1.5.1 Prescribing information (Summary of Products Characteristics)

1.5.1.1 Name of the medicinal Product

Adrenaline Injection BP 0.1%

1.5.1.2 Qualitative and Quantitative Composition

1.5.1.2.1 Qualitative declaration

Adrenaline acid tartrate BP

1.5.1.2.2 Quantitative declaration

Sr. No	Ingredients	Specification	Standard Quantity/ ml (mg)	Reason for Inclusion
1.	Adrenaline Acid Tartrate (A) Eq.to Adrenaline	BP	1.820	Beta adrenoceptor agonist
2.	Sodium Chloride (Inj. Grade)	BP	6.000	Tonicity agent
3.	Sodium Metabisulfite	BP	0.500	Antioxidant
4.	Methyl Hydroxybenzoate	BP	1.800	Preservative
5.	Propyl Hydroxybenzoate	BP	0.200	Preservative
6.	Disodium E.D.T.A.	BP	0.500	Chelating Agent
7.	Water for Injection	BP	Q.S	Vehicle

(A) = Quantity of active ingredient is to be calculated on 100% assay & on Dried basis.
Adrenaline Acid Tartrate BP eq. to Adrenaline
* = 5 % overages are added.

1.5.1.3 Pharmaceutical Form

Liquid Injection (I.M. /S.C. or I.V.Suitably diluted)

1.5.1.4 Clinical Particulars

1.5.1.4.1 Therapeutic Indications

Adrenaline injection is usually only given in cases of extreme emergency.
Adrenaline may be used following a heart attack, or to make the heart beat if it has stopped.
Adrenaline is also used in the emergency treatment of severe allergic reactions to insect bites or stings, medicines,
Foods or other substances. It may also be given during acute asthma attacks for severe breathing difficulties.

1.5.1.4.2 Posology and Method of Administration

Method of administration: Intramuscular. /Subcutaneous or Intravenous Suitably diluted

Recommended doses of Adrenaline in are shown Below.

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 (0.3-0.5mg), administered slowly. The dose may be repeated every 10 minutes if necessary. In severe reactions the dose can be increased to 1mL.
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.
Children (up to 12 years of age):100 - 500ug depending on age, or 50ug for infants under 1 year.

1.5.1.4.3 Contraindications

Contraindications arc relative as this product is intended for use in life-threatening emergencies.
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 dmgs arc contraindicated cg. 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 pat ients with organic brain damage or
during general anaesthesia with halogenated hydrocarbons or cyclopropane.
Adrenaline Injection should not be used in children with bodyweight below 30 kg.

1.5.1.4.4 Special Warnings and Special Precautions for Use

Adrenaline Injection contains sodium met bisulfite, 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 hemorrhage may occur due to a sharp rise in blood pressure.
Use with caution in patients with ventricular fibrillation, prefibrallatory rhythm, tachycardia, myocardial infarction,
Phenothiazine induced circulatory collapse and prostatic hypertrophy.
Adrenaline causes ECG changes including a decrease in T-wave amplih1de in all leads of normal persons.
Anginal pain may be induced by adrenaline in patients with coronary insufficiency.
Administer with caution to the elderly, and to individuals with diabetes, cardiovascular disease, hypertension, narrow angle glaucoma, hyperthyroidism and psychoneurosis. In patients with Parkinsonism the drug increases rigidity and tremor.
Syncope has occurred following administration to asthmatic children.
Use in Pregnancy: Categ01y A: Adrenaline has been given to a large number of pregnant women and women of Child bearing 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.
Use in Lactation: Adrenaline is excreted in breast milk.

1.5.1.4.5 Interaction with other FPPs and other Forms Of interaction

Sympathomimetic like ventolin & isoprenaline cause additive effects.
Beta-blockers antagonize therapeutic effects of adrenaline.
Digitalis potentiates the pro arrhythmic effects of adrenaline.
Phenothiazine causes a paradoxical decrease in blood pressure.
Monoamine oxidase inhibitors (MOA Is) potentiate the cardiovascular effects of adrenaline.

