

# NEW ZEALAND DATA SHEET

## 1. PRODUCT NAME

DBL™ Adrenaline Injection

Solution for injection, 1:1000 (1 mg in 1 ml).

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

DBL™ Adrenaline Injection 1:1,000 is a sterile solution of adrenaline acid tartrate in water containing adrenaline acid tartrate 1.8 mg/mL and sodium metabisulfite 1.0 mg/ml as an antioxidant. The solution also contains sodium chloride 8.0 mg/ml. The solution contains no antimicrobial preservatives.

### Excipient(s) with known effect

- Sodium metabisulfite

For full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

DBL™ Adrenaline Injection 1:1,000 is a sterile solution for injection.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the treatment of acute allergic reactions, life-threatening angioneurotic oedema, and anaphylactic shock resulting from reactions to drugs, animal serums, insect stings and other allergens.

### 4.2 Dose and method of administration

For subcutaneous or intramuscular use. Do not inject intravenously.

In emergency situations, adrenaline may be injected very slowly intravenously but **only** as the dilute solution of 1:10,000.

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

When used in anaphylactic shock volume replacement is an essential concomitant treatment since effective intravascular volume may have been depleted by increased vascular permeability in anaphylaxis.

For the relief of anaphylactic shock and life threatening angioneurotic oedema, adrenaline should be administered by intramuscular injection. For acute allergic reactions due to insect stings etc. either the intramuscular or subcutaneous route may be used.

### **Adults**

0.3 to 0.5 mL (0.3-0.5 mg), administered slowly. The dose may be repeated every 10 minutes if necessary. In severe reactions the dose can be increased to 1 mL.

### **Elderly patients**

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

### **Paediatric population**

100 – 500 µg depending on age, or 50 µg for infants under 1 year.

## **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 or 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, phenothiamine 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 increased 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.

DBL™ Adrenaline Injection contains a sulphate which may cause allergic type reactions in certain susceptible individuals.

## **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 events 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
- Sodium metabisulfite
- 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**

24 months.

## **6.4 Special precautions for storage**

Store below 25°C. Protect from light. Do not use if the injection is brown or contains a precipitate.

## **6.5 Nature and contents of container**

DBL™ Adrenaline Injection is available in a single use glass ampoule containing 1 mg adrenaline acid tartrate in 1 mL (1:1,000). It is supplied in packs of 5 or 50.

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**

Pfizer New Zealand Limited

P O Box 3998

Auckland, New Zealand, 1140

Toll Free Number: 0800 736 363

## **9. DATE OF FIRST APPROVAL**

08 March 1984

## **10. DATE OF REVISION OF THE TEXT**

19 February 2019

### Summary table of changes

<b>Section changed</b>	<b>Summary of new information</b>
All	New Data Sheet format in accordance with Medsafe guidance.