Package leaflet: Information for the user

Epipen Evo 300 microgram solution for injection in pre-filled pen (Auto-Injector)

adrenaline (epinephrine)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness 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 Evo Auto-Injector is and what it is used for
2. What you need to know before you use Epipen Evo Auto-Injector
3. How to use Epipen Evo Auto-Injector
4. Possible side effects
5. How to store Epipen Evo Auto-Injector
6. Contents of the pack and other information

1. What Epipen Evo Auto-Injector is and what it is used for

Epipen Evo Auto-Injector is a sterile solution in a pre-filled syringe in an auto-injector for emergency injection into the muscle (intramuscular).

Epipen Evo Auto-Injector is to be used for the emergency treatment of severe allergic reactions (anaphylaxis) caused by allergens in e.g. insect stings or bites, foods, drugs and other allergens as well as triggered by exercise or by unknown causes.

How Epipen Evo Auto-Injector works

The medicine in the Epipen Evo Auto-Injector is adrenaline (epinephrine) which is an adrenergic drug. It works directly on the cardiovascular (heart and circulation) system and respiratory (lung) system, countering the potentially fatal effects of anaphylaxis by rapidly constricting the blood vessels, relaxing muscles in the lungs to improve breathing, reducing swelling and stimulating heartbeat.

Anaphylactic reaction may occur within minutes after exposure and consist of: itching of the skin; raised rash (like a nettle rash); flushing; swelling of the lips, throat, tongue, hands and feet; wheezing; hoarseness; nausea; vomiting; abdominal cramps and in some cases, loss of consciousness.

The reaction is the result of the body trying to protect itself from the allergen (the foreign substance that causes the allergy) by releasing chemicals into the blood stream. Sometimes the cause of the allergic reaction is not known.

2. What you need to know before you use EPIPEN EVO Auto-Injector

Warnings and Precautions
There are no restrictions on the use of Epipen Evo Auto-Injector during an allergic emergency.

If you have an episode of anaphylaxis, you should see your doctor about testing for substances you may be allergic to, so these can be strictly avoided in future. It is important to be aware that an allergy to one substance can lead to allergies to a number of related substances.

Before you ever need to use Epipen Evo Auto-Injector, you should review the patient instructions and operation of the auto-injector in detail, with your healthcare provider.

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

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.

Tell your doctor if you have:
- heart problems (heart disease)
- a condition called congenital long QT syndrome or problems with heart rhythm
- high blood pressure
- an overactive thyroid (hyperthyroidism)
- diabetes
- increased pressure in your eye (glaucoma)
- severe kidney problems
- a tumor in your prostate (prostatic adenoma leading to residual urine)
- high calcium levels or low potassium levels in your blood
- Parkinson's disease

There is also a greater risk of getting side effects if you are elderly or pregnant.

Despite these concerns, adrenaline is essential for the treatment of anaphylaxis. Patients with these conditions, or anyone who may be in the position to give Epipen Evo Auto-Injector to a patient experiencing an allergic reaction, should be properly instructed as to the situations in which it should be given.

Handling of Epipen Evo Auto-Injector

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

Epipen Evo Auto-Injector **should only be injected into the outer thigh**. It should not be injected into the buttock.

Warnings: Accidental injection into the hands or fingers may result in loss of blood supply to the affected area. 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 sub-cutaneous fat layer, there is a risk for adrenaline not reaching the muscle tissue and a single dose of Epipen Evo Auto-Injector may not be sufficient in this case. A second injection may be needed; therefore, you should carry two injectors. Carefully follow the instructions for use given in section 3.

Children and adolescents

Children and adolescents over 30 kg weight:
The usual dose is 300 microgram for intramuscular use.

Children between 15 kg and 30 kg in weight:
Children with a body weight between 15 kg and 30 kg should be prescribed Epipen Evo Junior Auto-Injector containing 150 microgram adrenaline per dose. Epipen Evo Auto-Injector 300 microgram is not suitable for children < 30 kg.

Children below 15 kg in weight:
The suitability of Epipen Evo Junior Auto-Injector 150 micrograms has to be judged individually by the doctor. The use in children weighing less than 7.5 kg is not recommended unless in a life-threatening situation and under medical advice.

