

NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Adrenaline Aguettant 1:10000

Solution for injection, 1:10,000 (1 mg in 10 ml).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Adrenaline Aguettant 1:10,000 is a sterile solution of adrenaline acid tartrate in water containing adrenaline acid tartrate 0.1 mg/mL, and sodium chloride 9 mg/ml. The solution contains no antimicrobial preservatives. The pH of the solution is between 3.0 and 4.0.

Each 10 mL syringe contains 1.819 mg of adrenaline acid tartrate (equivalent to 1 mg adrenaline). Each 1 mL of Adrenaline Aguettant contains 0.1819 mg of adrenaline acid tartrate (equivalent to 0.1 mg adrenaline).

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Adrenaline Aguettant 1:10,000 is a sterile solution for injection presented in a pre-filled polypropylene syringe.

Adrenaline Aguettant 1:10,000 is a sterile solution for injection. Adrenaline Aguettant is a clear solution presented in a pre-filled polypropylene syringe. The pH of the solution is between 3.0 and 4.0.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adjunctive use in the management of cardiac arrest, and anaphylactic shock resulting from reactions to drugs, animal serums, insect stings and other allergens.

4.2 Dose and method of administration

Do not use if the injection is brown or contains a precipitate.

Adrenaline is given by subcutaneous or intramuscular injection. In extreme emergencies, where a more rapid effect is required, adrenaline may be given as a dilute solution (1 in 10,000 or 1 in 100,000) by slow intravenous injection or by slow intravenous infusion.

Adults

In cardiopulmonary resuscitation the initial dose is 1 mg (10 mL of 1:10,000) delivered intravenously, preferably through a central line, and repeated as often as every 2 to 3 minutes during CPR for up to an hour. Depending on the arrhythmia the dose may be increased after three injections of 1 mg to 5 mg or 100 µg/kg bodyweight.

Further bolus doses or continuous infusion may be required to maintain an adequate blood pressure after the patient generated pulse has returned.

Elderly patients

The adult dose is used but should be given very slowly with caution as these patients may be more sensitive to adrenaline.

Paediatric population

In cardiopulmonary resuscitation, the dose is 0.1 mL/kg bodyweight (0.01 mg/kg) intravenously initially then 100 µg/kg bodyweight. Doses may be repeated every five minutes if necessary.

For anaphylactic shock, if intravenous administration is required the dose is 10 µg/kg bodyweight at a rate of 1 ml (100 µg) or less per minute.

4.3 Contraindications

The following contraindications should be considered: hyperthyroidism, hypertension, ischaemic heart disease, diabetes mellitus, narrow angle glaucoma and known sensitivity to sympathomimetic amines.

Adrenaline should not be used in the presence of cardiac dilation.

Adrenaline should not be used in most patients with arrhythmias and cerebral arteriosclerosis, where vasopressor drugs may be contraindicated eg in thyrotoxicosis, in obstetrics when 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, during general anaesthesia with halogenated hydrocarbons and cyclopropane.

Adrenaline should not be injected into fingers, toes, ears, nose or genitalia.

4.4 Special warnings and precautions for use

Use with caution in patients with ventricular fibrillation, prefibrillatory rhythm, tachycardia, myocardial infarction, phenothiazine induced circulatory collapse and prostatic hypertrophy.

Administer slowly with caution to elderly patients and to patients with hypertension, diabetes mellitus, hyperthyroidism and psychoneurosis. Use with extreme caution in patients with long-standing bronchial asthma and emphysema who have developed degenerative heart disease. Anginal pain may be induced when coronary insufficiency is present. Use with caution in patients with narrow angle glaucoma.

Adrenaline may delay the second stage of labour by inhibiting contractions of the uterus.

Syncope has occurred following administration to asthmatic children.

In patients with Parkinsonian syndrome the drug increases rigidity and tremor.

Intra-arterial administration should be avoided since marked vasoconstriction may result in gangrene.