1.51.4.6 Pregnancy and Lactation

- Use in Pregnancy: Categ01y A: Adrenaline has been given to a large number of pregnant women and women of Child bearing 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.

Use in Lactation: Adrenaline is excreted in breast milk.

1.5.1.4.7 Effects on ability To Drive and use Machines

In patients receiving diuretics, some reduction in mental alertness may impair ability to drive or to operate machinery.

1.5.1.4.8 Undesirable Effects

Common symptomatic adverse events include anxiety, rest lessness, tachycardia, respiratory difficulty, tremor, weakness, dizziness, headache, dyspnoea, cold extremities, pallor, sweating, nausea, vomiting, sleeplessness, hallucinations, palpitations, fear and flushing or 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.

1.5.1.4.9 Overdose

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

Cardiac arrhythmias may lead to ventricular fibrillation and death.

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

Treatment : Adrenaline is rapidly inactivated in the body and treatment of acute toxicity is mainly supportive. If necessary, the combined alpha and beta mediated effects of adrenaline may be counteracted by labetalol. Individually, alpha mediated effects may be counteracted by phentolamine whilst beta mediated effects may be counteracted by beta blocking agents.

1.5.1.5 Pharmacological Properties

1.5.1.5.1 Pharmacodynamics Properties

Adrenaline is a sympathomimetic drug, acting on both alpha and beta receptors. Major effects arc increased systolic blood pressure, reduced diastolic pressure, tachycardia, hypcrglycaemia and hypokalacmia. It is a powerful cardiac stimulant. It has vasopressor properties, an antihistaminic action and is a bronchodilator.

1.5.1.5.2 Pharmacokinetic Properties

Pharmacokinetics: Its action is rapid in onset 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 and tissues. It crosses the placenta and is excreted in breast milk. It is approximately 50% bound to plasma proteins.

1.5.1.5.3 Preclinical Safety Data

Not Applicable

1.5.1.6 Pharmaceutical Particulars

1.5.1.6.1 List of Excipients

Sodium Chloride (Inj. Grade)
Sodium Metabisulfite
Methyl Hydroxybenzoate
Propyl Hydroxybenzoate
Disodium E.D.T.A.
Water for Injection

1.5.1.6.2 Incompatibilities

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

Adrenaline should not be mixed with sodium bicarbonate; the solution is oxidised to adrenochrome and then forms polymers.

1.5.1.6.3 Shelf Life

18 Months

1.5.1.6.4 Special Precautions for Storage

Store at 30°C. Do not refrigerate. Protect from light.

1.5.1.6.5 Nature and Contents of Container

A clear colourless solution filled in 1 ml ampoule (white ring autocut), such 10 ampoules are packed in blister pack using "LPL" logo paper foil, such 1 blister are packed in Printed Carton with packing insert

1.5.1.6.6 Instructions for use and handling and disposal

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

1.5.1.7 Marketing Authorization Holder And Manufacturing Site Addresses

1.5.1.7.1 Name and Address of Marketing Authorization Holder

Abacus Parenteral Drugs Limited
Plot 114, block 191,
Kinga, Mukono, P.O. Box 31376,
Kampala, Uganda
Phone: +256 312 380800
Fax: +256 312 380820
Website: http://www.abacusparenteral.com

1.5.1.7.2 Name and Address of manufacturing site(s)

Lincoln Parenteral Limited
11, Trimul Estate, Khatraj, Tal. Kalol,
Dist. Gandhinagar,
Gujarat, India.
Phone: +91-02764-665000, 281290, 281339,281340
Telefax: +91-02764-281809
E-mail: info@lincolnparenteral.com
Web site: www.lincolnparenteral.com

1.5.1.8 Marketing Authorization Number

To be included after obtaining first registration.

1.5.1.9 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

1.5.1.10 Date of Revision of the Text

1.5.1.11 Dosimetry (If Applicable)

Not Applicable

1.5.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable