

# ANAPEN®

## CONSUMER MEDICINE INFORMATION

### ANAPEN® and ANAPEN® JUNIOR

Adrenaline 300µg/0.3 mL Auto-Injector (ANAPEN®)  
Adrenaline 150µg/0.3 mL Auto-Injector (ANAPEN® JUNIOR)

#### What is in this leaflet?

This leaflet answers some common questions about ANAPEN® and ANAPEN® JUNIOR Adrenaline Auto-Injector. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you receiving ANAPEN® against the benefits this medicine is expected to have for you.

If you have any concerns about receiving this medicine, talk to your doctor or pharmacist before there is a situation where ANAPEN® and ANAPEN® JUNIOR is needed.

Please read this leaflet carefully before an emergency arises.

Keep this leaflet safely, with the ANAPEN® and ANAPEN® JUNIOR Auto-Injector. You will probably want to read it again.

#### What ANAPEN® and ANAPEN® JUNIOR are used for

ANAPEN® and ANAPEN® JUNIOR are only for the immediate EMERGENCY TREATMENT of a SEVERE ALLERGIC REACTION (also known as ANAPHYLAXIS). Your doctor or pharmacist will explain what this is like, so that you know when you must use Anapen.

ANAPEN® and ANAPEN® JUNIOR are used to treat people who have a severe allergic reaction caused by, for example:

- food
- insect bites or stings
- latex
- medicines
- other allergens, possibly unidentified.

See **Side effects** for information regarding allergy to sodium metabisulfite.

#### Avoiding known allergens is most important in preventing severe allergic reactions.

A severe allergic reaction 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 and diarrhea, 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® and ANAPEN® JUNIOR 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

The ANAPEN® Auto-Injector is intended for use in people who have been assessed and advised by their doctor as needing an ANAPEN® Auto-Injector to treat their severe allergic reaction and who:

- weigh more than 30kg, and
- are having a severe allergic reaction.

The ANAPEN® JUNIOR Auto-Injector is intended for use in people who have been assessed and advised by their doctor as needing an ANAPEN® JUNIOR Auto-Injector to treat their severe allergic reaction and who:

- weigh more than 15kg, and
- are having a severe allergic reaction.
- weigh less than 30kg, and

**Note:** For a child who weighs less than 15kg it is not recommended that the ANAPEN® or ANAPEN® JUNIOR Auto-Injector be used.

ANAPEN® or ANAPEN® JUNIOR:

- provides convenient first-aid.
- has a spring-activated, hidden needle.
- is for single use only.
- may be self-administered or administered by a carer.
- automatically injects one pre-measured dose of adrenaline.

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ANAPEN® and ANAPEN® JUNIOR may be prescribed by your doctor or you can purchase it directly from the pharmacist on the advice of the doctor or pharmacist. Ask your doctor or the pharmacist if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

This medicine is not addictive.

#### Before you use ANAPEN® or ANAPEN® JUNIOR

The ANAPEN® or ANAPEN® JUNIOR Auto-Injectors are simple to use. Please read and follow the step-by-step instructions.

An ANAPEN® Trainer is also available. You should ask your doctor or pharmacist to demonstrate the use of the ANAPEN® Trainer if this is the first time you are using ANAPEN® or ANAPEN® JUNIOR.

**Do not remove the grey safety cap until you need and are ready to use ANAPEN® or ANAPEN® JUNIOR.**

There is no *visible* needle. This helps overcome fear of injection. The hidden needle is very fine so that the injection does not usually hurt.

#### When you must not use it

Anapen is a life-saving treatment in the emergency management of severe allergic reactions. Therefore, it should not be withheld from anyone who is considered to need it.

**Do not use ANAPEN® or ANAPEN® JUNIOR**

- after the expiry date on the Auto-Injector and carton or
- if the packaging is torn, doesn't look quite right or shows signs of tampering.
- if you have an allergy to any of the ingredients listed at the end of this leaflet, in particular sodium metabisulfite.

If the ANAPEN® or ANAPEN® JUNIOR packaging is damaged or it is past the expiry date, return it to your pharmacist for disposal.

**You should not use ANAPEN® or ANAPEN® JUNIOR if you are in childbirth labour.** It can stop the contractions in the uterus.

#### Before you use it

ANAPEN® or ANAPEN® JUNIOR are effective as emergency treatment of a severe allergic reaction ONLY when used according to the directions in this leaflet.

