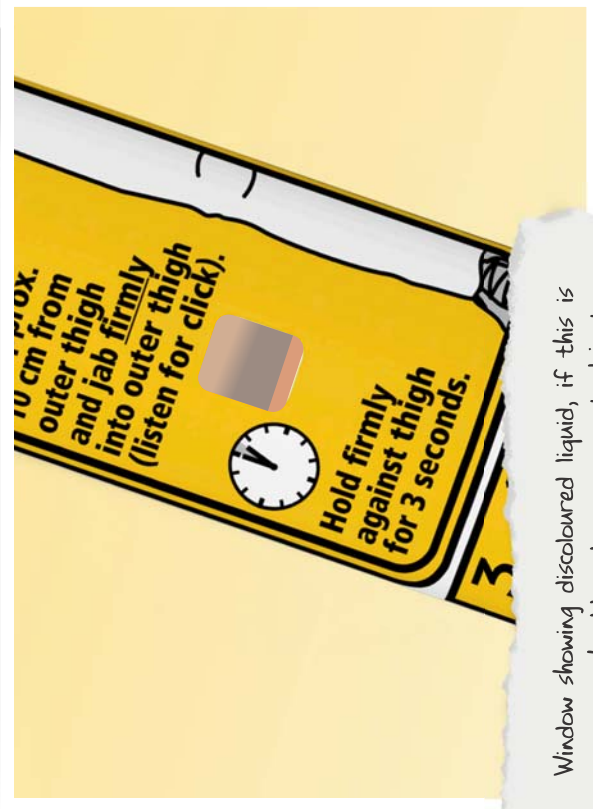
A: When you swing and jab the EpiPen®/EpiPen® Junior into your thigh, the needle and the dose of adrenaline will be released. After removing the EpiPen®/EpiPen® Junior, the orange end will extend to cover the needle and the viewing window will go dark. There will still be some adrenaline left in the pen, this is perfectly normal. You will quickly start to feel that the adrenaline is working. Remember, each EpiPen®/EpiPen® Junior can only be used once.



EpiPen® Junior - Suitable for people who weigh between 7.5 and 30kg.



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Window showing discoloured liquid, if this is seen you should replace your auto-injector.

Q: There is an “air” bubble in my EpiPen®/EpiPen® Junior, is it still okay to use?

A: The bubble is a type of gas called nitrogen, and it is perfectly normal to find it in an EpiPen®/EpiPen® Junior. Don't worry about using your pen as the bubble will not interfere with how it works.

Q: How do I store my EpiPen®/EpiPen® Junior?

A: Adrenaline is sensitive to light. Keep the auto-injector 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.

Do not store above 25°C. Do not refrigerate, freeze or expose the EpiPen®/EpiPen® Junior to extreme heat.

Please remember to check the contents of the glass cartridge in the EpiPen®/EpiPen® Junior auto-injector from time to time to make sure the liquid is still clear and colourless. Replace the auto-injector by the expiry date or earlier if the solution is discoloured or contains a precipitate (solid matter).



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Q: How do I dispose of an out-of-date EpiPen®/EpiPen® Junior which has not been used?

A: Contact your GP surgery or your pharmacist, who will be able to advise you.

Q: What do I do if I notice that my EpiPen®/EpiPen® Junior is out of date?

A: Make sure you see your GP or pharmacist as soon as possible to get a new pen. Set yourself an expiry alert on your mobile device to receive reminders when your pen is about to expire.

Q: What do I have to consider with the EpiPen®/EpiPen® Junior when travelling?

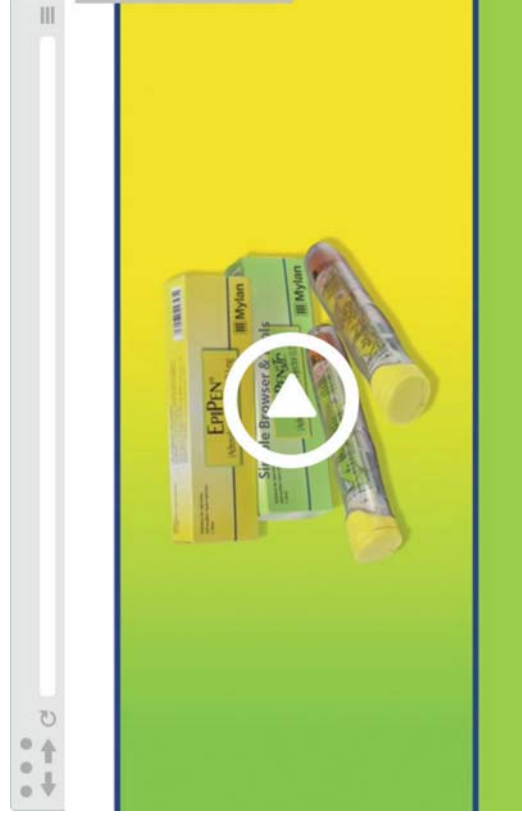
A: Be prepared to have enough devices with you, since there are countries where it is difficult to get an EpiPen®/EpiPen® Junior. Furthermore, some airlines request a medical certificate from your GP before you can fly. Inform your airline prior to your flight if this is necessary.

Any problems with your EpiPen®/EpiPen® Junior you should contact your GP surgery or your pharmacist, who will be able to advise you.



4 BE ONE WITH YOUR EPIPEN®/EPIPEN® JUNIOR

To directly train on the use of your EpiPen® / EpiPen® Junior scan the following QR-code using a QR code reader (e.g. i-ngma) or enter www.epipen.ie



Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the patient information leaflet.

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 the Patient Information Leaflet.

You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

You should also report any side effects to Mylan IRE Healthcare Limited Pharmacovigilance on +44(0)8001218267 and pv.ireland@viatris.com

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