PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

EPIPEN® AUTO-INJECTOR Solution for injection

EPIPEN® JUNIOR AUTO-INJECTOR Solution for injection

Epinephrine (Adrenaline)

Sugar free

Read all of this leaflet carefully before you start using EPIPEN because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- EPIPEN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse.This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What EPIPEN is and what it is used for
2. What you need to know before you receive EPIPEN
3. How to receive EPIPEN

4. Possible side effects
5. How to store EPIPEN
6. Contents of the pack and other information

1. What EPIPEN is and what it is used for

EPIPEN® and EPIPEN® Junior Auto-Injectors contain epinephrine (adrenaline), a medicine used to treat allergic emergencies (anaphylaxis). Anaphylaxis can be life threatening, can happen within minutes, and can be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or unknown causes.

Symptoms that signal the onset of an anaphylactic shock occur within minutes of exposure to the allergen and include:

- itching of the skin;
- raised rash (like a nettle rash or hives);
- skin rash, redness, or swelling;
- flushing (redness of the skin);
- swelling of the lips, throat, tongue, hands and feet or face;
- wheezing;
- hoarseness (changes in the way your voice sounds);
- shortness of breath (trouble breathing);
- fast heartbeat;
- weak pulse;
- feeling very anxious;
- confusion;
- nausea;
- vomiting;
- stomach cramps or diarrhoea;

- stomach pain;
- losing control of urine or bowel movements (incontinence);
- dizziness, fainting, or “passing out” (unconsciousness).

Always carry your EPIPEN® or EPIPEN® Junior Auto-Injector with you because you may not know when anaphylaxis may happen. Tell your family members and others where you keep your EPIPEN® or EPIPEN® Junior Auto-Injector and how to use it before you need it. You may be unable to speak in an allergic emergency.

The EPIPEN® or EPIPEN® Junior Auto-Injector is intended for immediate self-administration by a person with a history or recognized risk of going into anaphylactic shock. If you are at risk, you should always keep your EPIPEN® or EPIPEN® Junior Auto-Injector with you. It is designed as an emergency rescue therapy, but you must get medical attention as soon as possible after its use.

2. What you need to know before you use EPIPEN

There is no known reason why anyone should not use EPIPEN® or EPIPEN® Junior Auto-Injector during an allergic emergency.

Take special care with EPIPEN® Junior.

Adrenaline is essential for the treatment of anaphylaxis.

However, take special care with EPIPEN® or EPIPEN® Junior Auto-Injector:

- Particularly if you have heart disease as it may affect the medicines that you are taking and may bring on an attack of chest pain (angina)
- If you have heart problems or high blood pressure.
- If you have an overactive thyroid, thyroid problems.
- If you have diabetes
- If administering EPIPEN® Junior to patients who weigh less than 25 kg as there is a greater risk of getting side effects

- If you have increased pressure in your eye(s) (glaucoma).
- If you have severe kidney problems
- If you have a tumour in your prostate
- If you have high calcium levels or a low potassium level in your blood
- If you have Parkinson's disease

Make sure you have discussed this with your doctor if any of these apply to you.

Patients with these conditions, or anyone who may be in the position to administer EPIPEN® Junior Auto-Injector to a patient having an allergic reaction should be properly instructed on how and when to give it.

The instructions for use must be carefully followed in order to avoid accidental injection.

EPIPEN® Junior Auto-Injector should only be injected into the outer thigh. It should not be injected into the buttock due to the risk of accidental injection into a vein.

Do not use or administer EPIPEN® or EPIPEN® Junior Auto-Injector:

- If you are hypersensitive (allergic) to the epinephrine (adrenaline) or any other ingredients in the EPIPEN® or EPIPEN® Junior Auto-Injector listed in section 6.

If you are not sure, talk to your doctor or pharmacist before using or administering EPIPEN® or EPIPEN® Junior Auto-Injector.

Warnings and precautions

If you have asthma you may be at increased risk of severe allergic reaction.

Anyone who has an episode of anaphylaxis should see their doctor about testing for substances they may be allergic to, so these can be strictly avoided in future. It is important to be aware that and allergy to one substance can lead to allergies to a number of related substances. If you have food allergies it is important to check the ingredients in everything you ingest (including medicines) as even small amounts can cause severe reactions.

