

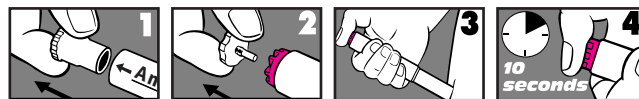
UCB Pharma will endeavour to send out the reminder alert at least two months prior to expiry of your product, however, UCB Pharma accepts no responsibility should the reminder not be received by you for whatever reason. While we offer this reminder service for our customers' added convenience, it is not intended to replace your own obligations in ensuring the product has not expired. You bear the ultimate responsibility to check the expiry date on the product before using it and to ensure that you have a current product at all times. The provision of this reminder does not in any way supplement or replace the medical advice that you must continue to obtain separately.

### INSTRUCTIONS FOR USE

FOR SINGLE USE ONLY. DISCARD SAFELY IMMEDIATELY AFTER USE.

#### IMPORTANT:

1. **DO NOT REMOVE** the black safety cap or the black needle cap until you need to use your Anapen.
2. **WHEN REMOVING THE BLACK NEEDLE CAP** (see diagram 1). The black needle cap is attached to a grey protective sheath that covers the needle and therefore may require reasonable force to remove.
3. After use replace the black needle cap and return the Anapen to your pharmacy or doctor for safe disposal.



1. **REMOVE THE BLACK NEEDLE CAP**
2. **REMOVE THE BLACK SAFETY CAP FROM THE RED FIRING BUTTON**
3. **HOLD ANAPEN AGAINST THE OUTER THIGH AND PRESS THE FIRING BUTTON**  
You can inject through light clothing if necessary.
4. **HOLD ANAPEN IN POSITION FOR 10 SECONDS** (This allows the full dose of adrenaline (epinephrine) to be injected)  
**GENTLY MASSAGE THE INJECTED SITE**

#### Overdose or accidental injection

If you take an overdose of adrenaline (epinephrine) or inject the Anapen accidentally into a blood vessel or finger you should seek immediate medical attention at the nearest hospital.

#### Shelf life and Storage

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

#### Legal category

POM.

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

Keep out of reach and sight of children.

This leaflet was last revised in September 2005.

Anapen is a registered trade mark.

AJ/1424/11/0067/04

## ANAPEN® PATIENT INFORMATION LEAFLET



**ANAPEN®**  
300 micrograms in 0.3ml solution for injection (pre-filled syringe)  
Adrenaline (epinephrine) auto-injector

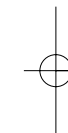
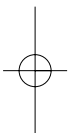
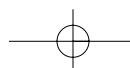
**ANAPEN® JUNIOR**  
150 micrograms in 0.3ml solution for injection (pre-filled syringe)  
Adrenaline (epinephrine) auto-injector

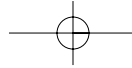


**Sterile solution for single dose intramuscular injection in allergic emergencies**

**Active ingredient:** Adrenaline (epinephrine) -  
Anapen 300 micrograms in 0.3ml.  
Anapen Junior 150 micrograms in 0.3ml.

**Anapen also contains:** Sodium metabisulphite (E223)  
Sodium chloride  
Hydrochloric acid  
Water for injections





**What is Anapen?**

Anapen consists of a pre-filled syringe of adrenaline (epinephrine) contained in an auto-injection device (auto-injector) which injects a single dose of adrenaline (epinephrine) into muscle. Anapen is produced in two dosage strengths: ANAPEN 300 micrograms in 0.3ml solution for injection and ANAPEN Junior 150 micrograms in 0.3ml solution for injection. Anapen is supplied in single units. Product Licence/Product Authorisation Holder: LINCOLN MEDICAL LTD., 13 Boathouse Meadow Business Park, Cherry Orchard Lane, Salisbury, SP2 7LD UK. Distributor: UCB Pharma Ltd., 208 Bath Road, Slough, Berkshire, SL1 3WE, UK. Manufacturer: Owen Mumford Ltd., Brook Hill, Woodstock, Oxon. OX20 1TU.

**What is Anapen used for?**

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.

