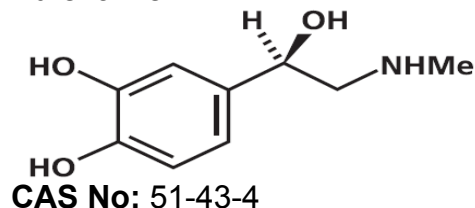


Product Information:**Anapen[®] and Anapen[®] Junior Adrenaline 300µg/0.3 mL and Adrenaline 150µg/0.3 mL**

PRODUCT INFORMATION

NAME OF MEDICINE

Adrenaline



DESCRIPTION

Name: (R)-1-(3,4-dihydroxyphenyl)-2-methylaminoethanol.**Empirical Formula:** C₉H₁₃NO₃**Molecular Weight** 183.20

It is a white odourless crystalline powder, soluble in solutions of mineral acids and alkalis.

The Anapen[®] and Anapen[®] Junior are auto-injector devices that provide adrenaline for intramuscular injection. Anapen[®] and Anapen[®] Junior contain 1 mL Adrenaline Injection 1:1000 USP and 1:2000 USP, respectively, and are designed to deliver a single 0.3 mL dose of 300 µg or 150 µg adrenaline. Each 0.3 mL of solution in Anapen[®] contains: **Active**; 300 µg adrenaline, **Inactive**; 1.8 mg sodium chloride, 510 µg sodium metabisulfite, hydrochloric acid to adjust pH and water for injections to 0.3 mL. Each 0.3 mL of solution in Anapen[®] Junior contains: **Active**; 150 µg adrenaline, **Inactive**; 1.8 mg sodium chloride, 510 µg sodium metabisulfite, hydrochloric acid to adjust pH and water for injections to 0.3 mL.

PHARMACOLOGY

Adrenaline is a sympathomimetic compound, acting on both α and β receptors. The major effects are increased systolic blood pressure, reduced diastolic pressure, hyperglycaemia, tachycardia, and hypokalaemia. It has vasopressor properties, an antihistaminic action and is a bronchodilator and is also a powerful cardiac stimulant. Its action is rapid and of short duration. Adrenaline is rapidly distributed to the heart, spleen, several glandular tissues and adrenergic nerves, and it is rapidly metabolised in the liver. It crosses the placenta and is excreted in breast milk.

INDICATIONS

For the emergency treatment of serious allergic reactions or anaphylaxis caused by peanuts or other foods, drugs, insect bites or stings and other allergens.

CONTRAINDICATIONS

Contraindications are relative as this product is intended for use in life-threatening emergencies.

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Anapen[®] and Anapen[®] Junior Adrenaline 300µg/0.3 mL and Adrenaline 150µg/0.3 mL

Anapen[®] should not be used in children with body weight below 30 kg.

Anapen[®] Junior should not be used in children with body weight below 15 kg and greater than 30 kg.

Anapen[®] and Anapen[®] Junior are contraindicated for use in patients with hypersensitivity to any of the ingredients (sodium chloride and sodium metabisulfite).

Adrenaline should not be used in the presence of cardiac dilation. Adrenaline should not be used in patients with certain types of arrhythmia, cerebral arteriosclerosis and where vasopressor drugs are contraindicated e.g. thyrotoxicosis and in obstetrics where maternal blood pressure is in excess of 130/80.

Adrenaline is also contraindicated in shock (other than anaphylactic shock), in patients with organic brain damage or during general anesthesia with halogenated hydrocarbons or cyclopropane.

PRECAUTIONS

Anapen[®] and Anapen[®] Junior adrenaline Auto-Injections contain sodium metabisulfite, a sulfite, which may itself cause allergic-type reactions in certain susceptible persons. The alternatives to using adrenaline in a life-threatening situation may not be satisfactory. The presence of a sulfite in this product should not deter administration for serious allergic reactions.

DO NOT INJECT INTRAVENOUSLY as cerebral haemorrhage may occur due to a sharp rise in blood pressure.

Use with caution in patients with heart disease e.g. Coronary heart and cardiac muscle diseases (angina may be induced), cor pulmonale, cardiac arrhythmias or tachycardia.

Adverse reactions may occur after administration of adrenaline in patients with:

- hyperthyroidism,
- pheochromocytoma,
- severe renal impairment,
- hypocalcaemia,
- cardiovascular disease,
- high intraocular pressure,
- prostatic adenoma leading to residual urine,
- diabetes

Administer with caution in the elderly, pregnant patients and children.

Adrenaline can cause potentially fatal ventricular arrhythmias including fibrillation, especially in patients with organic heart disease or those receiving other drugs that sensitize the heart to arrhythmias (see **Interactions with Other Drugs**).

Syncope has occurred following administration to asthmatic children.

Anapen[®] and Anapen[®] Junior are auto-injectors specifically for intramuscular injection only and should only be used in the anterolateral aspect of the thigh. The injected area should be lightly massaged for the 10 seconds after injection. Anapen[®] and Anapen[®] Junior should not be administered into

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the hands, feet, ears, nose, buttocks or the genitalia as it may result in loss of blood flow to the affected area. If accidental injection into one of these areas occurs, specialist medical advice must be sought immediately.

Use in Pregnancy: Category A

It has not been established that taking adrenaline during pregnancy is without risk to the foetus; however, if a patient is pregnant, it should not deter the patient from using Anapen[®] as the life of the patient may be in danger.

Adrenaline may delay the second stage of labour by inhibiting contractions of the uterus. Adrenaline may dramatically reduce placental blood flow; however this is likely to occur during anaphylactic shock.

Use in Lactation

Adrenaline is excreted in the breast milk. The use of adrenaline in breast feeding women is therefore not recommended.

Interactions with Other Medicines

Central Nervous System and other Medicines

The effects of adrenaline may be potentiated by tricyclic antidepressants mixed noradrenergic-serotonergic antidepressants like venlafaxine, sibutramine and milnacipran and monoamine oxidase inhibitors (sudden blood pressure increase and possible cardiac arrhythmia).

COMT blocking agents thyroid hormones, theophylline, oxytocin, parasympatholytics, some antihistamines (e.g. diphenhydramine, dexchlorpheniramine), levodopa and alcohol.

Other Sympathomimetic Agents

Adrenaline should not be administered with other sympathomimetic agents because of the danger of addictive effects and increased toxicity.

Alpha-adrenergic Blocking Agents

Alpha-adrenergic blocking agents such as ergot alkaloids and phentolamine can reverse the pressor response to adrenaline.

Beta-adrenergic Blocking Agents

Patients taking non-selective beta-blocking drugs when administered adrenaline for the treatment of an anaphylactic reaction may experience severe hypertension and bradycardia. Propranolol inhibits the bronchodilator effect of adrenaline. The risk of cardiac arrhythmias is higher when adrenaline is given to patients receiving digoxin or quinidine.

General Anaesthetics

Halothane and other anaesthetics such as cyclopropane and trichlorethylene increase the risk of adrenaline-induced ventricular arrhythmias and acute pulmonary oedema if hypoxia is present.

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Hypoglycaemic Agents

Adrenaline-induced hyperglycaemia may lead to loss of blood sugar control in diabetic patients treated with hypoglycaemic agents.

Incompatibilities

Adrenaline is physically incompatible with alkalis, metals, oxidising agents, sodium warfarin, hyaluronidase and many other drugs; it forms polymers with sodium bicarbonate.

ADVERSE REACTIONS

The occurrence of undesirable effects depends on the sensitivity of the individual patient and the dose administered. Common adverse reactions, even at low doses, include:

- anxiety,
- tachycardia,
- tremor,
- dizziness,
- dyspnoea,
- pallor,
- nausea and vomiting,
- hallucinations,
- fear and
- restlessness,
- respiratory difficulty,
- weakness,
- headache,
- cold extremities,
- sweating,
- sleeplessness,
- palpitations,
- flushing of redness of face and skin.

Psychomotor agitation, disorientation, impaired memory and psychosis may occur.

Potentially fatal ventricular arrhythmias, including ventricular fibrillation may occur and severe hypertension may lead to cerebral haemorrhage and pulmonary oedema.

DOSAGE AND ADMINISTRATION

Anapen[®] is intended for use in adults with body weight exceeding 30 kg. Anapen[®] Junior is intended for children with body weights between 15 and 30 kg. The use of Anapen[®] and Anapen[®] Junior in patients with body weight less than 15 kg is not recommended.

