

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using EPIPEN?

EPIPEN contains the active ingredient adrenaline (epinephrine). In some countries, adrenaline is known as epinephrine. EPIPEN is only to be used for the immediate EMERGENCY TREATMENT of a SEVERE ALLERGIC REACTION (also known as ANAPHYLAXIS).

For more information, see Section [1. Why am I using EPIPEN?](#) in the full CMI.

2. What should I know before I use EPIPEN?

EPIPEN 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. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use EPIPEN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EPIPEN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use EPIPEN?

- EPIPEN delivers one measured dose of adrenaline intended for a person who weighs more than 30 kg. It may be prescribed for a child who weighs from 15 kg up to 30 kg.

More instructions can be found in Section [4. How do I use EPIPEN?](#) in the full CMI.

5. What should I know while using EPIPEN?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using EPIPEN.Check the expiry date on EPIPEN and request for replacement prior to the expiry date.
Things you should not do	<ul style="list-style-type: none">Do not use EPIPEN to treat any other medical conditions including other types of shock unless advised by the doctor.Do not use EPIPEN if the solution is cloudy, coloured, contains sediment or the viewing window is obscured.Do not take off the blue safety release until required.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 blood vessels.
Driving or using machines	<ul style="list-style-type: none">Your ability to drive and use machines may be affected by the anaphylactic reaction and possible adverse effects to adrenaline.
Looking after your medicine	<ul style="list-style-type: none">Keep EPIPEN in a cool dry place below 25°C. Temperature excursions between 15°C to 25°C permitted. Do not refrigerate. Protect EPIPEN from light. Keep EPIPEN in the protective carry tube until required.

For more information, see Section [5. What should I know while using EPIPEN?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you experience a fast or noticeable heartbeat, difficulty breathing, chest pain or shortness of breath.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

EPIPEN®

Active ingredient(s): *adrenaline (epinephrine)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using EPIPEN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EPIPEN.**

Where to find information in this leaflet:

- [1. Why am I using EPIPEN?](#)
- [2. What should I know before I use EPIPEN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use EPIPEN?](#)
- [5. What should I know while using EPIPEN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using EPIPEN?

EPIPEN contains the active ingredient adrenaline (epinephrine).

EPIPEN 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.

EpiPen is used to treat people 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 Section 6. [Are there any 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 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 Auto-Injector is intended for use in people who have been assessed and advised by their doctor or pharmacist as needing an EpiPen Auto-Injector to treat their severe allergic reaction and who

- weigh more than 30 kg, and
- are having a severe allergic reaction.

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

For a person who weighs from 15 kg up to 30 kg, the doctor or pharmacist 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 amount of adrenaline).

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

EpiPen

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

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

2. What should I know before I use EPIPEN?

The EpiPen 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 and are ready to use it. The safety release stops EpiPen 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.

Warnings

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

Do not use EPIPEN if 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 has already “fired” and cannot be used again.

Check your EpiPen regularly (see Things you should do in Section [5. What should I know while using EPIPEN?](#)).

Do not use EpiPen

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

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

Help in using EpiPen

It is important to know how to use an EpiPen 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. 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.

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

EpiPen 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-subcutaneous fat layer, there is a risk of the adrenaline not reaching the muscle tissue resulting in a suboptimal effect. In such individuals there may be a higher likelihood of needing a second injection with an additional EpiPen.

Take care also when giving EpiPen to those

- having an anaesthetic

or who have:

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

You should tell your doctor or pharmacist if you have:

- depression, or are on medication for depression
- thyroid problems, or are 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with EPIPEN 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 works.

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

4. How do I use EPIPEN?

It is important to know how to use your EpiPen in an emergency (see Help in using EpiPen in Section [2. What should I know before I use EPIPEN?](#)).

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 Auto-Injector, ask your doctor or pharmacist for help.

How much to use

- EpiPen Auto-Injector delivers one measured dose of adrenaline. This dose is intended for a person who weighs more than 30 kg and has been assessed by their doctor or pharmacist as needing EpiPen.
- Your doctor or pharmacist may also advise EPIPEN Auto-Injector for a child who weighs from 15 kg up to 30 kg.

NOTE: Unless otherwise advised by the doctor or pharmacist, EpiPen Jr. Auto-Injector should be used for children who weigh from 15 kg up to 30 kg.

See also Section [1. Why am I using EPIPEN?](#)

When to take EPIPEN

Use EPIPEN immediately if you have 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 to use EPIPEN

General

- **Grip only the mid-section of the EpiPen Auto-Injector. Avoid touching either end, except when you remove the blue safety release. The blue safety release stops the EpiPen 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 any body, except the planned injection site. This is usually the thigh of the person 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 related injuries.**
- **Keep EpiPen away from the face and eyes.**

- **Never inject EpiPen into the buttock.**

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

Step 1

Flip open the yellow cap on the protective carry tube. Carefully tip and slide the EpiPen 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 Auto-Injector through the “viewing window”. Make sure the solution is clear, colourless and sediment-free. If the “viewing window” is obscured, the EpiPen has already “fired” and cannot be used again.

