

Package leaflet: information for the user

Anapen 500 micrograms / 0.3ml solution for injection in a pre-filled syringe

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 or your pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Anapen is and what it is used for
2. What you need to know before you use Anapen
3. How to use Anapen
4. Possible side effects
5. How to store Anapen
6. Contents of the pack and other information



1. What Anapen is and what it is used for

- Anapen consists of a pre-filled syringe of adrenaline contained in an automatic injection device (Auto-Injector). This injects a single dose of adrenaline into muscle.
- This medicine is for emergency only and you should seek immediate medical attention after using your Auto-Injector.
- Adrenaline is a natural hormone released in response to stress. In acute allergic reactions it improves blood pressure, heart function and breathing, and reduces swelling. Adrenaline is also known as epinephrine.
- Anapen is used for the emergency treatment of serious allergic reactions or anaphylaxis caused by peanuts or other foods, drugs, insect bites or stings and other allergens as well as exercise or an unknown cause.

2. What you need to know before you use Anapen

Do not use Anapen

There is no known reason why anyone should not use Anapen during an allergic emergency.

Warnings and Precautions

Talk to your doctor or pharmacist before using Anapen.

- Your doctor should have carefully instructed you when to use and the correct way to use your Anapen Auto-Injector.
- You should tell your doctor if you are suffering from heart disease, including angina, hyperthyroidism, high blood pressure, lowered potassium levels and increased calcium in the blood, disorders of the blood circulation, phaeochromocytoma (a type of tumour in the adrenal gland), raised pressure inside the eye (glaucoma), kidney or prostate disease diabetes or any other medical condition.
- If you have asthma you may be at increased risk of a 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 an 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
- Repeated local injection can result in skin damage at sites of injection. Accidental injection into a blood vessel may result in a sudden rise in blood pressure. Accidental injection into the hand or foot may result in loss of blood flow to the affected part. You should immediately seek medical advice at the nearest hospital.

If you have a thick-subcutaneous fat layer, there is a risk for the adrenaline not reaching the muscle tissue, resulting in a suboptimal effect.

Other medicines and Anapen

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

- Medicines for heart disease, such as digitalis (digoxin), beta-blockers, quinidine,
- Medicines for depression, such as tricyclic antidepressants, mono amine oxidase inhibitors (MAOIs), serotonin and noradrenaline reuptake inhibitors (SNRIs),
- Medicines for diabetes, your doctor may change the dosage of your medication after using Anapen,
- Medicines for Parkinson's disease,
- Medicines for thyroid disease,
- Other Medicines: antihistamines such as diphenhydramine or chlorpheniramine, theophylline, ipratropium and oxitropium (used to treat airways disease including asthma), oxytocin (used in labour in pregnancy), inhaled anaesthetics, alpha adrenergic blockers (used to treat high blood pressure), sympathomimetics (used to treat asthma, other airways disease and nasal congestion).

Anapen with alcohol

Alcohol may adversely affect this medicine by increasing the effects of this medicine.

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.

- It is not clear whether taking adrenaline during pregnancy is of risk to the unborn child. This should not deter you if you are pregnant from using Anapen in an emergency, as your life might be in danger. You should discuss this with your doctor before such an emergency occurs.
- Adrenaline would not be expected to have any effect on the breastfeeding infant.

Driving and using machines

You should not drive or use machinery after injecting this medicine, since you may still be experiencing the effects of an anaphylactic shock.

Anapen contains sodium metabisulfite (E223)

Sodium metabisulfite can cause allergic type reactions and difficulty in breathing especially in those with a history of asthma.

You should tell your doctor or pharmacist if you know you are allergic to sodium metabisulfite.

Anapen contains a small amount of sodium chloride (salt)

This medicinal product contains less than 1mmol sodium (23mg) per dose. i.e. essentially sodium free.

3. How to use Anapen

Always carry 2 units of auto-injectors in case the first administration fails or if one dose is not sufficient.

- Always use this medicine exactly as your doctor has told you.
- Check with your doctor or pharmacist if you are not sure.
- Only inject into the thigh muscle.
- For single use only, please ensure you discard safely immediately after use. Anapen delivers one single dose of 0.3mL liquid which is equal to 500 micrograms adrenaline. After use, a volume of 0.75mL will remain in the auto-injector but this cannot be reused.

The reaction usually starts within minutes of contact with the allergen and the person may experience:

- Itching of the skin, a raised urticarial rash (nettle rash), flushing and swelling of eyes, lips or tongue.
- Difficulty in breathing due to swelling of the throat. Wheezing, shortness of breath and coughing may result from tightening of the muscles in the lungs.
- Other symptoms of anaphylaxis including headache, vomiting and diarrhoea.
- Collapse and loss of consciousness due to a sudden lowering of blood pressure.

