CLEAN COPY OF THE PROPOSED PACKAGE INSERT

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

Pharma-Q Adrenaline Injection 1 mg/ml solution for injection

COMPOSITION:

Each 1 ml contains 1 mg adrenaline base as tartrate.

Sodium metabisulphite 0,1 % m/v as anti-oxidant.

Excipients: Nitrogen, sodium chloride, water for injection.

PHARMACOLOGICAL CLASSIFICATION:

A 5.1 Adrenomimetics

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Adrenaline (Epinephrine) is a sympathomimetic agent. It is a potent stimulator of both alpha and beta adrenergic receptors.

INDICATIONS:

Pharma-Q Adrenaline Injection 1 mg/ml is used for its sympathomimetic properties, such as relief of bronchial spasm, acute allergy and for cardiovascular resuscitation as well as anaphylactic shock.

CONTRAINDICATIONS:

Date of most recent Council submission: 15 September 2011
Date Compliant with Regulations 9 & 10: 6 March 2015

Pharma-Q Adrenaline Injection 1 mg/ml is contraindicated in:

- Patients with a hypersensitivity to adrenalin (epinephrine).
- Patients who suffer from:
  - Organic brain damage.
  - Hypertension.
  - Cardiovascular diseases such as ischaemic heart disease, aneurysms, arrhythmia or tachycardia, including angina pectoris, cardiac dilatation, arteriosclerosis, congestive heart failure, coronary artery disease, coronary insufficiency, degenerative heart disease, organic heart disease and cardiogenic shock.
  - Phenothiazines induced circulatory collapse or hypotension (see **INTERACTIONS**).
  - Hyperthyroidism or Parkinson's disease.
  - Suspected or diagnosed phaeochromocytoma.
- Patients receiving mono-amine oxidase inhibitors as adrenaline (epinephrine) interacts with monoamine oxidase inhibitors and should not be given to patients receiving such treatment or within 14 days of its termination.
- Patients who are pregnant or breastfeeding since safety and efficacy has not been established (see **PREGNANCY AND LACTATION**).

WARNINGS and SPECIAL PRECAUTIONS:

Pharma-Q Adrenaline Injection 1 mg/ 1 ml:

- Should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane, or other halogenated anaesthetics, as they may induce ventricular fibrillation (see **INTERACTIONS**).

Date of most recent Council submission: 15 September 2011
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- Should also be used with caution in patients with diabetes mellitus or closed-angle glaucoma (see **INTERACTIONS)**.

Pharma-Q Adrenaline Injection 1 mg/ml is not to be used if its colour is pinkish or darker than slightly yellow or if it contains a precipitate.

Effects on the ability to drive and use machines:

Pharma-Q Adrenaline Injection 1 mg/ml may cause mental confusion. Patients should be advised not to drive or operate hazardous machinery because loss of concentration could lead to serious accidents.

INTERACTIONS:

An increased risk of arrhythmias may occur if sympathomimetic agents are given to patients receiving:

- Cardiac glycosides.
- Quinidine.
- Tricyclic antidepressants.

PREGNANCY AND LACTATION:

Pharma-Q Adrenaline Injection 1 mg/ml is contra-indicated in pregnancy and lactation since safety and efficacy has not been established (see **CONTRAINDICATIONS**).

DOSAGE AND DIRECTIONS FOR USE:

Discard contents if discoloured.

The dosage of **Pharma-Q Adrenaline Injection 1 mg/ml** is:

Bronchial spasm:

By subcutaneous injection:

Date of most recent Council submission: 15 September 2011
Date Compliant with Regulations 9 & 10: 6 March 2015

Adults: 0,1 ml –0,5 ml of a 1 in 1000 aqueous solution (100 to 500 µg).

Children: 0,01 ml per kg body-mass, (10 µg per kg body-mass) to a maximum total dose of 0,5 ml (500 µg).

Acute allergy and anaphylactic shock:

By subcutaneous or preferably intramuscular injection:

Adults: 0,2 ml –0,5 ml of a 1 in 1000 solution. Up to 1 ml may be given and more than one dose may be required.

Cardiovascular resuscitation:

In emergencies:

A diluted solution is given slowly intravenously. The recommended dose is 0,5 ml to 1 ml, (0,5 mg to 1 mg) diluted 10 times to 5 to 10 ml (1 in 10 000 solutions). Doses may be given every 5 minutes during the prolonged resuscitation effort.

SIDE EFFECTS

Pharma-Q Adrenaline Injection 1 mg/ml may have side-effects.

Most of the adverse effects mimic the results of excessive stimulation of the sympathetic nervous system.

Nervous system disorders:

Frequency unknown: Fear; anxiety, restlessness, tremors, insomnia, irritability, confusion, headache, weakness and psychotic states.

Cardio-vascular disorders:

Frequency unknown: Palpitations, cardiac arrest, rapid pulse, anginal pain, hypotension with dizziness and flushing. Weakness and coldness of the extremities, even with small doses and especially when given in conjunction with local anaesthetics may occur.

Gastro-intestinal disorders:

Frequency unknown: Appetite may be reduced and nausea and vomiting and hypersalivation.

Date of most recent Council submission: 15 September 2011
Date Compliant with Regulations 9 & 10: 6 March 2015

Renal disorders:

Frequency unknown: Difficulty in micturition and urinary retention.

General disorders and administrative site disorders:

Frequency unknown: Dyspnoea, weakness, disturbances of glucose metabolism and sweating. Extravasation of parenterally-administered catecholamines may result in tissue necrosis and sloughing.

Stimulation of alpha-adrenergic receptors:

- Produces vasoconstriction with resultant hypertension. This vasoconstriction is sometimes sufficiently severe to produce gangrene when adrenaline (epinephrine) is infiltrated into the fingers and toes.
- The rise in blood pressure may also produce cerebral haemorrhage and pulmonary oedema.
- There may also be a reflex bradycardia but stimulation of β_1 adrenergic receptors of the heart may produce tachycardia and cardiac arrythmias, anginal pain, palpitations and cardiac arrest.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

For symptoms of overdosage see **SIDE EFFECTS** and **WARNINGS AND SPECIAL PRECAUTIONS**.

- Because of the rapid onset and short duration of action of **Pharma-Q Adrenaline Injection 1 mg/ 1 ml**, the treatment is primarily symptomatic and supportive.
- Severe toxic reactions should be treated with an immediate injection of rapidly acting alpha-adrenergic blocking agent, such as phentolamine followed by a beta blocker such as propranolol.
- Rapid acting vasodilator, such as glyceryl trinitrate may also been used.

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IDENTIFICATION:

A clear, practically colourless, slightly acid liquid. Gradually turns dark on exposure to light and air.

PRESENTATION:

1 ml clear or amber, type I glass ampoules in single pack (with syringe) or packs of 10 and 100.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

30/5.1/0395

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

PHARMA-Q HOLDINGS (PTY) LTD

50 Commando Road

Industria West, 2093

Johannesburg

DATE OF PUBLICATION OF THE PACKAGE INSERT:

Original date of registration: 12 February 2002

Revised package insert approval: 15 September 2011

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