

NEW ZEALAND CONSUMER MEDICINE INFORMATION

EPIPEN[®] JR

Adrenaline (epinephrine)* 150 µg/0.3 mL Auto-Injector

* In some countries, adrenaline is known as epinephrine



What is in this leaflet?

This leaflet answers some common questions about EpiPen[®] Jr. Adrenaline Auto-Injector. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of your child receiving EpiPen[®] Jr. against the benefits this medicine is expected to have for them.

If you have any concerns about your child receiving this medicine, talk to your doctor or pharmacist before there is a situation where EpiPen[®] Jr. is needed.

Please read this leaflet carefully before an emergency arises.

Keep this leaflet safely, with the EpiPen[®] Jr. Auto-Injector. You will probably want to read it again.

What EpiPen[®] Jr. is used for

EpiPen[®] Jr. is only to be used for the immediate EMERGENCY TREATMENT of a SEVERE ALLERGIC REACTION (also known as ANAPHYLAXIS). Your doctor or pharmacist will explain what this is like, so that you know when you must use EpiPen[®] Jr.

EpiPen[®] Jr. is used to treat children who have a severe allergic reaction caused by, for example, hypersensitivity to

- food
- medicines
- stinging insects

- insect bites
- latex or
- other allergens, possibly unidentified.

See Side effects for information regarding allergy to sodium metabisulfite.

Avoidance of known allergens is most important in preventing severe allergic reactions.

A severe allergic reaction, otherwise known as anaphylaxis, is overwhelming and life-threatening.

It affects the whole body, in particular the

- heart and blood circulation.

This may cause, for example, low blood pressure and collapse, or abnormal heart beat or function.

- air passages and lungs.

This causes difficulty in breathing, with noisy wheezing or gasping, possibly with sneezing and a very runny nose.

- stomach and bowels.

This may cause nausea, vomiting, diarrhoea and abdominal cramps, often severe.

- skin (very common).

This causes flushing, itching, skin rash, hives or swelling, which may be widespread or in one part of the body.

- brain.

There may be fits or confusion due to lack of oxygen.

Usually several parts of the body are affected. The patient feels extremely unwell.

It is important to act quickly to treat a severe allergic reaction.

The adrenaline in EpiPen[®] Jr. treats allergic emergencies. It

- shrinks abnormally wide blood vessels and
- makes the heart beat strongly.

This helps improve the very low blood pressure and poor circulation that occur in a severe allergic reaction.

Adrenaline also

- relaxes the lungs. This eases breathing and lessens wheezing.
- helps stop
-swelling, for example, of the face and lips
-skin rash and/or
-itching.

The EpiPen[®] Jr. Auto-Injector is intended for use in children who have been assessed and advised by their doctor as needing an EpiPen[®] Jr. Auto-Injector to treat their severe allergic reaction and who

- weigh from 15 kg up to 30 kg, and
- are having a severe allergic reaction.

NOTE: Selection of the appropriate dosage is determined according to patient body weight.

For a child who weighs from 15kg up to 30kg, the doctor may assess their severe allergic reaction as needing the larger dosage of adrenaline as provided by an EpiPen[®] Auto-Injector. (The EpiPen[®] Jr. Auto-Injector delivers a smaller dosage of adrenaline). Similarly, there may be instances

where the doctor will recommend the use of EpiPen® Jr. in some adults, based on careful medical assessment.

If you have any questions about this, talk to your doctor.

EpiPen® Jr.

- provides convenient first-aid
- may be self-administered or administered by a carer to the child
- has a spring-activated, hidden needle
- automatically injects one pre-measured dose of adrenaline
- is for single use only.

EpiPen® Jr. may be prescribed by your doctor. You can also purchase it directly from a pharmacy.

Before you use EpiPen® Jr.

The EpiPen® Jr. Auto-Injector is simple to use. Please read and follow the step-by-step instructions.

Do not remove the blue safety release until you need to use EpiPen® Jr. and are ready to use it. The safety release stops EpiPen® Jr. from “firing” or working.

There is no visible needle. This helps overcome fear of injection. The hidden needle is very fine so that the injection does not usually hurt.

