

4 Possible side effects

Like all medicines, **Anapen** can have side effects, although not everybody gets them.

- **Anapen contains sodium metabisulphite (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.
- Common side effects of adrenaline include a sensation of heart pounding (palpitations), rapid or uneven heart beat, sweating, nausea, vomiting, difficulty in breathing, dizziness, weakness, pale skin (pallor), trembling, headache, apprehension, nervousness, anxiety and coldness of extremities.
- Other less frequent side effects include hallucinations, fainting, dilated pupils, difficulty in urinating, muscle shakes, raised blood pressure and changes to the blood such as high sugar levels, low potassium levels and high acid content.
- Occasionally, at high doses, or in susceptible patients, a sudden increase in blood pressure which may cause bleeding into the brain, irregular heartbeat and heart attack and reduced blood flow to the skin, mucous tissues and kidneys may occur.

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

5 How to store Anapen

Keep out of reach and sight of children

- Do not use the Anapen Auto-Injector after the expiry date shown on the carton.
- Do not store above 25°C.
- To protect from light store in the original packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Never give your Anapen Auto-Injector to another person even if his or her symptoms are similar to yours. This medicine is for your personal use only.

6 Further Information

What Anapen contains

- The active substance is adrenaline (epinephrine) 300 micrograms in 0.3ml.
- The medicine also contains: Sodium metabisulphite (E223), Sodium chloride, Hydrochloric acid, Water for injections.

What Anapen looks like and the contents of the pack

Anapen consists of a pre-filled syringe of adrenaline solution for injection contained in an auto-injection device (Auto-Injector). **Anapen** is produced in two dosage strengths, **Anapen 300** micrograms in 0.3 ml solution for injection and **Anapen Junior** 150 micrograms in 0.3ml solution for injection.

Anapen is supplied in units of 1 or 2. Not all packs are available in some markets.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Lincoln Medical Limited, Unit 8 Wilton Business Centre, Wilton Salisbury, SP2 0AH, UK

Manufacturer: Owen Mumford Limited - Brook Lane Woodstock Oxon OX20 1TU UK

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

United Kingdom, Ireland, Greece, Cyprus, Austria: Anapen 300 micrograms in 0,3 ml Solution for Injection

Poland, Hungary, Czech Republic, Bulgaria, Romania: Anapen 300 micrograms/ 0,3 ml Solution for Injection

France, Luxembourg, Portugal: Anapen 0,30mg/0,3ml Solution for injection

Germany: Anapen 300 mikrogramm Solution for injection

Sweden: Anapen 0,30 mg/dos Solution for injection

The Netherlands: Anapen 0.3mg/dosis Solution for Injection

This leaflet was last approved: 11/12/07. Anapen is a registered trade mark

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Anapen[®] 300 micrograms

in 0.3 ml solution for injection
(pre-filled syringe)

Adrenaline (Epinephrine) Auto-Injector

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

- 1 - What **Anapen** is and what it is used for?
- 2 - Before you use **Anapen**
- 3 - How to use **Anapen**
- 4 - Possible side effects
- 5 - How to store **Anapen**
- 6 - Further 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.
- **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.
- **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 Before you use Anapen

Do not use Anapen

- If you are allergic (hypersensitive) to adrenaline or any of its other ingredients (see section below for information on sulphites).

Take special care with Anapen

- Your doctor should have carefully instructed you when to use and the correct way to use your **Anapen** Auto-Injector.
- This medicine is for emergency only and you should seek immediate medical attention after using your 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.

• 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.

Using other medicines

You should also tell your doctor if you are presently receiving medicines particularly

- Medicines for heart disease, such as digitalis (digoxin), beta-blockers, quinidine,
- Medicines for depression, such as tricyclic antidepressants, mono amine oxidase inhibitors (MAOI's), 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).

Inform your doctor, health professional or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Using Anapen with food and drink

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

Pregnancy & Breast-feeding

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

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.

Important information about some of the ingredients of Anapen:

Anapen contains sodium metabisulphite (E223) which can cause allergic type reactions and difficulty in breathing especially in those with a history of asthma. You should tell your doctor if you know you are allergic to sodium metabisulphite.

3 How to use Anapen

- Always use this medicine exactly as your doctor has instructed you.
- Check with your doctor or pharmacist if you are unsure.
- Only inject into the thigh muscle.
- For single use only, please ensure you discard safely immediately after use.

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 following 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.

For use in adults

- The usual dose is 300 micrograms.
- Larger adults may require more than one injection to reverse the effect of an allergic reaction.
- In circumstances where a single dose of adrenaline does not completely reverse the effect of an allergic reaction a repeat injection may be given after 10 to 15 minutes.

For use in children

- 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.

You should notify your doctor or attend the nearest hospital as soon as possible after use of **Anapen**. Make sure you explain that you have received an injection into your thigh muscle of adrenaline. Show the doctor the box and these instructions.

Important Instructions for use (See diagrams 1- 4 below)

- **DO NOT REMOVE** the black safety cap or the black needle cap until you need to use your **Anapen**.



1 Remove black needle cap.

This cap is attached to a grey protective needle sheath and may require reasonable force to remove.

2 Remove the black safety cap from the red firing button

3 Hold Anapen against outer thigh, and press the firing button.

Injection can be made through light clothing if necessary.

4 Hold Anapen in position for 10 seconds (This allows the full dose of adrenaline to be injected). Gently massage the injection site.

- After use replace the black needle cap and return the medicine to your pharmacy or doctor for safe 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.