The delivered dose of the Anapen[®] Auto-Injector should be injected intramuscularly into the anterolateral aspect of the thigh. The delivered dose is 0.3 mL of 1:1000 USP Adrenaline Injection (300 µg), which is the usual adult dose for anaphylactic reactions (allergic emergencies). To manage severe anaphylaxis, repeat Anapen[®] injections may be necessary. Each Anapen[®] Auto-Injector is used once only.

The delivered dose of the Anapen[®] Junior Auto-Injector should be injected intramuscularly into the anterolateral aspect of the thigh. The delivered dose is 0.3 mL of 1:2000 USP Adrenaline Injection (150 µg), which is the usual dose for paediatric anaphylactic reactions (depending on body weight of the child).

You should immediately notify a doctor or attend the nearest hospital as soon as possible after use of the Anapen[®] or Anapen[®] Junior.

DO NOT INJECT INTRAVENOUSLY.

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Appropriate steps should be taken to ensure that the patient thoroughly understands the indications and use of this device. The Anapen[®] and Anapen[®] Junior Auto-Injector should not be used for demonstration purposes. The “Anapen[®] Trainer” injector is available to assist with patient education and practice. The physician should review in detail with the patient, the Consumer Medicine Information, which includes usage instructions for the Anapen[®] and Anapen[®] Junior Auto-Injectors.

The Anapen[®] Auto-Injector is intended for immediate self-administration. It is designed as emergency supportive therapy only and is not a replacement or substitute for subsequent medical or hospital care.

Patients should be instructed to dispose of the device safely after use by placing the used Auto-Injector in a sharps disposal unit.

It is not recommended that patients drive or operate heavy machinery following administration of adrenaline, as it is likely that the patients will be affected by the symptoms of anaphylactic shock.

OVERDOSE*Effects*

Overdosage or inadvertent intravascular injection of adrenaline may cause cerebral haemorrhage resulting from a sharp rise in blood pressure. Death may also result from pulmonary oedema because of peripheral vascular constriction together with cardiac stimulation.

The pressor activities of adrenaline may be counteracted by rapidly acting vasodilators or alpha adrenergic blocking medicinal products. Should prolonged hypotension follow such measures, it may be necessary to administer another pressor medicinal product, such as noradrenaline.

Acute pulmonary oedema with respiratory embarrassment following adrenaline overdose should be managed by administration of rapidly acting alpha adrenaline blocking medicinal product such as phentolamine and/or with intermittent positive pressure respiration.

Adrenaline overdose may also result in transient bradycardia followed by tachycardia; these can be followed by potentially fatal cardiac arrhythmias which may be treated by beta blocking medicinal products. These must be preceded or accompanied by an alpha adrenergic blocker to control the alpha mediated effects on the peripheral circulation.

The Poisons Information Centre, telephone number 13 11 26, should be contacted for advice on the management of an overdose.

PRESENTATION AND STORAGE CONDITIONS

Package containing one Anapen[®] or Anapen[®] Junior Auto-Injector.

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Anapen[®] and Anapen[®] Junior Adrenaline 300µg/0.3 mL and Adrenaline 150µg/0.3 mL

The Anapen[®] Auto-Injector contains 1 mL Adrenaline Injector 1:1000 USP and delivers a single 300 µg/0.3 mL adrenaline dose.

The Anapen[®] Junior Auto-Injector contains 1 mL Adrenaline Injector 1:2000 USP and delivers a single 150 µg/0.3 mL adrenaline dose.

Adrenaline is light sensitive and should be stored in the tube provided.

STORE AT 15°C TO 25°C. DO NOT REFRIGERATE OR FREEZE. PROTECT FROM LIGHT.

NAME AND ADDRESS OF SPONSOR:

Link Medical Products PTY LTD

18/6a Prosperity Parade,

Warriewood, NSW 2102

Australia

POISON SCHEDULE OF MEDICINE

Schedule 3 (Pharmacist Only Medicine)

DATE OF TGA APPROVAL

27 October 2008

Anapen AUST R 134653

Anapen Junior AUST R 135008

Version 2.0