Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Adrenaline Epinephrine Injection BP 1/1000, 1mg in 1ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains Adrenaline (Epinephrine)
Acid Tartrate equivalent to 1mg Adrenaline (Epinephrine)

Excipients - Contains Sodium Metabisulphate (E223)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear colourless sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Adrenaline Injection may be used to relieve bronchial spasm in acute attacks of asthma. It may also be used to provide rapid relief of hypersensitivity reactions to drugs and other allergens, and in the emergency treatment of anaphylactic shock.
Adrenaline Injection may be used in follow-up treatment in cardiopulmonary resuscitation.

4.2 Posology and method of administration

Adrenaline Injection is for subcutaneous, intramuscular injection or intravenous injection after dilution.

Adults: The usual dose is 0.3 to 0.5mg (0.3 to 0.5ml). If necessary, this may be repeated at 15 to 20 minute intervals for two doses, then subsequently every four hours as required. A dose of 1mg (1ml) can be given as a single injection in severe allergic reactions and anaphylactic shock.

Children: The usual single dose is 0.01mg (0.01ml) per kg body weight, up to a maximum single dose of 0.5mg. If necessary, this may be repeated at the same intervals as described for adult dosage.

Elderly: The dosage is the same as for younger adults but particular caution is required when administering adrenaline to elderly patients (see Warnings and Precautions).

Cardiopulmonary Resuscitation

As follow-up treatment in cardiopulmonary resuscitation, a subcutaneous dose of 0.3mg (0.3ml) may be given after intravenous or intracardiac administration of the 1:10,000 dilution.

4.3 Contraindications

Use during labour.

Use with local anaesthesia of peripheral structures including digits, ear lobe.

Use in the presence of ventricular fibrillation.

Adrenaline should not be used in the presence of cardiac dilatation, coronary insufficiency, organic brain disease or arteriosclerosis, except in emergencies where the potential benefit clearly outweighs the risk.

Use if solution is discoloured.

4.4 Special warnings and precautions for use

Before intravenous administration, Adrenaline Injection BP 1/1,000 (1mg in 1ml) must be diluted to a 1/10,000 (1mg/10ml) solution. Constant vigilance is required to ensure that the correct strength of adrenaline solution is used.

Adrenaline should only be administered with great caution in the elderly, those with cardiovascular disease (including hypertension and ischaemic heart disease), diabetes mellitus, hyperthyroidism, long-standing asthma or emphysema, closed angle glaucoma.

Repeated local administration may produce necrosis at the sites of injection.

Prolonged administration may induce metabolic acidosis, renal necrosis and adrenaline-fastness or tachyphylaxis.

Adrenaline should only be used in specialised units having adequate monitoring and surveillance available and appropriate resuscitative equipment, except in emergencies such as anaphylactic shock where rapid administration of adrenaline may be life saving.

Do not admix with other agents.

This medicinal product contains 3.27mg sodium per ml. i.e. essentially sodium free.

Sodium metabisulphite, one of the excipients of this medicinal product, may rarely cause severe hypersensitivity reactions and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use with tricyclic antidepressants, digitalis glycosides, parenterally used diuretics, guanethidine, methyldopa, reserpine or other similar agents may potentiate the effects of adrenaline.

Adrenaline should be avoided or used with extreme caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics in view of the risk of inducing fibrillation.

4.6 Pregnancy and lactation

Adrenaline should only be used during pregnancy and lactation if considered essential by the physician.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Side effects include tachycardia, palpitations, dyspnoea, tremor, headache, dizziness and coldness of the extremities.

In therapeutic doses adrenaline may cause effects such as anxiety, fear, dry mouth, arrhythmias and restlessness. Other effects that may occur include difficulty in micturition, urinary retention, altered metabolism (including disturbances of glucose metabolism), sweating and hypersalivation.

4.9 Overdose

Possible signs of overdosage include restlessness, confusion, pallor, tachycardia, bradycardia, cardiac arrhythmias and cardiac arrest. Treatment is primarily symptomatic and supportive. Prompt injection of a rapidly-acting alpha-adrenoceptor blocking agent such as phentolamine, followed by a beta-blocker such as propranolol, has been tried to counteract the pressor and arrhythmogenic effects of adrenaline. A rapidly-acting vasodilator such as glycetyl trinitrate has also been used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Adrenaline is a direct-acting sympathomimetic agent with pronounced effects on both alpha and beta adrenergic receptors. The effects of adrenaline include increased rate and force of cardiac contraction, cutaneous vasoconstriction and broncho-dilatation.

5.2 Pharmacokinetic properties

Absorption is more rapid after intramuscular than after subcutaneous administration. Adrenaline is rapidly inactivated in the body and metabolites are excreted in urine. Adrenaline crosses the placenta.

5.3 Preclinical safety data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium Metabisulphite
Sodium Hydroxide
Hydrochloric Acid
Water for injections

6.2 Incompatibilities

In the absence of compatability studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life

Unopened: 2 years.
The product should be used immediately after opening.

6.4 Special precautions for storage

Keep the container in the outer carton.
Do not store above 25°C.

6.5 Nature and contents of container

1 ml, clear glass ampoules, glass type I Ph. Eur.

Pack size: 10 x 1 ml ampoules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Single use only.
If only part used, discard the remaining solution.

7 MARKETING AUTHORISATION HOLDER

Antigen Pharmaceuticals Limited,
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8 MARKETING AUTHORISATION NUMBER

PA 73/35/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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