Other medicines and Epipen Evo Auto-Injector
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important if you take any of the following:
- Medicines that may make the heart sensitive to uneven beats (arrhythmias), such as digitalis, quinidine
- Antidepressants such as tricyclic antidepressants or monoamine oxidase inhibitors (MAO inhibitors), since the effects of adrenaline may be increased.
- Medicines for treatment of Parkinson's disease such as catechol-O-methyl transferase inhibitors (COMT inhibitors), and levodopa since the effect of adrenaline may be increased.
- Medicines for heart disease or medicines to treat disorders of the nervous system called alpha and beta blocking medicines as they can reduce the effect of adrenaline.
- Medicines for thyroid disease
- Medicine that makes you breathe more easily, used for asthma (theophylline)
- Medicine used in labour (oxytocin)
- Medicines that act on the nervous system (parasympatholytics)
- Medicines used to treat allergies such as diphenhydramine or chlorpheniramine (antihistamines)

If you are diabetic you must carefully monitor your glucose levels after use of Epipen Evo Auto-Injector as adrenaline can affect the amount of insulin made by the body and thus increase the blood sugar level.

Epipen Evo with food, drink and alcohol
Food or drink has no influence on the use of Epipen Evo Auto-Injector.
Tell your doctor if you are taking alcohol since the effect of adrenaline can be increased.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

In an acute life-threatening situation, do not hesitate to use Epipen Evo Auto-Injector, since your and your child's lives may be in danger.

Breast-feeding
Epipen Evo Auto-Injector is not expected to have any effect on the nursing infant.

Driving and using machines
The ability to drive and use machines will not be affected by the administration of an adrenaline injection. However, you should not drive as you may still suffer from the symptoms of an anaphylactic reaction.

Epipen Evo Auto-Injector contains sodium metabisulphite (E223)
Sodium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm.
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Epipen Evo Auto-Injector

For single use only.

Epipen Evo Auto-Injector is intended for immediate (self-)administration as emergency supportive therapy only and is not a substitute for immediate medical care.

Epipen Evo Auto-Injector should be administered as soon as symptoms of anaphylaxis are recognized.

If symptoms do not improve or deterioriate, a second injection with an additional Epipen Evo Auto-Injector may be administered 5–15 minutes after the first injection. You should carry two Epipen Evo Auto-Injector with you at all times.

Call local emergency services immediately even if symptoms get better after the injection.

The Epipen Evo Auto-Injectors must be replaced immediately after use.

Dosage
The dose will be decided by your doctor, who will adjust it individually for you.
Epipen Evo Auto-Injector is intended to be used by people with a body weight above 30 kg. The usual adult dose for allergic emergencies is 300 microgram adrenaline for intramuscular use.

Adults, children and adolescents
The usual dose for adults, children and adolescents over 30 kg weight is 300 microgram adrenaline for intramuscular use.

For children and adolescents below 30 kg, see section 2 "Children and Adolescents"

If you detect signs of an acute allergic reaction, use Epipen Evo Auto-Injector immediately.

Sometimes a single dose of adrenaline may not be sufficient to completely reverse the effects of a serious allergic reaction. For this reason, your doctor is likely to prescribe more than one Epipen Evo for you. If your symptoms have not improved or have deteriorated within 5-15 minutes after the first injection, either you or the person with you should give a second Epipen Evo injection. **For this reason, you should carry two Epipen Evo Auto-Injector with you at all times.**

It is recommended that your family members, carers or teachers are also instructed in the correct use of Epipen Evo Auto-Injector.

Important Information - Before Use:

- A Epipen Evo Trainer is available for the Epipen Evo Auto-Injector. The Epipen Evo Trainer has a grey colour. The grey Epipen Evo Trainer contains no medicine and no needle.
- Practice with your Epipen Evo Trainer periodically, but always carry your Epipen Evo Auto-Injectors in case of an allergic emergency (anaphylaxis).
- If you will be administering Epipen Evo Auto-Injector to a young child, ask a healthcare provider to show you how to properly hold the leg in place while administering a dose.
- Do not try to take the Epipen Evo Auto-Injector apart.
- Do not drop the Epipen Evo Auto-Injector. If the auto-injector is dropped, check for damage and leakage. Contact your healthcare provider to replace the auto-injector if damage or leakage is noticed or suspected.
- **Keep the Epipen Evo Auto-Injector and all medicines out of the sight and reach of children.**

Directions for use

Before you ever need to use it, fully familiarise yourself with the Epipen Evo Auto-Injector (refer to the Diagram), when and how it should be used.