Give WITH CAUTION to those who have

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

Take care also when giving ANAPEN® or ANAPEN® JUNIOR to those

- having an anaesthetic

or who have:

- diabetes
- allergy to ingredients included in the ANAPEN® or ANAPEN® JUNIOR
- heart disease
- brain damage

**You should tell your doctor or pharmacist if you have any of the following medical conditions:**

- depression, or are on medication for depression
- heart disease or high blood pressure
- brain damage
- lung disease
- high pressure in the eye (narrow angle-glaucoma)
- ever had an allergic reaction to any other medicines, foods, preservatives or dyes.
- ever had an allergic reaction to sodium metabisulfite or to any of the ingredients listed at the end of this leaflet.
- thyroid problems, or are on thyroid medication
- diabetes
- stroke
- angina or chest pain
- asthma

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.** Your doctor can discuss with you the risks and benefits involved.

If you are not sure you should be given this medicine, talk to your doctor.

**If you have not told your doctor about any of the above information, tell him/her before you use ANAPEN® or ANAPEN® JUNIOR.**

#### Taking other medicines

**Tell your doctor or pharmacist if you are taking other medicines, including any medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.** Some medicines may interfere with ANAPEN® and ANAPEN® JUNIOR including:

- medicines for high blood pressure, especially those known as "beta-blockers", and other medicines for heart problems.
- medicines for depression, especially "tricyclic antidepressants"

- corticosteroids
- general anaesthetics
- antihistamines
- diuretics
- thyroid hormone
- medicines for diabetes

These medicines may affect how well the adrenaline in ANAPEN® and ANAPEN® JUNIOR works. You may need different amounts of your medicines or you may need to take different medicines. Your doctor or pharmacist have more information on medicines to be careful with or avoid and can tell you what to do if you are taking any of these medicines.

You should discuss any concerns you have with your doctor or pharmacist.

#### How to use ANAPEN® or ANAPEN® JUNIOR

**It is important to know how to use your ANAPEN® or ANAPEN® JUNIOR in an emergency (see Help in using ANAPEN® or ANAPEN® JUNIOR).**

**Carefully follow all directions given to you by your doctor or pharmacist.** They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet or on the ANAPEN® or ANAPEN® JUNIOR Auto-Injector, ask your doctor or pharmacist for help in using ANAPEN® or ANAPEN® JUNIOR.

#### Help in using ANAPEN® and ANAPEN® JUNIOR

**It is important to know how to use an ANAPEN® or ANAPEN® JUNIOR BEFORE a severe allergic reaction causes a medical emergency.**

Ask your doctor or pharmacist how you can get an 'ANAPEN® TRAINER' device for practice.

An ANAPEN® TRAINER device is similar to the real ANAPEN® or ANAPEN® JUNIOR. However, the ANAPEN® TRAINER has

- NO medicine (adrenaline) *and*
- NO needle

Ask your doctor or pharmacist to show you how to practice with the ANAPEN® TRAINER. If you practice using the ANAPEN® TRAINER, you will learn how to use the real ANAPEN® or ANAPEN® JUNIOR.

#### When to use it

Use ANAPEN® or ANAPEN® JUNIOR immediately if you have signs and symptoms of a severe allergic reaction, as described by your doctor or pharmacist. Symptoms do vary. However, the symptoms are likely to include:

- collapse
- wheezing
- skin rash, hives
- difficulty in breathing
- swelling, especially of the face, lips, tongue or throat
- itching

#### How much to use

- ANAPEN® Auto-Injector delivers one measured dose of adrenaline. This dose is for a person who weighs more than 30kg and has been assessed by their doctor as needing ANAPEN®.
- Your doctor may also advise ANAPEN® JUNIOR Auto-Injector for a child who weighs from 15kg up to 30kg.

See also "What ANAPEN® and ANAPEN® JUNIOR are used for" above.

#### How to use it

##### General

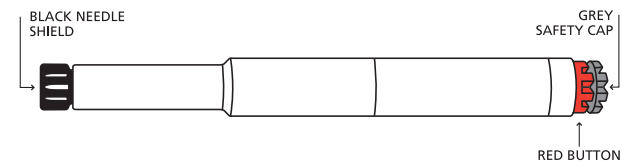
**It is suggested that practice with the ANAPEN® TRAINER be undertaken prior to the use of the ANAPEN® or ANAPEN® JUNIOR for the first time.**

**Carefully follow the step-by-step directions to make sure the ANAPEN® or ANAPEN® JUNIOR works correctly.**

#### Instructions for use of Anapen auto-injector (see diagrams 1-4 below)

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

**Do not put thumb, fingers or hand over the device once the black needle shield is removed.**



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**1** REMOVE BY PULLING BLACK NEEDLE SHIELD

**2** REMOVE BY PULLING GREY SAFETY CAP FROM RED BUTTON

**3** HOLD NEEDLE END FIRMLY AGAINST OUTER THIGH AT 90° ANGLE

**4** PRESS RED BUTTON SO IT CLICKS AND HOLD FOR 10 SECONDS

**Step 1**  
**Remove by pulling the black needle shield.** This may require reasonable force to remove. Do this only when you are ready to use your ANAPEN® or ANAPEN® JUNIOR. Do not dispose of this cap. It can be used to transport the used ANAPEN® or ANAPEN® JUNIOR to a pharmacist or doctor or hospital for safe disposal.