**Who should not use Anapen?**

Do not use Anapen if you are allergic to adrenaline (epinephrine) or any of its other ingredients. (See section below for information on sulphates).

**Precautions to take before using Anapen**

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

You should have been carefully instructed by your doctor when to use and the correct way to use your Anapen. Anapen 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, other diseases of the blood and blood circulation, high intraocular pressure, kidney or prostate disease, diabetes or any other medical conditions.

You should also tell your doctor if you are presently receiving any medicines particularly those for heart disease, such as digitalis (digoxin); beta-blockers; quinidine; medicines for depression, such as tricyclics; mono amine oxidase inhibitors (MAOIs); serotonin and noradrenaline reuptake inhibitors (SNRIs); medicines for Parkinsons disease; antihistamines such as diphenhydramine or chlorpheniramine; medicines to treat thyroid disease, medicines to treat disorders of the nervous system; theophylline; oxytocin; certain anaesthetics or any other medicine.

Alcohol may adversely affect this medicine by increasing its effects.

If you are being treated for diabetes, your doctor may change the dosage of your medication after using Anapen.

Accidental injection into the hand or foot may result in loss of blood flow to the affected part and you should immediately seek medical advice at the nearest hospital.



It has not been established that taking adrenaline (epinephrine) during pregnancy is without risk to the foetus; however, if you are pregnant this should not deter you 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 (epinephrine) would not be expected to have any effect on the nursing infant.

**How to use your Anapen Auto-Injector**

USE ONLY BY THE INTRAMUSCULAR ROUTE.

Your doctor should have carefully explained the circumstances under which you should use Anapen. If this has not been done or if you have any doubts or questions you must immediately talk to your doctor before attempting to use Anapen. 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 may follow swelling of the throat, and wheezing, shortness of breath and coughing may result from tightening of the muscles in the lungs. Other symptoms of anaphylaxis include headache, vomiting and diarrhoea. Collapse and loss of consciousness may be due to a sudden lowering of blood pressure. When you experience these signs and symptoms use the Anapen Auto-Injector immediately by intramuscular injection. You must only inject Anapen into the muscle on the outer part of your thigh, not the buttock.

**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 some circumstances a single dose of adrenaline (epinephrine) may not completely reverse the effects of an acute allergic reaction and for such patients a repeat injection may be given after 10-15 minutes.

**Use in children:** The appropriate dose may be 150 micrograms (Anapen Junior) or 300 micrograms (Anapen) of adrenaline (epinephrine), depending on the body weight of the child and the discretion of the doctor. The auto-injector of Anapen Junior is designed to deliver a single dose of 150 micrograms adrenaline (epinephrine). 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 intramuscular injection of adrenaline (epinephrine). Show the doctor the box and these instructions.

**Possible undesirable effects with Anapen**

Common side effects of adrenaline (epinephrine) include heart flutter (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 people, a sudden increase in blood pressure, irregular heartbeat and reduced blood flow may occur.

If you experience any other adverse effects following the use of Anapen you should inform your doctor.

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

**EXPIRY DATE ALERT FORM**

Your Anapen should be replaced before the expiry date marked on the carton and on the Auto-Injector itself.

For added safety and convenience, Celltech offer all patients prescribed Anapen an Expiry Date Alert Service. We will contact you by post to remind you when you need to replace your Anapen. Just fill in the form and return it to:

**Medical Information Department,  
UCB Pharma Ltd,  
FREEPOST (SCE14832)\*,  
Slough SL1 3BR**

\* The Freepost service is not available in the Republic of Ireland.

Please complete this section in CAPITAL letters:

Batch No: (see pack).....

Expiry Date: (see pack).....

Your Name: .....

Your Address: .....

.....

.....

..... Post Code: .....

Date when you received your Anapen: .....

.....

Data Protection Act 1998

The personal data provided by you on the Expiry Date Alert Form will be used by Celltech Pharmaceuticals Limited for the purpose of reminding you that you need to replace your Anapen and for no other purpose. By completing and returning this form you are giving Celltech your explicit consent to use your personal data for this purpose.

