

CONSUMER MEDICINE INFORMATION

What is in this leaflet?

This leaflet answers some common questions about EpiPen® Adrenaline (epinephrine) 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 you receiving EpiPen® against the benefits this medicine is expected to have for you.

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

Please read this leaflet carefully before an emergency arises.

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

What EpiPen® is used for

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 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 (epinephrine) 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 (epinephrine) 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 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 15kg up to 30kg, the doctor may assess their severe allergic reaction as needing the larger dosage of adrenaline (epinephrine) as provided by an EpiPen[®] Auto-Injector. (The EpiPen[®] Jr. Auto-Injector delivers a smaller amount of adrenaline (epinephrine)).

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

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 (epinephrine)
- is for single use only.

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

Before you 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.

When you must not use it

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 must do).

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, epinephrine) 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).

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
- are pregnant or planning to become pregnant
- ever had an allergic reaction to sodium metabisulfite.

Taking other medicines

Tell your doctor or pharmacist if you are 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[®] 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 (epinephrine) in EpiPen[®] works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

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

How to use EpiPen[®]

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

When to use it

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 much to use

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

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

See also “What EpiPen[®] is used for” above.

How to use it

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.**
- **Keep EpiPen[®] away from the face and eyes.**

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

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 10 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 (epinephrine) 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

Gently rub the thigh in the area of the injection for about 10 seconds.

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 (epinephrine) 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 (epinephrine) treatment may be needed.

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

Step 9

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

Take your used EpiPen® Auto-Injector with you.

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

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 (overdose)

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 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[®]

Things you must 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 must 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. EpiPen[®] Jr. is generally recommended for children who weigh 15 kg to 30kg. (See also “What EpiPen[®] is used for” above).**
- **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 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 (epinephrine).

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 it step 3).**
- **Do not bump the EpiPen[®] Auto-Injector until you intentionally push the orange end firmly into the thigh (see How to use it step 4).**
- **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.

Side effects

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

Tell your doctor or pharmacist if you experience any unpleasant side effects after using EpiPen[®], 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. You may not experience any of them.

Adrenaline (epinephrine)

Tell your doctor or pharmacist if you have 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.

More severe side effects can occur occasionally. They are caused by adrenaline (epinephrine) 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 (epinephrine) may also cause disorientation and impaired memory.

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 asthma. However, the active ingredient, adrenaline (epinephrine), 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[®].

Storing EpiPen[®] before use

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

Storage

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.

Do not store EpiPen[®] 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[®] where children cannot accidentally reach it.

After using EpiPen[®]

Disposal

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 (epinephrine) 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.**

Product description

Ingredients

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

The Australian Registration Number is AUST R 42978.

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

Supplier

EpiPen® is distributed in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Distributed in New Zealand by:

Mylan NZ Ltd

Auckland, New Zealand.

Phone: 0800 168 169

Supplied by:

DEY® Pharma L.P., an affiliate of Mylan, Inc., Napa, CA 94558, USA.

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