Accidental injection into the hands or fingers may result in reduced blood supply to these areas.

If there is an accidental injection into these areas, you should go immediately to the nearest hospital casualty department for treatment.

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. Therefore you should ensure you carry two auto- injectors with you at all times. In case of injection performed by a caregiver, immobilisation of the patient's leg should be ensured during injection to minimize the risk of injection site laceration.

The needle should never be reinserted after use.

Other medicines and EPIPEN

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This applies especially to the medicines listed below taken at the same time when EPIPEN® or EPIPEN® Junior Auto-Injector was used.:

- Antidepressants such as tricyclic antidepressants or monoamine oxidase inhibitors, since the effects of adrenaline may be increased.
- Thyroid hormones (such as levothyroxine sodium).
- Catechol-O-methyl-transferase (COMT) inhibitors such as entacapone, tolcapone and opicapone.
- Theophylline (a phosphodiesterase inhibiting medicine used in the treatment of respiratory diseases such as chronic obstructive pulmonary disease and asthma).
- Oxytocin (a hormone secreted by the body which control key aspects of the reproductive system and human behaviour).
- Certain medicines that may an affect on the body’s rest and digestive response

(parasymphatic nervous system).

- Levodopa (a medicine used for Parkinson's disease).
- Certain antihistamines (notably chlorpheniramine, tripelennamine and diphenhydramine).
- Medicines that make the heart sensitive to uneven beats (such as digitalis, mercurial diuretics or quinidine).
- Beta-adrenergic blocking medicine such as propranolol.
- Rapidly acting vasodilators or alpha-adrenergic blocking medicines, such as phentolamine.
- Ergot alkaloids (a medicine used in the treatment of migraines).

Diabetic patients should carefully monitor their glucose levels after use of EPIPEN® or EPIPEN® Junior Auto-Injector as adrenaline can reduce the amount of insulin made by the body, thus increasing the blood glucose level.

Using EPIPEN® or EPIPEN® Junior Auto-Injector with food and drink

This is for a once-off emergency treatment only. The effects of EPIPEN® and EPIPEN® Junior may be potentiated by alcohol.

Pregnancy and breastfeeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

There is limited experience of the use of adrenaline during pregnancy.

If you are pregnant, do not hesitate to use EPIPEN® or EPIPEN® Junior Auto-Injector in an emergency, since you and your baby's lives may be in danger. Discuss this with your doctor if you are pregnant.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you use EPIPEN.

Driving and using machines

The ability to drive and use machines is unlikely to be affected by the administration of EPIPEN® or EPIPEN® Junior Auto-Injector (an adrenaline injection) but may be affected by an anaphylactic reaction. If affected, do not drive.

3. How to use EPIPEN

Do not share medicines prescribed for you with any other person.

You should be confident that you know exactly how and when to use it. Always use EPIPEN® or EPIPEN® Junior Auto-Injector exactly as your doctor has told you. If you are at all unsure about how to use it, ask to have the instructions repeated by your doctor, nurse or pharmacist.

If you have been stung by an insect, try to remove the stinger with your fingernails, do not squeeze, pinch or push it deeper into the skin. If possible, put an ice pack on the area of the sting. Keep warm and avoid exercise. For allergic reactions caused by food make sure you remove any remaining food from the mouth immediately.

Dosage:

Each EPIPEN® or EPIPEN® Junior Auto-Injector contains only 1 dose of medicine.

EPIPEN® and EPIPEN® Junior Auto-Injectors should only be injected into the middle of your outer thigh (upper leg). It can be injected through your clothing if needed. It should not be injected into the buttock (your bottom).

The dose will be checked by your doctor, who will adjust it individually for you. The usual dose for allergic emergencies is shown below and must be injected into muscle (intramuscular use).

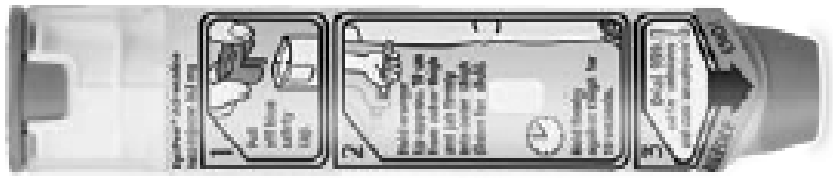
- Patients greater than or equal to 30 kg: EPIPEN 0,3 mg
- Patients 15 to 30 kg: EPIPEN Junior 0,15 mg

Inject EPIPEN® and EPIPEN® Junior Auto-Injectors intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary.