When you experience these signs and symptoms use the Anapen Auto-Injector immediately. You must only inject this medicine into the muscle on the outer part of your thigh, not the buttock. 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 Anapen 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 injection. For this reason you should carry more than one Anapen with you at all times.

In case of a second injection needed it is recommended to inject in the opposite thigh.

Use in adults

- The recommended dose is 300 micrograms for individuals under 60 kg bodyweight.
- For adults over 60 kg, the 300 micrograms dose may not be sufficient and these patients may need Anapen 500 micrograms in the autoinjector to reverse the effect of an allergic reaction.

Use in children: Anapen 500 micrograms is not recommended for use in children.

Use in children and adolescents

- The appropriate dose is 150 micrograms or 300 micrograms.
- This depends on the body weight of the child and the discretion of the doctor.
- An Auto-Injector that delivers 150 micrograms of adrenaline is also available. A dosage below 150 micrograms cannot be administered in sufficient accuracy in children weighing

less than 15 kg and use is therefore not recommended unless in a life-threatening situation and under medical advice.

Children between 15 kg and 30 kg

The usual dose is 150 micrograms.

Children over 30 kg

The usual dose is 300 micrograms.

Anapen is designed as emergency treatment. You should always get medical help **immediately** after using Anapen. Dial xxx; ask for an ambulance and state ‘anaphylaxis’ **even if symptoms appear to be improving**. You will need to go to hospital for observation and further treatment as required. This is because the reaction may happen again at some time later.

While waiting for the ambulance you should lie down with your legs 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.

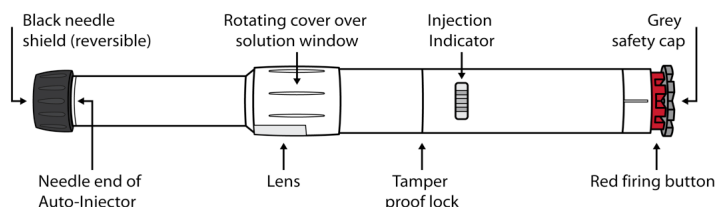
Unconscious patients should be placed on their side in the recovery position.

Instructions for use

It is recommended that your family members, carers or co-workers are also instructed in the correct use of Anapen.

A Parts of the Anapen Auto-injector:

Before you use your Anapen Auto-Injector, you need to know about the parts of the Auto-Injector. These are shown in the picture.

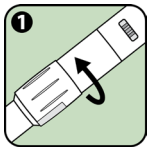


- **Rotating cover over solution window:** You rotate the cover over the solution windows to line up the lenses with the solution windows on the Auto-Injector body.
- **Solution window:** You look through the lens into this window before the injection to check that the solution is clear and ready to use.
- **Injection indicator:** Before the injection, you can see a white plastic plunger through the window. This means that the Anapen Auto-Injector has not been fired by mistake or tampered with. After the injection, the injection indicator turns red. This indicates that the Anapen Auto-Injector has been fired correctly.
- **Black needle shield (reversible):** This protects the needle when you are not using the Anapen Auto-Injector. You pull the needle shield off before the injection. After the injection, turn the black needle shield around and put it back onto the same end of Anapen Auto-Injector, to cover the needle.
- **Grey safety cap:** This covers the red firing button. It stops the button from being pushed by mistake.

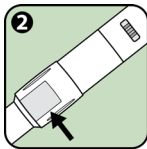
Do not remove the black needle shield or the grey safety cap until you need to use your Anapen Auto-Injector.

B. Checking your Anapen Auto-Injector

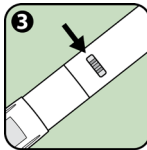
Before you use your Anapen Auto-Injector, and on a regular basis, you must check it as follows:



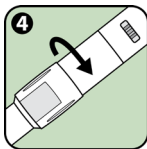
1. Rotate the cover over the solution windows fully anticlockwise as indicated by the arrow to line up the lenses with the solution windows on the auto-injector body.



2. Look through the lens into the **solution window**. Check that the solution is clear and colourless. If it is cloudy, coloured or contains particles, discard the Anapen Auto-Injector.



3. Make sure that the **injection indicator** is not red. If it is red, this means that the Anapen Auto-Injector has already been fired and you must discard it.

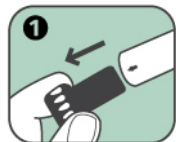


4. Rotate the cover over the solution windows fully back clockwise as shown by the arrow, to ensure both solution windows are covered. Put the Anapen Auto-Injector back in the carton until you need to use it.