**Step 2**  
**Remove by pulling the grey safety cap from the red firing button.**

**Step 3**  
**Hold needle end firmly against the outer thigh at 90° angle.**

**Step 4**  
**Press the red firing button so it clicks and hold for 10 seconds**, if necessary, inject through light clothing. This will ensure that the full dose of adrenaline is administered. Gently massage the injection site for approximately 10 seconds after removal of the ANAPEN® or ANAPEN® JUNIOR.

**Step 5**  
**Record the time ANAPEN® or ANAPEN® JUNIOR was given. Seek further medical attention for yourself immediately. Although you have received adrenaline from ANAPEN®, you should seek medical attention.**

To avoid injury, follow the used Anapen disposal instructions below (see *Disposal*).

**Additional information about treatment of insect sting allergy**

Use ANAPEN® or ANAPEN® JUNIOR immediately if you have been stung by the insect and experience the signs and symptoms as described by your doctor or pharmacist.

If the insect's sting is easily accessible, remove the sting with your fingernails. Do not squeeze, pinch or push the sting deeper into the skin. If available, ice packs or sodium bicarbonate soaks may then be applied to the stung area.

Keep warm, calm, and as still as possible.

**If you use too much (overdose)**

Because each ANAPEN® or ANAPEN® JUNIOR contains only one dose, overdose is unlikely. Overdose may lead to a rise in blood pressure. This may cause bleeding in the brain or fluid in the lung. Symptoms of overdose may include feeling unwell, flushing or abnormal heart beats, and headaches.

If you think you or anyone else may have used too much of this medicine,

- consult your doctor immediately or
- telephone the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 POISON (0800 764 766) in New Zealand) for advice, or
- go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. Urgent medical attention may be required.

Ask your doctor or pharmacist if you have any concerns.

**Things to note about ANAPEN® or ANAPEN® JUNIOR**

**Things you must do**

Check what the expiry date is on your ANAPEN® or ANAPEN® JUNIOR.  
 Mark this expiry date on your calendar or diary.  
 Replace your ANAPEN® or ANAPEN® JUNIOR prior to this expiry date.  
 The ANAPEN® or ANAPEN® JUNIOR Auto-Injectors can be damaged and made unusable if it is mishandled. ANAPEN® and ANAPEN® JUNIOR are NOT toys. Keep it out of reach of children.

**Things you must not do**

- Do not use ANAPEN®**
- to treat any other medical conditions unless your doctor tells you to.
  - in a child who weighs 15kg to 30kg unless recommended by your doctor. ANAPEN® JUNIOR is generally recommended for children who weigh 15kg to 30kg. (See also "What ANAPEN® is used for" above).

- in a child who weighs less than 15kg. Talk to your doctor if this is the case.
- Do not use ANAPEN® JUNIOR**
- to treat any other medical conditions unless your doctor tells you to.
  - in a child who weighs more than 30kg unless recommended by your doctor. ANAPEN® is generally recommended for children who weigh more than 30kg. (See also "What ANAPEN® and ANAPEN® JUNIOR is used for" above).
  - in a child who weighs less than 15kg. Talk to your doctor if this is the case.

**Do not take off the grey safety cap until you need to use ANAPEN® or ANAPEN® JUNIOR and are ready to use it.** Remember that the ANAPEN® and ANAPEN® JUNIOR Auto-Injectors are activated ("triggered", ready to "fire") as soon as you take off the grey safety cap.

**Do not touch or place on any person or object while you are taking off the grey safety cap and/or after you have taken off the grey safety cap.**

After you take off the black needle shield and grey safety cap

- Do not touch Red Button until needle end is placed against thigh and ready to use.

**Do not inject into hands, feet, ears, nose, buttocks, genital area or into a blood vessel.** If this does happen accidentally you must immediately seek medical attention.

**Side effects**

Like all medicines, ANAPEN® or ANAPEN® JUNIOR can cause some side effects. Side effects not listed in this leaflet may occur in some patients.