When you must not use it

EpiPen® Jr. is a life-saving treatment in the emergency management of severe allergic reactions. Therefore, it should not be withheld from anyone who is considered to need it.

The EpiPen® Jr. Auto-Injector has a clear “viewing window” so you can see the contents.

Do not use EpiPen® Jr. if the contents

- are coloured or
- contain sediment or

- **if the “viewing window” is obscured.**

These changes indicate that the effectiveness of the drug product may be decreased.

When the “viewing window” is obscured, the auto-injector has already “fired” and cannot be used again.

Check your EpiPen® Jr. regularly (see Things you must do).

Do not use EpiPen® Jr.

- **after the expiry date on the EpiPen® Jr. Auto-Injector and carton or**
- **if the packaging is torn, doesn’t look quite right or shows signs of tampering.**

If the EpiPen® Jr. packaging is damaged or it is past the expiry date, return it to your pharmacist for disposal.

Help in using EpiPen® Jr.

It is important to know how to use an EpiPen® Jr. BEFORE a severe allergic reaction causes a medical emergency.

Ask your doctor or pharmacist how you can get an EpiPen® Training Device for practice.

An EpiPen® Training Device is similar to the real EpiPen® Jr. However, the EpiPen® Training Device has

- **NO medicine (adrenaline) and**
- **NO needle and**
- **“fires” quietly and less forcefully.**

Ask your doctor or pharmacist to show you how to practice with the EpiPen® Training Device. If you practice using the EpiPen® Training Device, it will help you to learn how to use the real EpiPen® Jr.

It is important to regularly ask your doctor or pharmacist to demonstrate use with an EpiPen® Training Device.

EpiPen® Jr. is effective as emergency treatment of a severe allergic reaction ONLY when used according to the directions in this leaflet.

Give WITH CAUTION to those who have

- high blood pressure
- thyroid problems
- high pressure in the eye (narrow-angle glaucoma).

Take care also when giving EpiPen® Jr. to those

- having an anaesthetic

or who have:

- diabetes
- heart disease
- allergy to EpiPen® Jr.
- brain damage.

You should tell your doctor or pharmacist if your child has:

- depression, or is on medication for depression
- thyroid problems, or is on thyroid medication
- heart disease or high blood pressure
- diabetes
- high pressure in the eye (narrow angle glaucoma)
- asthma
- ever had an allergic reaction to sodium metabisulfite.

Taking other medicines

Tell your doctor or pharmacist if your child is taking other medicines, including any medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with EpiPen® Jr. including:

- medicines for high blood pressure, especially those known as “beta-blockers”, and other medicines for heart problems
- medicines for depression, especially “tricyclic antidepressants”
- thyroid hormone
- medicines for diabetes
- antihistamines.

These medicines may affect how well the adrenaline in EpiPen® Jr. works. Your doctor or pharmacist can tell you what to do if your child is taking any of these medicines.

You should discuss any concerns you have with your doctor or pharmacist.

How to use EpiPen® Jr.

It is important to know how to use your EpiPen® Jr. in an emergency (see Help in using EpiPen® Jr.).

Follow carefully all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet or on the EpiPen® Jr. Auto-Injector, ask your doctor or pharmacist for help.

When to use it

Use EpiPen® Jr. immediately if your child has signs and symptoms of a severe allergic reaction, as described by your doctor or pharmacist. Symptoms do vary. However, the symptoms are likely to include:

- collapse
- difficulty in breathing
- wheezing
- swelling, especially of the face, lips, tongue or throat
- flushing of the face
- irregular or faint pulse
- vomiting, diarrhoea, stomach cramps
- skin rash, hives
- itching.

How much to use

- EpiPen® Jr. Auto-Injector delivers one measured dose of adrenaline. This dose is intended for a child who weighs 15 kg to 30 kg and has been assessed by their doctor as needing EpiPen® Jr.

NOTE: Your child's doctor may advise EpiPen® Auto-Injector for the treatment of an anaphylactic attack in children who weigh from 15 kg up to 30 kg after careful assessment of their body weight and the severity of their symptoms.

Similarly, there may be instances where the doctor will recommend the use of EpiPen® Jr. in some adults, based on careful medical assessment.

See also "What EpiPen® Jr. is used for" above.