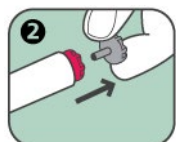
C. Using the Anapen Auto-Injector

If the black needle shield has been removed, **do not put your thumb, fingers or hand over the open end (needle end) of the Anapen Auto-Injector.**

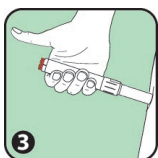
To use the Anapen Auto-Injector, follow the steps below:



1. Remove the black needle shield by pulling hard, in the direction of the arrow. This also removes a grey protective needle shield.



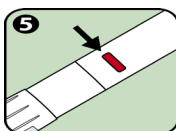
2. Remove the grey safety cap from the red firing button, by pulling as indicated by the arrow.



3. Hold the open end (needle end) of Anapen against the outer part of your thigh. If necessary, you can use Anapen through light clothing, such as denim, cotton or polyester.



4. Press the red firing button so that it clicks. **Keep holding the Anapen Auto-Injector against your thigh for 10 seconds.** Slowly remove Anapen from your thigh. Then gently massage the injection area.



5. **The injection indicator will have turned red.** This shows that the injection is complete. If the injection indicator is not red, you must repeat the injection with a new Anapen.



6. After the injection, the needle sticks out. To cover it, click the wide end of the black needle shield back on the open end (needle end) of Anapen Auto-Injector (as indicated by the arrow).

Give your used Anapen to the hospital or pharmacist for proper disposal.

If you use more Anapen than you should

- If you inject too much adrenaline or inject the medicine accidentally into a blood vessel or finger you should seek immediate medical attention at the nearest hospital.
- If you have further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

The following side effects are based upon experience with the use of adrenaline but the frequency of side effects cannot be estimated:

- Changes to the blood such as high sugar levels, low potassium levels, high acid content
- Anxiety, hallucinations
- Headache, dizziness, trembling, fainting
- Dilated pupils
- Rapid or uneven heart beat, irregular heartbeat and heart attack, sensation of heart pounding (palpitations)
- Raised blood pressure, sudden increase in blood pressure which may cause bleeding into the brain, reduced blood flow to the skin (mucous tissues and kidneys), coldness of extremities
- Difficulty in breathing
- Nausea, vomiting
- Difficulty in urinating
- Sweating, pale skin (pallor), weakness, apprehension, nervousness, muscle shakes

Anapen contains sodium metabisulfite (E223) which can cause allergic type reactions and difficulty in breathing especially in those with a history of asthma. You should seek immediate medical attention if you experience these side effects.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Anapen

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

Do not store above 25°C.

Do not use this medicine after the expiry date (Exp.date:) which is stated on the carton and the auto-injector. The expiry date refers to the last day of that month.

Discard and replace Anapen after the expiry date. Check the solution regularly through the inspection window to make sure the solution is clear and colourless.

Discard and replace Anapen if the solution is cloudy, coloured or contains particles.

You should inspect your pen regularly as shown in Section 3 of this leaflet under the heading “Instructions for use”. This is to ensure your Anapen can be used in an emergency.

Keep the auto-injector in the outer carton in order to protect from light.

Store Anapen lying down.

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

6. Contents of the pack and other information

What Anapen contains

- The active substance is adrenaline (epinephrine) 500 micrograms in 0.3ml.
- Other ingredients are: sodium metabisulfite (E223), sodium chloride, hydrochloric acid, water for injections.

What Anapen looks like and contents of the pack

Anapen consists of a pre-filled syringe* of adrenaline solution for injection contained in an auto injection device (Auto-Injector). One dose of 0.3 ml contains 500 micrograms of adrenaline (epinephrine). Anapen is a clear colourless solution practically free from particles.

Anapen is supplied in packs of 1 or 2 auto-injectors with a thermoformed tray protection into the cardboard. Not all pack sizes may be marketed.

* Exposed needle length: 10 mm ± 1.5 mm.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Bioprojet Pharma
9 rue Rameau
75002 Paris
France

Manufacturer:

Owen Mumford Limited,
Primsdown Industrial Estate,
Worcester Road, Chipping Norton,
Oxfordshire OX7 5XP,
UK.

LYOFAL - SALON DE PROVENCE, ZA La Gandonne,
452 rue du Rémoulaire, SALON DE PROVENCE,
13300, France

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

Anapen: Austria, Cyprus, Czech Republic, France, Germany, Greece, Hungary, Ireland, Poland, Portugal, Slovenia, Spain

Chenpen: Belgium Italy

This leaflet was last revised in April 2020