

ANAPEN®

ANAPEN® Junior 150 – contains adrenaline(epinephrine) 150 micrograms/0.3mL

ANAPEN® 300 - contains adrenaline(epinephrine) 300 micrograms/0.3mL

ANAPEN® 500 - contains adrenaline(epinephrine) 500 micrograms/0.3mL

adrenaline(epinephrine)

Consumer Medicine Information

This leaflet provides important information about using ANAPEN®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ANAPEN®.**

Where to find information in this leaflet:

1. Why am I using ANAPEN®?
2. What should I know before I use ANAPEN®?
3. What if I am taking other medicines?
4. How do I use ANAPEN®?
5. What should I know while using ANAPEN®?
6. Are there any side effects?
7. Product details

1. Why am I using ANAPEN®?

ANAPEN® contains the active ingredient

adrenaline(epinephrine).

Adrenaline belongs to the group of adrenergic and dopaminergic agents which are classified as cardiac stimulants. It is the medicinal product of choice to provide rapid relief of hypersensitivity reactions to allergies.

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 immediate EMERGENCY TREATMENT of a SEVERE ALLERGIC REACTION (also known as ANAPHYLAXIS) caused by peanuts or other foods, medicines, latex, insect bites or stings and other allergens.

ANAPEN® is intended for use in people who have been assessed and advised by their doctor or pharmacist as needing an ANAPEN® to treat their severe allergic reaction.

2. What should I know before I use ANAPEN®?

ANAPEN® is a pre-filled syringe of adrenaline contained in an automatic injection device (Auto-Injector). This injects a single dose of adrenaline into muscle.

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.
- 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

Avoidance of known allergens is most important in preventing severe allergic reactions. A severe allergic reaction, otherwise known as anaphylaxis, is overwhelming and

life-threatening. It affects the whole body, in particular the

- heart and blood circulation.
This may cause, for example, low blood pressure and collapse, or abnormal heart beat or function.
- air passages and lungs.
This causes difficulty in breathing, with noisy wheezing or gasping, possibly with sneezing and a very runny nose.
- stomach and bowels.
This may cause nausea, vomiting, diarrhoea and abdominal cramps, often severe.
- skin (very common).
This causes flushing, itching, skin rash, hives or swelling, which may be widespread or in one part of the body.
- brain.
There may be fits or confusion due to lack of oxygen.

Usually several parts of the body are affected. The patient feels extremely unwell.

It is important to act quickly to treat a severe allergic reaction.

The adrenaline in ANAPEN® treats allergic emergencies. It

- shrinks abnormally wide blood vessels and
- makes the heart beat strongly.

This helps improve the very low blood pressure and poor circulation that occur in a severe allergic reaction.

Adrenaline also

- relaxes the lungs. This eases breathing and lessens wheezing.
- helps stop
 - swelling, for example, of the face and lips
 - skin rash and/or
 - itching.

Warnings

Do not use ANAPEN® if:

- you are allergic to adrenaline(epinephrine), or any

of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.

Give WITH CAUTION to those who have:

- high blood pressure
- thyroid problems
- high pressure in the eye (narrow-angle glaucoma).

Take care also when giving ANAPEN® to those:

- having an anaesthetic or who have:
- diabetes
- heart disease
- allergy to ANAPEN®
- brain damage.

You should tell your doctor or pharmacist if you have:

- allergies to any other medicines, foods, preservatives or dyes.
- depression, or are on medication for depression
- thyroid problems, or are on thyroid medication
- heart disease, including angina or high blood pressure
- diabetes
- high pressure in the eye (narrow angle glaucoma)
- asthma
- are pregnant or planning to become pregnant
- ever had an allergic reaction to sodium metabisulfite.
- lowered potassium levels
- increased calcium in the blood
- Disorders of the blood circulation
- phaeochromocytoma (a type of tumour in the adrenal gland)
- kidney or prostate disease

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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 is excreted in breast milk

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ANAPEN® and affect how it works. These include:

- Medicines for heart disease, such as digitals (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).

These medicines may be affected by ANAPEN® or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ANAPEN®.