How to use it

General

- Grip only the *mid-section* of the EpiPen® Jr. Auto-Injector. Avoid touching either end, except when you remove the blue safety release. The blue safety release stops the EpiPen® Jr. from "firing" or working.
- Never place thumb, fingers or hand over the orange end as this contains the needle.
- Always point the orange end (which holds the needle) away from any part of the body, except the planned injection site. This is usually the thigh of the child who has the severe allergic reaction.
- Always hold the leg firmly during injection especially in people who are uncooperative and kick or move during an injection. This will reduce the risk of injection injuries.
- Keep EpiPen® Jr. away from the face and eyes.
- Never inject EpiPen® Jr. into the buttock.

Carefully follow the step-by-step directions to make the EpiPen® Jr. work properly.

Step 1

Flip open the green cap on the protective carry tube. Carefully tip and slide the EpiPen® Jr. Auto-Injector out of the carry tube. Never place thumb, fingers or hand over the orange end as this contains the needle. Check the contents of the

EpiPen® Jr. Auto-Injector through the "viewing window". Make sure the solution is clear, colourless and sediment-free. If the "viewing window" is obscured, the EpiPen® Jr. has already "fired" and cannot be used again.

Step 2

Make a fist around the EpiPen® Jr. Auto-Injector, with your thumb nearest to the blue safety release (see FIGURE 1).

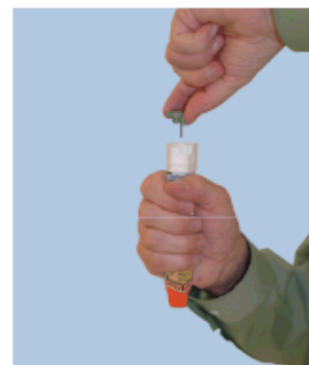


FIGURE 1

Step 3

Activate the EpiPen® Jr. Auto-Injector by removing the blue safety release with your other hand (also shown in FIGURE 1). This "triggers" the EpiPen® Jr. It is now ready to

- "fire" the needle and
- inject the medicine through the needle into the child's thigh muscle.

After you remove the blue safety release do not touch or place thumb, fingers or hand over the orange end as this contains the needle.

Step 4

Hold the EpiPen® Jr. Auto-Injector at a 90° angle (right angle) to the outer part of the child's thigh. Hold the orange end about 5cm away from the thigh (see FIGURE 2).



FIGURE 2

Step 5

Hold the child's leg firmly, especially if they are uncooperative or may kick or move during the injection.

Push the orange end **FIRMLY** into the child's outer mid-thigh until a "click" is heard or felt. Keep pressing the EpiPen[®] Jr. Auto-Injector firmly against the thigh for approximately 3 seconds (see FIGURE 3).



FIGURE 3

NOTE: EpiPen[®] Jr. may be used either

- through clothing, as shown in FIGURE 3, or
- directly on to skin.

When you press the orange end of the EpiPen[®] Jr. Auto-Injector firmly against the thigh, the hidden needle "fires". It injects the measured dose of adrenaline into the child's thigh muscle.

Step 6

Carefully take the EpiPen[®] Jr. Auto-Injector away from the thigh.

The orange needle cover will extend to cover the needle. (see FIGURE 4).



FIGURE 4

Check the "viewing window" - it should now be obscured. If it isn't, the EpiPen[®] Jr. has not "fired" or worked. If the "viewing window" is not obscured, repeat steps 2-6 above.

Step 7

Record the time EpiPen[®] Jr. was given.

Step 8

Seek further medical attention for your child immediately. Although the child has received adrenaline from EpiPen[®] Jr., he/she may need more medical treatment.

Either

- **Contact your doctor or**
- **Call an ambulance (telephone 000 in Australia or 111 in New Zealand). State that adrenaline treatment may be needed.**

NOTE: EpiPen[®] Jr. is only for immediate emergency treatment of a severe allergic reaction. Further treatment is usually needed.

Step 9

Explain to the doctor that your child has had EpiPen[®] Jr. (intramuscular adrenaline).

Take your used EpiPen[®] Jr. Auto-Injector with you.

To avoid injury, follow the used EpiPen[®] Jr. disposal instructions below (see Disposal).