EPIPEN® and EPIPEN® Junior Auto-Injectors are for single dose administration only and the unused portion must be discarded.

Caregivers of young children who are prescribed an EPIPEN® or EPIPEN® Junior and who may be uncooperative and kick or move during an injection to hold the leg firmly in place and limit movement prior to and during an injection.

Caution: Never put your thumb, fingers, or hand over the orange tip. The needle comes out of the orange tip. Do not remove blue safety release until ready to use. Accidental injection into finger, hands or feet may cause a loss of blood flow to these areas. If this happens, go immediately to the nearest emergency room. Tell your healthcare provider where on your body you received the accidental injection.



Blue safety cap **Orange tip**

A dose of 0,3 ml (0,23 – 0,37 ml) injection fluid is automatically injected intramuscularly by the auto-injector.

Grasp unit with the orange tip pointing downward, form a fist around the unit (orange tip down). With your other hand, pull off the blue safety release.

Diagram 1



Hold the orange tip near outer thigh. **DO NOT INJECT INTO BUTTOCK**. Take the shaft

firmly in the hand with the orange plastic tip directed to the upper thigh whilst pushing hard against the skin until the mechanism releases the injection needle. The device should be held in position for at least 3 seconds.



Remove the unit from the thigh (the orange needle cover will extend to cover the needle).



After this the device is removed from the thigh and the injection area massage for 10 seconds. A doctor should be consulted as soon as possible and the used device taken along.

Intravascular injection should be avoided at all costs.

- Always carry your EPIPEN® or EPIPEN® Junior Auto-Injector with you in case of an allergic emergency.
- Do not drop the carrier tube or auto-injector. If the carrier tube or Auto-Injector is dropped, check for damage and leakage. Discard the auto-injector and carrier tube and replace if damaged or leakage is noticed or suspected.

Get emergency medical help right away. You may need further medical attention. You may need a second EPIPEN® or EPIPEN® Junior Auto-Injector should symptoms persist or recur. More than two sequential doses of epinephrine (adrenaline) for a single episode should only be administered by a healthcare professional.

Note:

- There is a possibility of biphasic anaphylaxis which is characterized by initial resolution followed by recurrence of sumptoms some hours later.
- Related allergens should be investigated whenever possible so that specific allergens can be characterized.
- Children under 15 kg in body weight should be carefully monitored for signs and symptoms of adrenaline overdosage.
- Take your unused Auto-Injector with you when you go to see the healthcare professional.
- Tell the healthcare professional that you have received an injection of epinephrine (adrenaline). Show the healthcare professional where you received the injection.
- Give your used EPIPEN® or EPIPEN® Junior Auto-Injector to a healthcare professional for inspection and proper disposal.
- Ask for a refill, if needed.
- The used Auto-Injector with extended needle cover will not fit in the carrier tube.
- Most of the liquid medicine stays in the Auto-Injector and cannot be reused.

  You have received the correct dose of the medicine if the orange needle tip is extended and the window is blocked.

If you use more EPIPEN than you should

In case of overdose or accidental injection of adrenaline, as in EPIPEN® or EPIPEN® Junior Auto-Injector, you should always seek immediate medical help. Your blood pressure may rise sharply and it will need to be monitored.

4. Possible side effects

EPIPEN can have side effects.

Not all side effects reported for EPIPEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using EPIPEN, please consult your health care provider for advice.

EPIPEN® or EPIPEN® Junior Auto-Injectors may cause serious side effects.

If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you use the EPIPEN® or EPIPEN® Junior Auto-Injector. Talk to your healthcare professional about all your medical conditions.

The EPIPEN® or EPIPEN® Junior Auto-Injector should only be injected into the middle of your outer thigh (upper leg). Do not inject the EPIPEN® or EPIPEN® Junior into your:

- Veins
- Buttocks
- Fingers, toes, hands, or feet

If you accidentally inject EPIPEN® or EPIPEN® Junior into any If you accidentally inject EPIPEN® or EPIPEN® Junior into any other part of your body, go to the nearest emergency room right away. Tell the healthcare provider where on your body you received the accidental injection.

