

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 contains the active ingredient adrenaline (epinephrine). Adrenaline belongs to a group of medicines called adrenergic and dopaminergic agents which are classified as cardiac stimulants. In some countries, adrenaline is known as epinephrine.

Adrenaline is a natural hormone released in response to stress. Adrenaline is known to:

- shrink abnormally wide blood vessels and
- make the heartbeat 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, throat, tongue, hands and feet
 - skin rash and/or
 - itching.

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, usually several parts of the body. In particular:

- heart and blood circulation.

This may cause, for example, low blood pressure and collapse, or abnormal heartbeat 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.

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

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.

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

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.

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.

When you must not use it

Do not use EpiPen Jr if

- the packaging is torn, doesn't look quite right or shows signs of tampering
- the contents:
 - are cloudy or
 - 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 cannot be used again.

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

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;
- has NO needle and;
- “fires” quietly and less forcefully and;
- can be reset and reused.

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).

If you have a thick layer of fat under your skin, the adrenaline in EpiPen may not reach your muscle tissue. In some cases this might make EpiPen not work as well and may result in needing a second injection with an additional EpiPen Jr.

Take care also when giving EpiPen Jr to those

- having an anaesthetic

or who have

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

Check with your doctor or pharmacist if your child has

- heart disease or high blood pressure
- Parkinson's disease
- depression, or is on medication for depression
- thyroid problems, or is on thyroid medication
- diabetes
- high pressure in the eye (narrow angle glaucoma)
- asthma
- ever had an allergic reaction to sodium metabisulfite
- severe kidney problems
- a tumour in your prostate (prostatic adenoma leading to residual urine)
- high calcium levels or low potassium levels in your blood.

Talk to your doctor if you are allergic to sodium metabisulfite or any of the ingredients listed at the end of this leaflet and have not consulted your doctor or specialist beforehand.

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 and affect how it works. These include medicines for:

- heart disease (e.g. digitalis (digoxin), quinidine, alpha and beta blocking medicines)
- treatment of Parkinson's disease (e.g. catechol-O-methyl transferase inhibitors or levodopa)
- depression (especially “tricyclic antidepressants” or monoamine oxidase inhibitors)
- thyroid hormone (e.g. levothyroxine sodium or thyroid hormones)
- diabetes
- making you breathe more easily, used for asthma (e.g. theophylline)
- used in labour (e.g. oxytocin)
- acting on the nervous system (parasympatholytics)
- treating allergies (antihistamines e.g. diphenhydramine or chlorpheniramine)

- anaesthesia (e.g. halothane, cyclopropane or trichlorethylene).

These medicines may affect how well the adrenaline in EpiPen Jr works.

People with diabetes should carefully monitor their glucose levels after use of EpiPen Jr Auto-Injector as adrenaline can affect the amount of insulin made by the body, thus increasing the blood glucose level.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements your child is taking and if these affect EpiPen Jr.

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
- in some cases, loss of consciousness.

In case the first administration is not sufficient, you should carry two EpiPen Jr Auto-Injector pens with you at all times.

How much to use

For single use only. EpiPen Jr Auto-Injector delivers a fixed dose of adrenaline. The EpiPen Jr Auto-Injector must be replaced immediately after use. The usual dose is 0.15 mg adrenaline for injection into muscle (intramuscular use).

The dose will be decided by your doctor, who will adjust it individually for your child.

Use in children weighing between 15 kg and 30 kg

EpiPen Jr is intended for a child who weighs between 15 kg and 30 kg and has been assessed by their doctor or pharmacist.

NOTE: Selection of the appropriate dosage is determined according to the careful medical assessment, patient's body weight and the severity of their symptoms. The doctor or pharmacist may choose to recommend more or less than this amount.

For a child who weighs between 15 kg and 30 kg, the doctor or pharmacist may advise EpiPen Auto-Injector for the treatment of an anaphylactic attack after careful assessment of their body weight and the severity of their symptoms.

There may be instances where the doctor or pharmacist 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 or pharmacist.

How to use it

Important information – Before use:

- **Before you ever need to use it, fully familiarise yourself with the EpiPen Jr Auto-Injector, when and how it should be used.**
- It is recommended that your family members, carers, teachers are also instructed in the correct use of the Auto-Injector.
- 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.
- Always point the orange end (which holds the needle) away from any part of the body, except the planned injection site. This is 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.
- Always keep the Auto-Injector away from the face and eyes.
- Never inject the Auto-Injector 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. Check the contents of the EpiPen Jr Auto-Injector through the viewing window. Make sure the solution is clear, colourless and sediment-free.

