

Consumer Medicine Information

ANAPEN[®] 500, ANAPEN[®] 300 and ANAPEN[®] 150

Adrenaline 500 µg/0.3 mL Auto-Injector (ANAPEN[®] 500)

Adrenaline 300 µg/0.3 mL Auto-Injector (ANAPEN[®] 300)

Adrenaline 150 µg/0.3 mL Auto-Injector (ANAPEN[®] 150)

What is in this leaflet?

This leaflet answers some common questions about **ANAPEN[®] 500, ANAPEN[®] 300** and **ANAPEN[®] 150** Adrenaline Auto-Injectors. 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[®] 500, ANAPEN[®] 300 and ANAPEN[®] 150 is needed.

Please read this leaflet carefully *before* an emergency arises.

Keep this leaflet safely, with the **ANAPEN[®] 500, ANAPEN[®] 300** and **ANAPEN[®] 150** Auto-Injector. You will probably want to read it again.

What ANAPEN[®] 500, ANAPEN[®] 300 and ANAPEN[®] 150 are used for

ANAPEN[®] 500, ANAPEN[®] 300 and **ANAPEN[®] 150** 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[®] 500, ANAPEN[®] 300 and **ANAPEN[®] 150** are used to treat people who have a severe allergic reaction caused by, for example:

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

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[®] 500**, **ANAPEN[®] 300** and **ANAPEN[®] 150** 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[®] 500 Auto-Injector** is intended for use in people who have been assessed and advised by their doctor as needing an **ANAPEN[®] 500 Auto-Injector** to treat their severe allergic reaction and who:

- weigh 60 kg or more or patients at high risk of severe anaphylaxis for whom the 300 microgram dose may not be sufficient , and
- are having a severe allergic reaction.

The **ANAPEN[®] 300 Auto-Injector** is intended for use in people who have been assessed and advised by their doctor as needing an **ANAPEN[®] 300 Auto-Injector** to treat their severe allergic reaction and who:

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

The **ANAPEN® 150 Auto-Injector** is intended for use in people who have been assessed and advised by their doctor as needing an **ANAPEN® 150 Auto-Injector** to treat their severe allergic reaction and who:

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

Note: For a child who weighs less than 15kg it is not recommended that the **ANAPEN® 500**, **ANAPEN® 300** or **ANAPEN® 150** auto-injector be used.

ANAPEN® 500, ANAPEN® 300 and ANAPEN® 150:

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

ANAPEN® 500, ANAPEN® 300 and ANAPEN® 150 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® 500, ANAPEN® 300 or ANAPEN® 150

The **ANAPEN® 500, ANAPEN® 300 or ANAPEN® 150** 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® 500, ANAPEN® 300 or ANAPEN® 150**.

Do not remove the grey safety cap until you need and are ready to use ANAPEN® 500, ANAPEN® 300 or ANAPEN® 150.

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® 500, ANAPEN® 300 and ANAPEN® 150

- **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 metabisulphite.

If the **ANAPEN® 500**, **ANAPEN® 300** or **ANAPEN® 150** packaging is damaged or it is past the expiry date, return it to your pharmacist for disposal.

You should not use ANAPEN® 500, ANAPEN® 300 or ANAPEN® 150 if you are in childbirth labour. It can stop the contractions in the uterus.

Before you use it

ANAPEN® 500, ANAPEN® 300 or ANAPEN® 150 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
- thyroid problems
- high pressure in the eye (narrow-angle glaucoma).

Take care also when giving **ANAPEN® 500, ANAPEN® 300 or ANAPEN® 150** to those

- having an anaesthetic

or who have:

- diabetes
- heart disease
- allergy to ingredients included in the **ANAPEN® 500, ANAPEN® 300 or ANAPEN® 150**
- 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
- thyroid problems, or are on thyroid medication
- heart disease or high blood pressure
- diabetes
- brain damage
- stroke
- lung disease
- angina or chest pain
- high pressure in the eye (narrow angle glaucoma)
- asthma
- 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.

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[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150

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[®] 500, ANAPEN[®] 300** and **ANAPEN[®] 150** 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
- diuretics
- general anaesthetics
- thyroid hormone
- antihistamines.
- medicines for diabetes

These medicines may affect how well the adrenaline in **ANAPEN[®] 500, ANAPEN[®] 300** and **ANAPEN[®] 150** 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[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150

It is important to know how to use your ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150 in an emergency (see *Help in using ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150*).

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[®] 500, ANAPEN[®] 300** or **ANAPEN[®] 150** Auto-Injector, ask your doctor or pharmacist for help in using **ANAPEN[®] 500, ANAPEN[®] 300** and **ANAPEN[®] 150**.

Help in using ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150

It is important to know how to use an ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150 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[®] 500, ANAPEN[®] 300** or **ANAPEN[®] 150**. However, the **ANAPEN[®] Trainer** has

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

- **NO** needle *and*

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[®] 500**, **ANAPEN[®] 300** or **ANAPEN[®] 150**.