For Allergic Emergencies (Anaphylaxis)

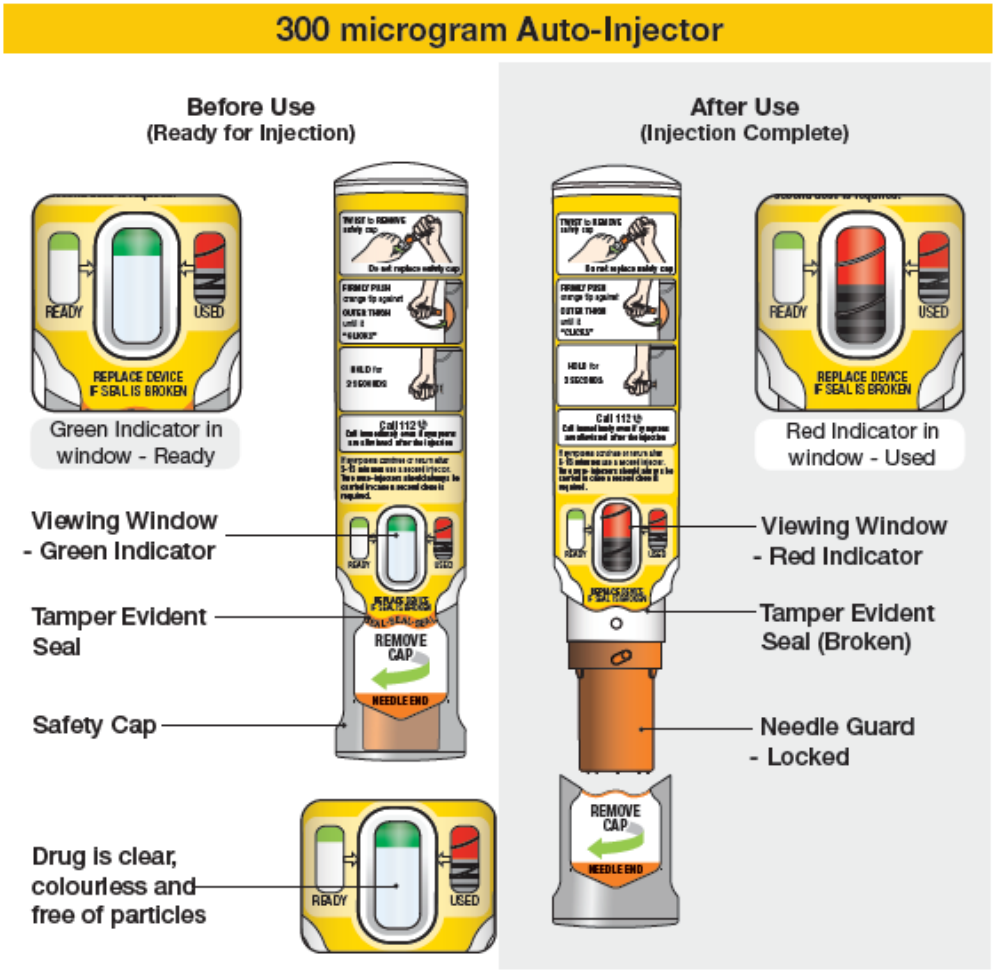
Read these instructions carefully before you use your Epipen Evo Auto-Injector.

When your doctor prescribes Epipen Evo Auto-Injector, you must make sure you understand the reason it has been prescribed for you. You should be confident that you know exactly how to use the device. Always use this medicine exactly as your doctor or pharmacist 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.

It is recommended that your family members, carers or teachers are also instructed in the correct use of Epipen Evo Auto-Injector. In case of injection performed by a caregiver, hold the leg in place during injection to minimize the risk of leg injuries.

Follow these directions only when ready to use.

If you have any questions, ask a healthcare provider.



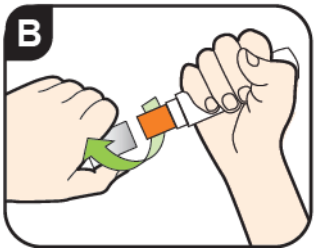
Inspect Your Epipen Evo Auto-Injector



- Check the medicine through the auto-Injector viewing window (See Figure A) and make sure the medicine is clear, colourless and free of particles.
- Check the tamper evident seal (See Figure A), for signs of tampering. Replace the auto-injector if the seal is broken.
- Check the expiration date located in the black panel on the side of your Epipen Evo Auto-Injector. Replace the auto-injector if the expiration date has passed.

A dose of Epipen Evo Auto-Injector requires 2 tasks: Prepare and Administer

Prepare



1 Remove auto-injector from carton.
2 Read Instructions for Use on auto-injector label.
3 Twist to remove safety cap (See Figure B).