**Tell your doctor or pharmacist if you experience any unpleasant side effects after using ANAPEN® or ANAPEN® JUNIOR even if you do not think the effect is connected with the medicine or is listed in this leaflet. Ask your doctor or pharmacist to answer any questions you may have.**

**Do not be alarmed by the following list of side effects. You may not experience any of them.**

**Adrenaline**

Tell your doctor or pharmacist if you have any of the following:

- fear or anxiety
- restlessness
- respiratory difficulty (difficulty breathing or shortness of breath)
- weakness
- headache
- pallor
- nausea and vomiting
- hallucinations
- flushing or redness of face and skin
- tension
- tachycardia (fast or noticeable heart beat)
- tremor
- dizziness
- cold extremities
- sweating
- sleeplessness
- pale skin colour

More severe side effects can occur occasionally. They are caused by adrenaline stimulating the heart and increasing the blood pressure. Rarely, these side effects can cause, for example, a stroke, lung problems or severe irregular heartbeat.

Adrenaline may also cause disorientation and impaired memory.

**Sodium metabisulfite**

ANAPEN® or ANAPEN® JUNIOR contain a very small quantity of sodium metabisulfite as a preservative. In people who are allergic to sodium metabisulfite, this could cause a severe asthma. However, the active ingredient, adrenaline, in ANAPEN® is expected to overcome any allergic reaction to sodium metabisulfite. In an emergency, the risk of exposure to the very small amount of sodium metabisulfite is generally outweighed by the benefits of ANAPEN® or ANAPEN® Junior.

**Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.** Other side effects not listed above may occur in some people.

**Storing ANAPEN® or ANAPEN® JUNIOR before use**

Always handle the ANAPEN® or ANAPEN® JUNIOR Auto-Injector carefully, so as not to accidentally activate it or make it "fire".

**Storage**

Keep ANAPEN® or ANAPEN® JUNIOR available with the person for whom it is intended.  
 Keep ANAPEN® or ANAPEN® JUNIOR in a cool dry place at 15°C to 25°C. Do not refrigerate or freeze. Protect from light.  
**Do not place ANAPEN® or ANAPEN® JUNIOR in the fridge. Do not leave ANAPEN® or ANAPEN® JUNIOR in your car.** Extreme temperatures may cause the auto-injector unit to malfunction.

**Do not store ANAPEN® or ANAPEN® JUNIOR or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.** Heat and dampness can destroy some medicines.

Keep ANAPEN® or ANAPEN® JUNIOR where children cannot accidentally reach it.

**After using ANAPEN® or ANAPEN® JUNIOR**

**Disposal**

After the ANAPEN® or ANAPEN® JUNIOR auto-injector has "fired", the needle is exposed and could cause injury. You may replace the black needle cap back onto the ANAPEN® or ANAPEN® JUNIOR.

After use, continue to handle the ANAPEN® or ANAPEN® JUNIOR Auto-Injector safely and with care. Do this even if you think the ANAPEN® or ANAPEN® JUNIOR Auto-Injector has not "triggered", "fired" or worked properly.

You CANNOT RE-USE the ANAPEN® or ANAPEN® JUNIOR Auto-Injector even though some adrenaline is left inside it. After use, do not throw away the ANAPEN® or ANAPEN® JUNIOR Auto-Injector.

- Do not touch or bend the exposed Needle
- Give your used ANAPEN® or ANAPEN® JUNIOR to your doctor or emergency healthcare professional. This is for inspection, if required, and also for safe disposal. The used ANAPEN® or ANAPEN® JUNIOR Auto-Injector, should be placed in a rigid sharps disposal unit.

**Product description**

**Ingredients**

The ANAPEN® Auto-Injector holds 1mL of solution. It delivers a 0.3mL dose of solution. This dose provides 300µg of adrenaline.

The injection also contains small amounts of

• sodium chloride	1.8mg/0.3mL
• sodium metabisulfite	510µg/0.3mL
• hydrochloric acid	30-35 mg/0.3 mL
• water for injections	6600-6660 mg/0.3 mL

It does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

ANAPEN® JUNIOR Auto-Injector holds 1mL of solution. It delivers a 0.3mL dose of solution. This dose provides 150µg of adrenaline.

The injections also contains small amounts of

• sodium chloride	1.8mg/0.3mL
• sodium metabisulfite	510µg/0.3mL
• hydrochloric acid	20-30 mg/0.3 mL
• water for injections	6600-6660 mg/0.3 mL

It does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

This is not all the information available on ANAPEN® or ANAPEN® JUNIOR. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

**Supplier**

ANAPEN® (AUST R 134653) and ANAPEN® JUNIOR (AUST R 135008) are distributed in Australia by:  
 Link Medical Products Pty Ltd  
 18/6a Prosperity Parade,  
 Warriewood NSW 2102 Australia

This leaflet was prepared in December 2009.