When to use it

Use **ANAPEN[®] 500**, **ANAPEN[®] 300** or **ANAPEN[®] 150** 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
- difficulty in breathing
- wheezing
- swelling, especially of the face, lips, tongue or throat
- skin rash, hives
- itching.

How much to use

- **ANAPEN[®] 500** Auto-Injector delivers one measured dose of adrenaline. This dose is for a person who weighs 60 kg or more or at high risk of severe anaphylaxis and has been assessed by their doctor as needing **ANAPEN[®] 500**.
- **ANAPEN[®] 300** Auto-Injector delivers one measured dose of adrenaline. This dose is for a person who weighs more than 30 kg and has been assessed by their doctor as needing **ANAPEN[®] 300**.
- Your doctor may also advise **ANAPEN[®] 150** Auto-Injector for a child who weighs from 15 kg up to 30 kg.

See also "What **ANAPEN[®] 500**, **ANAPEN[®] 300** and **ANAPEN[®] 150** are used for" above.

How to use it

General

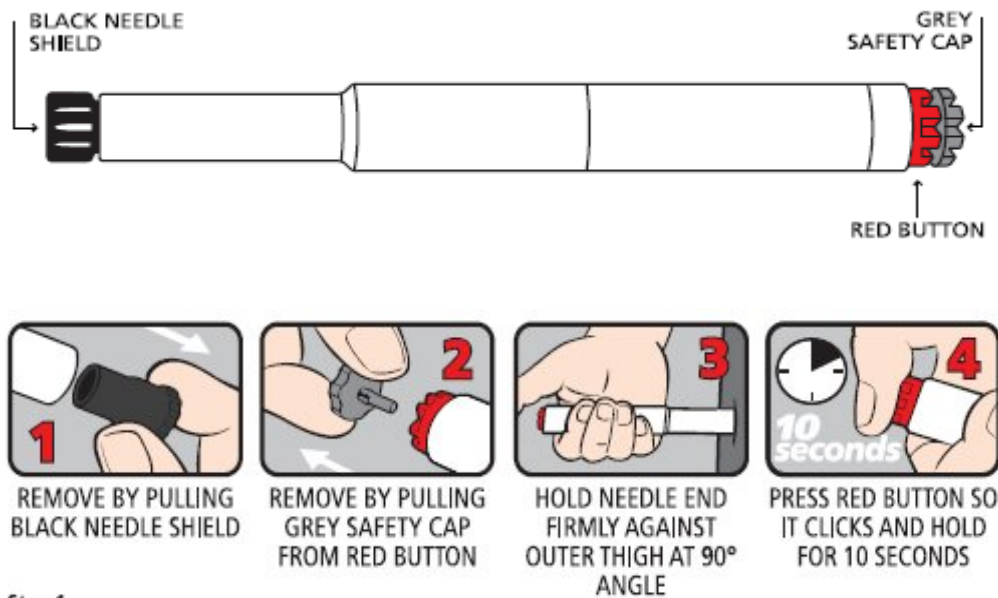
It is suggested that practice with the **ANAPEN[®] Trainer** be undertaken prior to the use of the **ANAPEN[®] 500**, **ANAPEN[®] 300** or **ANAPEN[®] 150** for the first time.

Carefully follow the step-by-step directions to make the **ANAPEN[®] 500**, **ANAPEN[®] 300** and **ANAPEN[®] 150** work 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.



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[®] 500**, **ANAPEN[®] 300** or **ANAPEN[®] 150**. Do not dispose of this cap. It can be used to transport the used **ANAPEN[®] 500**, **ANAPEN[®] 300** or **ANAPEN[®] 150** 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 90⁰ 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[®] 500**, **ANAPEN[®] 300** or **ANAPEN[®] 150**.

Step 5

Record the time ANAPEN[®] 500, **ANAPEN[®] 300** or **ANAPEN[®] 150** 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[®] 500**, **ANAPEN[®] 300** or **ANAPEN[®] 150** 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[®] 500**, **ANAPEN[®] 300** or **ANAPEN[®] 150** contains only one dose, overdosage is unlikely. Overdosage 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[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150

Things you must do

Check what the expiry date is on your **ANAPEN[®] 500**, **ANAPEN[®] 300** or **ANAPEN[®] 150**.

Mark this expiry date on your calendar or diary.

Replace your **ANAPEN[®] 500**, **ANAPEN[®] 300** or **ANAPEN[®] 150** prior to this expiry date.

The **ANAPEN[®] 500**, **ANAPEN[®] 300** or **ANAPEN[®] 150** Auto-Injectors can be damaged and made unusable if it is mishandled. **ANAPEN[®] 500**, **ANAPEN[®] 300** and **ANAPEN[®] 150** are NOT toys. Keep it out of reach of children.