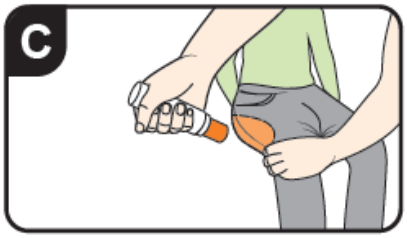
Do not remove safety cap if not preparing for an injection.

Note:

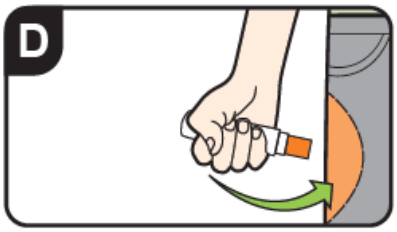
- The safety cap is made to fit tightly. Twist firmly to remove**.**
  Do not replace the safety cap after it is removed.
- To avoid an accidental injection, never put your thumb, fingers or hand over the orange tip. If an accidental injection happens, get medical help right away.

Administer

4 Hold leg firmly in place (if administering to a child). (See figure C).



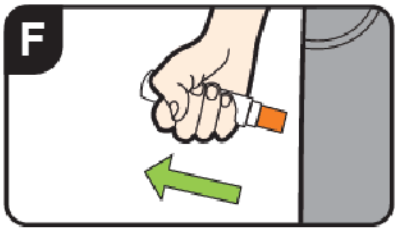
5 Firmly push the auto-injector against the **outer thigh** until you hear a click (See Figure D). The click signals that the injection has started. The auto injector can be used through clothes/trousers.



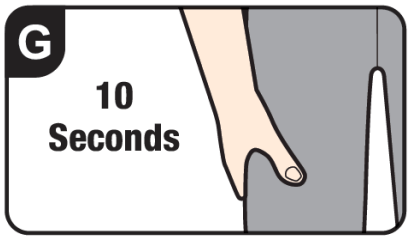
6 Hold in place for **3 seconds** (count slowly 1, 2, 3) (See Figure E). The injection is now complete.



7 Remove auto-injector from injection site (See Figure F). The orange tip will extend to cover the needle and block the viewing window with a red indicator.



8 Massage injection site for 10 seconds (See Figure G).



Call emergency services (112) immediately even if symptoms get better after the injection. Call for immediate medical assistance, ask for an ambulance and state "anaphylaxis" (pronounced ana-fill-axis).

Remember you may need a second auto-injector.

- A second dose of adrenaline may be required if symptoms continue or return after 5 – 15 minutes. Repeat steps 1-8 if a second dose is required.
- Two auto-injectors should always be carried in case a second dose is required.

Important Information –After injection

- Dial 112, even if symptoms get better after the injection. You will need to go to hospital for observation and further treatment as required. This is because the reaction may reoccur again at some time later.
- While waiting for the ambulance you should lie down with your feet raised unless this makes you breathless in which case you should sit up. Ask someone to stay with you until the ambulance arrives in case you feel unwell again.
- Unconscious patients should be placed on their side in the recovery position.

Important Information – After Use

- Epipen Evo Auto-Injector is a single-use injectable device that deliver a fixed dose of adrenaline.
- **The Auto-Injector cannot be reused**. Do not attempt to reuse Epipen Evo Auto-Injector after the auto-injector has been activated.
- After the Auto-Injector has been used, the safety cap cannot be replaced.
- The correct dose has been administered if the orange needle tip is extended and the viewing window is blocked with a red indicator.

Dispose and Replace:

- Tell a healthcare provider that you have received an injection of adrenaline. Show a healthcare provider where you received the injection.
- Take your used Epipen Evo Auto-Injector to a healthcare provider for inspection and proper disposal.
- After use ask for a replacement.

If you use more Epipen Evo Auto-Injector than you should

In case of overdose or accidental injection of the adrenaline, you should always seek immediate medical help.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare cases of serious skin and soft tissue infections (injection site infection) have been reported. In case of signs of injection site infection such as swelling, redness, heat or pain always seek immediate medical help.

Accidental injection of the auto-injector in hands or feet have been reported and may result in loss of blood supply to the affected area. In case of accidental injection always seek immediate medical help.

Allergic reactions can appear in patients sensitized to sodium metabisulphite.

Rare: (may affect up to 1 in 1,000 people): damage to the heart muscle (stress cardiomyopathy) has been seen in patients treated with adrenaline.