Additional information about treatment of insect sting allergy

Use EpiPen[®] Jr. immediately if you or your child have been stung or

bitten by the insect and experience the signs and symptoms as described by your doctor or pharmacist.

If the insect's sting is easily accessible, remove the sting with your fingernails. Do not squeeze, pinch or push the sting deeper into the skin. If available, ice packs or sodium bicarbonate soaks may then be applied to the stung area.

Keep warm, calm, and as still as possible.

If you use too much (overdose)

Because each EpiPen[®] Jr. contains only one dose, overdosage is unlikely. Overdosage may lead to a rise in blood pressure. This may cause bleeding in the brain or fluid in the lung.

If you think you or anyone else may have used too much of this medicine,

- consult your doctor immediately or
- telephone the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 POISON (0800 764 766) in New Zealand) for advice, or
- go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. Urgent medical attention may be required.

Things to note about EpiPen[®] Jr.

Things you must do

Check what the expiry date is on your EpiPen[®] Jr.

Mark this expiry date on your calendar or diary.

Replace your EpiPen[®] Jr. prior to this expiry date.

Also note on your calendar or diary to check the contents of your EpiPen[®] Jr. each month. Do this through the "viewing window".

Make sure the solution is clear, colourless and sediment-free. If not, obtain a new EpiPen® Jr. immediately.

If the “viewing window” is obscured this means the EpiPen® Jr. has already “fired” or worked. It cannot be used again. Return it to your doctor or pharmacist for disposal. Obtain a new EpiPen® Jr. immediately.

The EpiPen® Jr. Auto-Injector can be damaged and made unusable if it is mishandled.

EpiPen® Jr. is NOT a toy. Keep it out of reach of children.

Things you must not do

Do not use EpiPen® Jr.

- to treat any other medical conditions including other types of shock unless your doctor tells you to.
- if the solution is brown or contains any particles or cloudiness.
- in a child who weighs more than 30 kg unless advised by your doctor. EpiPen® is generally recommended for any adult or child who weighs more than 30 kg.
- in a child who weighs less than 15 kg. Talk to your doctor if this is the case so that a careful assessment can be made and the appropriate dose selected based on the individual's weight and the life-threatening nature of the reaction(s) for which EpiPen® Jr. is being prescribed.

Do not take off the blue safety release until you need to use EpiPen® Jr. and are ready to use it.

Remember that the EpiPen® Jr. Auto-Injector is activated (“triggered”, ready to “fire”) as soon as you take off the blue safety release.

Do not touch the orange end on any person or object while you are taking off the blue safety

release and/or after you have taken off the blue safety release.

The orange end holds the hidden needle, ready to “fire” and inject the adrenaline.

After you take off the blue safety release

- **Do not “click” on either end of the EpiPen® Jr. Auto-Injector. The EpiPen® Jr. Auto-Injector does not work like a retractable ball-point pen (see How to use it step 3).**
- **Do not bump the EpiPen® Jr. Auto-Injector until you intentionally push the orange end firmly into the child's thigh (see How to use it step 4). This will help prevent accidental activation of the EpiPen® Jr. Auto-Injector prior to use.**

Do not inject into hands, feet, ears, nose, buttocks, genital area or into a blood vessel.

If this does happen accidentally you must immediately seek medical attention.

Do not inject into the buttock.

Rare cases of serious skin infections have been reported following injection into the buttock. If you develop signs or symptoms of infection, such as persistent redness, warmth, swelling or tenderness at the adrenaline injection site, you must seek medical attention immediately.

Side effects

Like all medicines, EpiPen® Jr. can cause some side effects. Side effects not listed in this leaflet may occur in some patients.

Tell your doctor or pharmacist if your child experiences any unpleasant side effects after using EpiPen® Jr., even if you do not think the effect is connected with the medicine or is listed in this leaflet. Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following list of side effects. Your child may not experience any of them.

Adrenaline

Tell your doctor or pharmacist if your child has any of the following:

- fast or noticeable heart beat
- difficulty breathing
- shortness of breath
- dizziness
- pale skin colour
- weakness
- tremor
- headache
- throbbing
- sweating
- nausea or vomiting
- sleeplessness
- coldness
- hallucinations
- restlessness
- anxiety
- fear
- flushing or redness of face and skin.