Things you must not do

Do not use ANAPEN[®] 500 or ANAPEN[®] 300

- **to treat any other medical conditions** unless your doctor tells you to.
- **in a child who weighs 15 kg to 30 kg unless recommended by your doctor.** **ANAPEN[®] 150** is generally recommended for children who weigh 15 kg to 30kg. (See also "What Anapen is used for" above).
- **in a child who weighs less than 15 kg.** Talk to your doctor if this is the case.

Do not use ANAPEN[®] 150

- **To treat any other medical conditions** unless your doctor tells you to.
- **In a child who weighs more than 30 kg unless recommended by your doctor.** **ANAPEN[®] 300** is generally recommended for children who weigh

more than 30 kg (See also "What **ANAPEN[®] 500**, **ANAPEN[®] 300** and **ANAPEN[®] 150** are used for" above).

- **in a child who weighs less than 15 kg.** Talk to your doctor if this is the case.

Do not take off the grey safety cap until you need to use ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150 and are ready to use it. Remember that the **ANAPEN[®] 500, ANAPEN[®] 300 and ANAPEN[®] 150** Auto-Injectors can be *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, and genital area or into a blood vessel. If this does happen accidentally you must immediately seek medical attention.

Side effects

Like all medicines, **ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150** 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[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150 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,
- tension
- restlessness,
- tachycardia (fast or noticeable heart beat)
- respiratory difficulty (difficulty breathing or shortness of breath)
- tremor,
- weakness,
- dizziness,
- headache,
- cold extremities,
- pallor,
- sweating,
- nausea and vomiting,
- sleeplessness,
- hallucinations,
- pale skin colour

- flushing or redness of face and skin.

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[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150 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[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150**.

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[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150 before use

Always handle the **ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150** Auto-Injector carefully, so as not to accidentally activate it or make it "fire".

Storage

Keep **ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150** available with the person for whom it is intended.

Keep **ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150** in a cool dry place at 15°C to 25°C. Do not refrigerate. Protect from Light.

Do not place ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150 in the fridge. Do not leave ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150 in your car. Extreme temperatures may cause the auto-injector unit to malfunction.

Do not store ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150 or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep ANAPEN 500, ANAPEN[®] 300 or ANAPEN[®] 150 where children cannot accidentally reach it.

After using ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150

Disposal

After the **ANAPEN[®] 500, ANAPEN[®] 300 or ANAPEN[®] 150** auto-injector has "fired", the needle is exposed and could cause injury. Using a flat surface you may replace

the black needle cap back onto the **ANAPEN® 500**, **ANAPEN® 300** or **ANAPEN® 150**.

After use, continue to handle the **ANAPEN® 500**, **ANAPEN® 300** or **ANAPEN® 150** auto-injector safely and with care. Do this even if you think the **ANAPEN® 500**, **ANAPEN® 300** or **ANAPEN® 150** auto-injector has not "triggered", "fired" or worked properly.

You CANNOT RE-USE the **ANAPEN® 500**, **ANAPEN® 300** or **ANAPEN® 150** auto-injector even though some adrenaline is left inside it.

After use, do not throw away the **ANAPEN® 500**, **ANAPEN® 300** or **ANAPEN® 150** auto-injector.

- Do not touch or bend the exposed needle.
- Give your used **ANAPEN® 500**, **ANAPEN® 300** or **ANAPEN® 150** to your doctor or emergency healthcare professional. This is for inspection, if required, and also for safe disposal. The used **ANAPEN® 500**, **ANAPEN® 300** or **ANAPEN® 150** auto-injector should be placed in a rigid sharps disposal unit.

Product description

Ingredients

ANAPEN® 500 Auto-injector holds 1 mL of solution. It delivers a 0.3 mL dose of the solution. This dose provides 500 µg of adrenaline.

The injection also contains small amounts of

- sodium chloride 1.8 mg/0.3 mL
- sodium metabisulfite 510 µg/0.3 mL
- hydrochloric acid q.s to pH 3.4
- Water for injections q.s. to 0.3 mL

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

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

The injection also contains small amounts of

- sodium chloride 1.8 mg/0.3 mL
- sodium metabisulphite 510µg/0.3 mL
- hydrochloric acid q.s to pH 3.4
- Water for injections q.s. to 0.3 mL

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

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

The injection also contains small amounts of

- sodium chloride 1.8 mg/0.3 mL
- sodium metabisulfite 510µg/0.3 mL
- hydrochloric acid q.s to pH 3.4
- Water for injections q.s. to 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® 500**, **ANAPEN® 300** or **ANAPEN® 150**. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Supplier

ANAPEN® 500 (AUST R 170544), **ANAPEN® 300** (AUST R 134653) and **ANAPEN® 150** (AUST R 135008) are distributed in Australia by:

Link Medical Products PTY LTD.
5 Apollo Street,
Warriewood NSW 2102 Australia

ANAPEN® 500, **ANAPEN® 300** and **ANAPEN® 150** are distributed in New Zealand by:

Link Pharmaceuticals Ltd.
Level 31, Vero Centre
48 Shortland Street
Auckland 1140
New Zealand

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