Frequency not known: (frequency cannot be estimated from the available data):
- Apprehension, nervousness or anxiety
- Headache
- Dizziness
- Tremor
- Fast or irregular heartbeat (palpitations, cardiac arrhythmia)
- Irregular and uncoordinated contractions to the lower chambers of the heart (ventricular fibrillation)
- Severe chest pains
- Sometimes severe rapid heartbeat
- High blood pressure
- Paleness
- Difficulty breathing
- Feeling sick, vomiting
- Sweating
- Weakness
- Injection site infection, injection site bruising, bleeding, discoloration, redness of the skin, coldness, numbness, and skeletal injury.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Epipen Evo Auto-Injector

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C. Do not refrigerate or freeze.

Protect from light, **do not** expose to extreme cold or heat. For example, **do not** store in your vehicle's glove box.

Keep the auto-injector in the outer carton in order to protect from light.
The solution darkens in colour upon exposure to air or light. **Please remember to inspect the contents of the syringe in the Epipen Evo Auto-Injector regularly to make sure the liquid is still clear and colourless. Replace the Auto-Injector by the expiry date or earlier if the solution is discoloured or contains a precipitate (solid matter).**

Inspect the auto-injector if dropped. Replace if you notice damage or leakage.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Epipen Evo contains

The active substance is adrenaline. Each pre-filled pen of 0.3 ml solution contains adrenaline tartrate equivalent to 300 microgram adrenaline (epinephrine).

The other ingredients are:
Sodium metabisulphite (E223)
Sodium chloride
Disodium edetate
Hydrochloric acid (for pH adjustment)
Water for injections

What Epipen Evo looks like and contents of the pack

Clear and colourless solution for injection in pre-filled pen (auto-injector). The auto-injector contains a glass syringe which is assembled into a plastic auto-injector pen.

The Epipen Evo Auto-Injector contains 0.3ml solution for injection. Each auto-injector delivers one single dose of adrenaline tartrate equivalent to 300 microgram adrenaline (epinephrine).

The needle length after activation (exposed and protected) is approximately 13.5 mm.

Pack sizes:
1 Pre-filled pen
2 x 1 Pre-filled pens.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Viatris Healthcare Limited,
Damastown Industrial Park,
Mulhuddart Dublin 15,
DUBLIN Ireland

Manufacturer
Meda Pharma GmbH & Co.KG
Benzstrasse 1
Bad Homburg
61352
Germany

This medicine is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicine
Sweden	EpiPen Twist 300 mikrogram injektionsvätska, lösning i förfylld autoinjektor
Austria	EpiPen N 300 Mikrogramm, Injektionslösung in einem FertigPen
Estonia	Epixust
Latvia	Epixust 300 mikrogrami šķīdums injekcijām pildspalvveida pilnšļircē
Lithuania	Epixust 300 mikrogramų injekcinis tirpalas užpildytame švirkštiklyje
Czechia	EpiPen Neo
Cyprus	Epipen 300 micrograms Solution for injection in pre-filled pen
Hungary	EpiPen Neo 300 mikrogramm oldatos injekció előre töltött tollban
Ireland	Epipen Evo 300 microgram solution for injection in pre-filled pen
Italy	Epipen
Malta	Epipen 300 micrograms Solution for injection in pre-filled pen
Poland	EpiPen
Romania	EpiPen Neo 300 micrograme soluţie injectabilă în stilou injector preumplut
Slovakia	EpiPen Neo 300 mikrogramov injekčný roztok v naplnenom pere
Slovenia	Epipen ADR 300 mikrogramov/0,3 ml raztopina za injiciranje v napolnjenem injekcijskem peresniku
Spain	Altellus Neo 300 microgramos adultos, solución inyectable en pluma precargada
Bulgaria	ЕпиПен Н 300 микрограма инжекционен разтвор в предварително напълнена писалка EpiPen N 300 micrograms solution for injection in pre-filled pen
Netherlands	EpiPen Evo 300 microgram, oplossing voor injectie in een voorgevulde pen 1 mg/ml
Greece	Epipen 300 micrograms Solution for injection in pre-filled pen
Belgium	EpiPen Next 300 microgram oplossing voor injectie in een voorgevulde pen
Croatia	Orduxato 0,3 mg otopina za injekciju u napunjenoj brizgalici

France	ADRENALINE VIATRIS 0,30 mg/0,30 ml, solution injectable en stylo pré-rempli
Denmark	EpiPen Neo
Iceland	EpiPen Neo
Finland	Epinadren 300 mikrogrammaa, injektioneste, liuos, esitäytetty kynä
Norway	EpiPen Neo 300 mikrogram injeksjonsvæske
Portugal	Epipen N 300 microgramas, solução injetável em seringa pré-cheia

This leaflet was last revised in July 2026