Check the expiration date located on the side of the Auto-Injector. Replace the Auto-Injector if the expiration date has passed.

Do not take off the blue safety release if you are not preparing for an injection.

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

Note: To avoid an accidental injection, never place thumb, fingers

or hand over the orange end as this contains the needle. If an accidental injection happens, get medical help right away.

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.**
- Do not “click” on either end of the EpiPen Jr Auto-Injector. The Auto-Injector does not work like a retractable ball-point pen.
- **Do not bump the EpiPen Jr Auto-Injector if you are not preparing for an injection.** This will help prevent accidental activation of the EpiPen Jr Auto-Injector prior to use.

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 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 the “viewing window” is not obscured, repeat steps 2-6 above.

Step 7

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 111 in New Zealand). State your child have had EpiPen Jr (intramuscular adrenaline) even if symptoms appear to be improving.**

While waiting for the ambulance your child should lie down with the feet raised unless this makes your child breathless in which case your child should sit up. Stay with your child until the ambulance arrives in case your child feels unwell again.

Unconscious patients should be placed on their side in the recovery position.

Step 8

Record the time EpiPen Jr was given.

Step 9

With severe, persistent allergic reactions, repeat injections with an additional EpiPen Jr may be necessary. The EpiPen Jr dose may be repeated every 5 to 15 minutes if symptoms recur or have not subsided. **Two Auto-Injectors should always be carried in case a second dose is required.**

Do not inject more than two sequential doses of EpiPen Jr unless under medical supervision. An overdose of adrenaline could cause harm.

Your child 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.

Important information – After use

- EpiPen Jr Auto-Injector is a single-use injectable device that delivers a fixed dose of adrenaline.
- The Auto-Injector **cannot be reused**. Do not try to reuse EpiPen Jr after the Auto-Injector has been activated.
- The correct dose has been administered if the orange needle tip is extended and the viewing window is blocked.
- Do not tamper with the orange needle cover.
- Do not replace the blue safety release.
- After the Auto-Injector has been used, the extended needle cover will not fit back into the carry tube.
- To avoid injury, follow the used EpiPen Jr disposal instructions (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, overdose 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 that you have used too much EpiPen Jr, you may need urgent medical attention.

You should immediately:

- consult your doctor or
- telephone the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or
- go to Accident and Emergency at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Things to note about EpiPen Jr

Things you must do

Check the expiry date on your EpiPen Jr and mark this expiry date on your calendar or diary.

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

Obtain a new EpiPen Jr immediately when:

- the solution is brown or contains any particles or cloudiness
- the viewing window is obscured. Return it to your doctor or pharmacist for disposal.
- the Auto-Injector has previously been used
- the Auto-Injector is about to expire.

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.
- Do not use EpiPen Jr in a child who weighs more than 30 kg unless advised by your doctor or pharmacist. EpiPen is generally recommended for any adult or child who weighs 30 kg or more.
- **Do not use EpiPen Jr 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 is selected based on the individual's weight and the life-threatening nature of the reaction(s) for which EpiPen is being prescribed.
- **Do not use EpiPen Jr if the solution is brown or contains any particles or cloudiness.**
- **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.**
- **Do not inject into hands, feet, ears, nose, buttocks, genital area or into a blood vessel.**
- **If this dose happens accidentally you must immediately seek medical attention.**

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

These side effects are minor and short lasting.

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

- fast or noticeable heartbeat
- 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
- skeletal injury.

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.

In case of signs or symptoms of injection site infection, such as swelling, persistent redness, heat (warmth) or pain (tenderness) always seek medical help immediately.

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, severe irregular heartbeat, 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 allergic reactions (hypersensitivity) or breathing difficulty (bronchospasm) in certain groups of people, especially those with history of 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.

Store below 25°C. Temperature excursions between 15°C to 25°C are permitted.

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

Store EpiPen in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the fridge
- the bathroom or near a sink
- in the car or on a windowsill.

Extreme temperatures e.g. heat and dampness may cause the Auto-Injector unit to malfunction.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep EpiPen Jr where children cannot accidentally reach it.

After using EpiPen Jr

Disposal

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

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.

Give your used EpiPen Jr to the doctor, pharmacist 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

Contains sulfites.

The EpiPen Jr Auto-Injector is packed in a non-waterproof 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.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

EpiPen® Jr is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

30 April 2025 (based on the datasheet dated 7 April 2025)

EPIPEN® is a Viatrix company trade mark.