$EPIPEN^{\circ}$ Adrenaline (Epinephrine) 300 µg/0.3 mL Auto-Injector

Guide to using EpiPen®

Read this page BEFORE an emergency occurs. If you have any questions about this leaflet or about EpiPen® Auto-Injector, ask your doctor or pharmacist. Keep this leaflet with the EpiPen® Auto-Injector.

IMPORTANT INFORMATION

EpiPen® is for emergency treatment of adults or children who have a severe allergic reaction (anaphylaxis) caused by hypersensitivity to (for example):

- · stinging insects
- medicines
- atex
- · other allergens insect bites.

A severe allergic reaction, otherwise known as anaphylaxis, is life-threatening. Typical symptoms include:

- collapsedifficulty breathing and/or wheezing
 - irregular or faint pulse

flushing of the face

- swelling (eg face, lips, topuge or throat) vomiting, diarrhoea, stomach cramps.

Selection of the appropriate dose is determined according to body weight.

The EniPen® Auto-Injector is intended for adults and children who weigh more than 30 kg, have a severe allergic reaction, and have been assessed and advised by their doctor or pharmacist as needing the EpiPen® Auto-Injector. For a child 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 (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 or pharmacist.

EpiPen® is life-saving in the emergency management of severe allergic reactions. It should not be withheld from anyone who is considered to need it. Discuss with your doctor or pharmacist any precautions or potential interactions. EpiPen® Auto-Injector:

- automatically injects one x 0.3 mL pre-measured dose of adrenaline (epinephrine). This dose provides 300 µg of adrenaline (epinephrine).
- · may be self-administered or administered by a carer
- · cannot be reused.

For further information see the Consumer Medicine Information (CMI) for EpiPen® Auto-Injector. The CMI can be obtained from your pharmacist or downloaded from www.mylan.com.au. For New Zealand consumers, please download the CMI from www.Medsafe.govt.nz/consumers/cmi.

Do NOT remove the blue safety release until you need, and are ready to use, EpiPen®. The safety release stops EpiPen® from working.

When to Use

EpiPen® is only for the immediate EMERGENCY TREATMENT of a SEVERE ALLERGIC REACTION. Your doctor or pharmacist will explain when you must use

If you experience the signs and symptoms described by your doctor or pharmacist:

- Use EpiPen® immediately, through clothing if necessary. Carefully follow 'DIRECTIONS FOR USE'.
- Keep calm, and still.

If you have been stung by an insect:

- Use EpiPen® immediately, through clothing if necessary.
- If the sting is easily accessible, remove with your fingernails. Do not squeeze, pinch or push the sting deeper into the skin. Ice packs or sodium bicarbonate soaks may then be applied to the stung area. Keep warm, calm, and as still as possible.

Care and Storage of EpiPen® Auto-Injector

- Keep available ready for use at all times. Handle carefully, so as not to make it "fire" accidentally.
- Never place thumb, fingers or hands over the orange end as this contains the needle.
- Do not remove blue safety release until ready to use. The blue safety release stops EpiPen® from "firing" or working.

Storage

- Keep in a cool dry place below 25°C. Temperature excursions between 15°C to 25°C
- Do not place in the fridge. Do NOT leave EpiPen® in your car. Extreme temperatures may cause the auto-injector unit to malfunction.
- Protect from light.
- Keep in the protective carry tube until needed.

Thinas vou must do

- Check the expiry date on your EpiPen® Auto-Injector. Replace it BEFORE this expiry date.
- Each month, check the contents through the "viewing window" of your EpiPen® Auto-Injector. Make sure the solution is clear, colourless and sediment-free
- If it's not, the EpiPen® should not be used. Return it to your doctor or pharmacist for safe disposal. Obtain a new EpiPen® immediately.

EpiPen® may be prescribed by your doctor or purchased directly from a pharmacy. Ask your doctor or pharmacist how you can get an EpiPen® Training Device to practice or demonstrate.

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

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 Australia Phone: (02) 9298 3999

Medical Information Phone: 1800 028 365

www.mylan.com.au

Phone: 0800 168 169

and is distributed in New Zealand by. Mylan New Zealand Limited Auckland New Zealand

Made in USA

EpiPen® is a registered trademark of Mylan, Inc.

EpiPen® DIRECTIONS FOR USE

WARNINGS

- Grip only the mid-section of the EpiPen® Auto-Injector. Never put thumb, fingers or hand over the orange end. The orange end contains the needle
- Do *NOT* remove the blue safety release until ready to use. The blue safety release stops the EpiPen® 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 usually the outer mid-thigh
- Keep EpiPen® away from the face and eyes.
- Do not "click" on either end of the EpiPen® Auto-Injector. The EpiPen® Auto-Injector does not work like a retractable ball-point pen.
- 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

HOW TO USE EpiPen® Auto-Injector

- 1) Carefully tilt and slide the EpiPen® Auto-Injector out of its protective carry tube.
- 2) 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 and the needle cover is extended. the EpiPen® has already "fired" and cannot be used again.
- 3) Make a fist around the EpiPen $\!\!\!^{\otimes}$ Auto-Injector, with your thumb nearest to the blue safety release (see FIGURE 1).
- 4) Pull off the blue safety release with your other hand (also shown in FIGURE 1).
- Hold the leg firmly and place the EpiPen® Auto-injector at a 90° angle (right angle) to the outer part of your Hold the orange end about 5 cm away from the thigh (see FIGURE 2).
- Push the orange end FIRMLY into the outer mid-thigh until a "click" is heard or felt. Administer through clothing if necessary.
 Hold the EpiPen® Auto-Injector firmly against the thigh for approximately *3 seconds* (see FIGURE 3).
- 7) Carefully take the EpiPen® Auto-Injector away from the thigh. The orange needle cover will extend to cover the needle
- 8) Check the "viewing window" it should now be obscured. If it is not obscured, the EpiPen® has not "fired" or worked. If the "viewing window" is not obscured, repeat steps 3-7 above.
- 9) Note the time EpiPen® [adrenaline (epinephrine)] was given.
- 10) You CANNOT RE-USE the EpiPen® Auto-Injector even though some adrenaline (epinephrine) is left inside it.
- 11) Do not tamper with the orange needle cover. Do not replace the blue safety release. Your used EpiPen® Auto-Injector with extended orange needle cover will not fit back into the carry tube.
- 12) See 'IMMEDIATELY AFTER USE' box.



FIGURE 1

showing a person preparing an EpiPen® Auto-Injector. Figures 2, 3 and 4 show the steps as the EpiPen®. is self-administered.





FIGURE 3



FIGURE 4

IMMEDIATELY AFTER USE

- Seek further medical attention for yourself immediately.
 - Either Contact your doctor or
- Call an ambulance (telephone 000 in Australia or 111 in New Zealand).
- Explain that you have had EpiPen® [intramuscular adrenaline (epinephrine)]. Give your used EpiPen® Auto-Injector, to the doctor's office or to a hospital for
- inspection and safe disposal in a rigid sharps disposal unit.

EpiPen® may cause side effects such as:

- difficulty breathing, shortness of breath fast or noticeable heart beat
 - hallucinations coldness
- skin colour: pale or red; flushing
- sleeplessness, restlessness
- nausea or vomiting

tremor

197.00 mm

- · anxiety, fear

 - sweating

headache

weakness

if you notice these, or other worrying symptoms, talk to your doctor or pharmacist.

LFFS300/6 EpiPenSnr CMI.A 3025



CCL Label

MELBOURNE

Job No:

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