Intramuscular injection into the buttocks should be avoided as gas gangrene is a possibility.

Local ischaemic necrosis can occur from repeated injections in one site.

4.5 Interaction with other medicines and other forms of interaction

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

Rapidly acting vasodilators can counteract the marked pressor effects of adrenaline.

The effects of adrenaline may be potentiated by tricyclic antidepressants, some antihistamines and thyroid hormones.

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.

Severe hypertension and bradycardia may occur with non-selective beta-blocking drugs. Propranolol inhibits the bronchodilator effect of adrenaline. The risk of cardiac arrhythmias is higher when adrenaline is given to patients receiving digoxin or quinidine.

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

Patients on monoamine oxidase inhibitors should not receive sympathomimetic treatment.

4.6 Fertility, pregnancy and lactation

Fertility

No data available.

Pregnancy

Category A. Adrenaline has been given to a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed. Adrenaline may delay the second stage of labour by inhibiting contractions of the uterus.

Lactation

Adrenaline is excreted in breast milk.

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

Common symptomatic adverse effects include anxiety, restlessness, tachycardia, tremor, weakness, dizziness, headache, dyspnoea, cold extremities, pallor, sweating, nausea, vomiting, sleeplessness, hallucinations and flushing or redness of face and skin. Psychomotor agitation, disorientation, impaired memory and psychosis may occur.

The potentially severe adverse effects of adrenaline arise from its effect upon blood pressure and cardiac rhythm. Ventricular fibrillation may occur and severe hypertension may lead to cerebral haemorrhage and pulmonary oedema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

4.9 Overdose

Effects

Cardiac arrhythmias leading to ventricular fibrillation and death. Severe hypertension leading to pulmonary oedema and cerebral haemorrhage.

Overdosage of adrenaline can result in severe metabolic acidosis because of elevated blood concentration of lactic acid.

Treatment

Combined alpha and beta adrenergic blocking agents such as labetalol may counteract the effects of adrenaline, or a beta blocking agent may be used to treat supraventricular arrhythmias and phentolamine to control the alpha mediated effects on the peripheral circulation. Rapidly acting vasodilators such as nitrates and sodium nitroprusside may also be helpful.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Adrenaline is a direct-acting sympathomimetic agent exerting its effect on alpha and beta adrenoreceptors. Major effects are increased systolic blood pressure, reduced diastolic pressure, tachycardia, hyperglycaemia and hypokalaemia. It is a powerful cardiac stimulant. It has vasopressor properties, an antihistaminic action and is a bronchodilator. Its action is rapid in onset and of short duration.

5.2 Pharmacokinetic properties

Adrenaline is rapidly distributed to the heart, spleen, several glandular tissues and adrenergic nerves. It crosses the placenta and is excreted in breast milk. It is approximately 50% bound to plasma proteins. The onset of action is rapid and after intravenous infusion the half life is approximately 5-10 minutes.

Adrenaline is rapidly metabolised in the liver and tissues. Up to 90% of the IV dose is excreted as metabolites in the urine.

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

No data available.

Reproductive and developmental toxicity

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sodium chloride
- Hydrochloric acid
- Sodium hydroxide
- Water for injection

6.2 Incompatibilities

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

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Store below 25°C. Store in original container. Do not freeze. Do not use if coloured or if there is any precipitate visible.

6.5 Nature and contents of container

Adrenaline Aguetant 1:10,000 is available in single use polypropylene pre-filled syringe containing 1 mg adrenaline acid tartrate in 10 mL (1:10,000). It is presented in packs of 1 or 10.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Restricted Medicine

8. SPONSOR

Juno Pharmaceuticals NZ Limited
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Auckland 2241

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9. DATE OF FIRST APPROVAL

22 December 2022

10. DATE OF REVISION OF THE TEXT

Not applicable

Summary table of changes

Section changed	Summary of new information