Step 2

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



FIGURE 1

Step 3

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

- “fire” the needle and
- inject the medicine through the needle into the 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 Auto-Injector at a 90° angle (right angle) to the outer part of the thigh. Hold the orange end about 5cm away from the thigh (see FIGURE 2).



FIGURE 2

Step 5

If you are administering the EpiPen to another person, hold their leg firmly, especially if they are uncooperative.

Push the orange end **FIRMLY** into the outer mid-thigh until a “click” is heard or felt. Keep pressing the EpiPen Auto-Injector firmly against the thigh for approximately 3 seconds (see FIGURE 3).



FIGURE 3

NOTE: EpiPen 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 Auto-Injector firmly against the thigh, the hidden needle “fires”. It injects the measured dose of adrenaline into the thigh muscle.

Step 6

Carefully take the EpiPen 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 has not “fired” or worked. If the “viewing window” is not obscured, repeat steps 2-6 above.

Step 7

Record the time EPIPEN was given.

Step 8

Seek further medical attention for yourself immediately. Although you have received adrenaline from EpiPen, you 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.

Step 9

With severe, persistent allergic reactions, repeat injections with an additional EpiPen may be necessary. The EpiPen dose may be repeated every 5 to 15 minutes if symptoms recur or have not subsided.

Do not inject more than two sequential doses of EpiPen unless under medical supervision.

Step 10

Explain to the doctor that you have had EpiPen (intramuscular adrenaline).

Take your used EpiPen Auto-Injector with you.

To avoid injury, follow the used EpiPen disposal instructions below (see When to discard your medicine (as relevant) in Section [5. What should I know while using EPIPEN?](#)).

Additional information about treatment of insect sting allergy

Use EpiPen immediately if you 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 EPIPEN

Because each EpiPen 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 that you have used too much EPIPEN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26, New Zealand telephone 0800 POISON or 0800 764 766) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

5. What should I know while using EPIPEN?

Things you should do

Check what the expiry date is on your EpiPen.

Mark this expiry date on your calendar or diary.

Replace your EpiPen prior to this expiry date.

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

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

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

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

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

Things you should not do

Do not use EpiPen

- 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 15 kg to 30 kg unless advised by your doctor or pharmacist. EpiPen Jr. is generally recommended for children who weigh 15 kg to 30 kg. (see also Section [1. Why am I using EPIPEN?](#)).
- in a child who weighs less than 15 kg. Talk to your doctor or pharmacist if this is the case so that a careful assessment can be made and the appropriate dose selected based on the child’s weight and the life-threatening nature of the reaction(s) for which EpiPen is being prescribed.

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

Remember that the EpiPen 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 Auto-Injector. The EpiPen Auto-Injector does not work like a retractable ball-point pen (see How to use EPIPEN - Step 3 in Section [4. How do I use EPIPEN?](#)).**
- **Do not bump the EpiPen Auto-Injector until you intentionally push the orange end firmly into the thigh (see How to use EPIPEN - Step 4 in Section [4. How do I use EPIPEN?](#)).**

This will help prevent accidental activation of the EpiPen 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.

Driving or using machines

Your ability to drive and use machines may be affected by the anaphylactic reaction and possible adverse effects to adrenaline.

Looking after your medicine

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

Keep EpiPen available with the person for whom it is intended.

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

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

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

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

- **in the bathroom or near a sink, or**
- **in the car or on window sills.**

Heat and dampness can destroy some medicines.

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

Keep it where children cannot accidentally reach it.

When to discard your medicine (as relevant)

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

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

After use, do not just throw away the EpiPen 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, to the doctor’s office or to a hospital. This is for inspection, if required, and also for safe disposal. The used EpiPen, should be placed in a rigid sharps disposal unit.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> 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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These side effects are minor and short lasting.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> stroke lung problems severe irregular heartbeat disorientation and impaired memory. 	<p>More severe side effects can occur occasionally. They are caused by adrenaline stimulating the heart and increasing the blood pressure.</p> <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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.

Sodium metabisulfite

EPIPEN 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 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or New Zealand at <https://nzphvc.otago.ac.nz/reporting>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What EPIPEN contains

Active ingredient (main ingredient)	Adrenaline (epinephrine)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> sodium chloride sodium metabisulfite hydrochloric acid.
Potential allergens	Sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What EPIPEN looks like

EPIPEN (AUST R 42978) delivers one x 0.3 mL dose of adrenaline (epinephrine). This EPIPEN dose provides 300 µg of adrenaline (epinephrine).

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

The EPIPEN Auto-Injector is packed in a non-waterproof protective plastic carry tube. This carry tube has a yellow cap. The carry tube is supplied in a cardboard pack.

Who distributes EPIPEN

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Distributed in New Zealand by:

Viatris Ltd

PO Box 11-183

Ellerslie

AUCKLAND

www.viatris.co.nz

Telephone 0800 168 169

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