These side effects are minor and short lasting.

Accidental injection into the hands, fingers or feet may result in the following:

- fast or noticeable heart beat
- pale skin colour at the site of accidental injection
- feeling of coldness at the site of accidental injection
- bruising or discolouration at the site of accidental injection
- bleeding.

If an accidental injection occurs at one of these areas, seek medical attention immediately.

Injection related injuries, such as needle cuts and bent needles, have been reported in people who are uncooperative and kick or move during the injection.

Rare cases of serious skin infections have been reported following injection into the buttock.

More severe side effects can occur occasionally. They are caused by adrenaline stimulating the heart and

increasing the blood pressure. Rarely, these side effects can cause, for example, a stroke, lung problems or severe irregular heartbeat.

Adrenaline may also cause disorientation and impaired memory.

Sodium metabisulfite

EpiPen® Jr. contains a very small quantity of sodium metabisulfite as a preservative. In people who are allergic to sodium metabisulfite, this could cause, for example, severe asthma. However, the active ingredient, adrenaline, in EpiPen® Jr. is expected to overcome any allergic reaction to sodium metabisulfite. In an emergency, the risk of exposure to the very small amount of sodium metabisulfite is generally outweighed by the benefits of EpiPen® Jr.

Storing EpiPen® Jr. before use

Always handle the EpiPen® Jr. Auto-Injector carefully, so as not to accidentally activate it or make it “fire” or work.

Storage

Keep EpiPen® Jr. available with the child for whom it is intended.

Keep EpiPen® Jr. in a cool dry place below 25°C. Temperature excursions between 15°C to 25°C are permitted.

Do not place EpiPen® Jr. in the fridge. Do not leave EpiPen® Jr. in your car. Extreme temperatures may cause the auto-injector unit to malfunction.

Protect EpiPen® Jr. from light. Keep EpiPen® Jr. in the protective carry tube until required.

Do not store EpiPen® Jr. or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep EpiPen® Jr. where children cannot accidentally reach it.

After using EpiPen® Jr.

Disposal

After the EpiPen® Jr. Auto-Injector has “fired” or worked, the orange needle cover will extend to cover the exposed needle. After use, continue to handle the EpiPen® Jr. Auto-Injector safely and with care. Do this even if you think the EpiPen® Jr. Auto-Injector has not “triggered”, “fired” or worked properly.

You CANNOT RE-USE the EpiPen® Jr. Auto-Injector even though some adrenaline is left inside it.

After use, do not just throw away the EpiPen® Jr. Auto-Injector.

- **Do not tamper with the orange needle cover.**
- **Do not replace the blue safety release.**
- **The used auto-injector with extended needle cover will not fit back into the carry tube.**
- **Give your used EpiPen® Jr., to the doctor’s office or to a hospital. This is for inspection, if required, and also for safe disposal. The used EpiPen® Jr. should be placed in a rigid sharps disposal unit.**

Product description

Ingredients

EpiPen® Jr. delivers one x 0.3 mL dose of adrenaline (epinephrine). This EpiPen® Jr. dose provides 150 µg of adrenaline (epinephrine).

The EpiPen® Jr. Auto-Injector holds 2 mL of adrenaline (epinephrine) 1:2,000 solution.

The injection also contains small amounts of

- sodium chloride
- sodium metabisulfite
- hydrochloric acid.

It does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

The EpiPen® Jr. Auto-Injector is packed in a protective plastic carry tube. This carry tube has a green cap. The carry tube is supplied in a cardboard pack.

This is not all the information available on EpiPen® Jr. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Supplier

Distributed in New Zealand by:

Mylan NZ Ltd
Auckland,
New Zealand.
Phone: 0800 168 169

Supplied by:

Mylan Speciality L.P., an affiliate of Mylan Inc., Napa, CA 94558, USA.

Produced for Mylan Speciality L.P., Napa, CA, 94558 by:

Meridian Medical Technologies Inc., Columbia, MD, 21046, USA, a Pfizer company.

EpiPen® is a registered trademark of Mylan, Inc.

7 April 2017 (based on the datasheet dated 7 April 2017)