Less frequently, patients who have used EPIPEN® or EPIPEN® Junior may develop infections at the injection site within a few days of an injection. Some of these infections can be serious. Call your healthcare provider right away if you have any of the following at an injection site:

- redness that does not go away,
- swelling,
- tenderness,
- the area feels warm to the touch.

Tell your doctor immediately or go to the casualty department at you nearest hospital if you notice any of the following:

Less frequent

- cerebral bleeding,
- fast, irregular or “pounding” heartbeat.

Frequency unknown

- Cardiac arrest.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown

- breathing problems (wet lung (fluid on the lungs) and shortness of breath),
- abnormal heart rhythm,
- chest pain,
- low blood pressure with dizziness and fainting,
- high blood pressure,
- psychosis,
- fear, anxiety, restlessness, sleeplessness, confusion, irritability, headaches, dizziness and involuntary, rhythmic shaking in one or more parts of the body (tremor),
- feelings of over excitement, nervousness or anxiety,
- impaired blood supply following accidental injections of the pens in the hands or feet,
- drooling (hypersalivation),
- loss of appetite,
- nausea and/or vomiting,
- trembling, weakness,
- paleness,
- excessive sweating,
- difficulty in urinating and urinary retention,
- accidental injections can lead to injury at the injection site resulting in bruising, bleeding, discoloration, reddening of the skin or skeletal injury.

Cuts on the skin, bent needles, and needles that remain in the skin after the injection, have happened in young children who do not cooperate and kick or move during an injection. If you inject a young child with EPIPEN® or EPIPEN® Junior, hold their leg firmly in place before and during the injection to prevent injuries. Ask your healthcare provider to show you how to properly hold the leg of a young child during injection.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications:
https://www.sahpra.org.za/wp-content/uploads/2021/05/2.33_Post-Marketing-Reporting-of-ADRs-to-Human-Medicines-in-SA_Version-8_May2021.pdf
By reporting side effects, you can help provide more information on the safety of EPIPEN.

5. How to store EPIPEN

Store all medicines out of reach of children.

- Store at or below 25°C, protected from light.
- Do not refrigerate.
- Do not expose to extreme cold or heat. For example, do not store in your vehicle's glove box and do not store in the refrigerator or freezer.
- Examine the contents in the clear window of your auto-injector periodically. The solution should be clear. If the solution is discoloured (pinkish or brown colour) or contains solid particle, replace the unit.
- Always keep your EPIPEN® or EPIPEN® Junior Auto-Injector in the carrier tube to protect

it from damage; however, the carrier tube is not waterproof.

- The blue safety release helps to prevent accidental injection of the device. Keep the blue safety release on until you need to use it.
- Do not use after the expiry date stated on the label / carton.

EPIPEN is intended for single patient use only.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EPIPEN contains:

- The active substance is epinephrine (adrenaline).
- Each 0,3 ml of EPIPEN® AUTO-INJECTOR contains:

  Epinephrine (Adrenaline) 0,3 mg

  Antioxidant: sodium metabisulfite 0,5 mg/dose

  Each 0,3 ml of EPIPEN® Junior AUTO-INJECTOR contains:

  Epinephrine (Adrenaline) 0,15 mg

  Antioxidant: sodium metabisulfite 0,5 mg/dose

  Sugar free.
- The other ingredients are sodium chloride, sodium metabisulfite (E223), hydrochloric acid (for pH adjustment) and Water for Injection.

What EPIPEN looks like and contents of the pack

EPIPEN contains a clear, colourless solution, free from foreign visible particles.

This pre-filled disposable automatic injection device is designed to deliver a single dose. It consists of a glass cartridge, containing the medicine, sealed by a rubber plunger at one end and by a rubber diaphragm, which has been inserted into an aluminium hub with attached stainless steel needle at the other end.

Holder of Certificate of Registration and Manufacturer

Viatris Healthcare (Pty) Ltd.

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Registration numbers

EPIPEN® Auto-injector: 27/5.1/0063

EPIPEN® Junior Auto-injector: 38/5.1/0278

Access to the corresponding Professional Information

To be confirmed.