SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT

ADRESTAR INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Adrenaline Acid Tartrate BP

Equivalent to Adrenaline.....1 mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Liquid Injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adrenaline Injection BP may be used in the treatment of acute allergy and anaphylactic shock 4.

4.2 Posology and method of administration

Intramuscular (IM) adrenaline is recommended by the Resuscitation Council UK as the first line treatment for anaphylaxis in all healthcare settings. The patient should be monitored as soon as possible (i.e. pulse, blood pressure, ECG, pulse oximetry).

This will help monitor the patient's response to adrenaline.

The best site for IM injection is the anterolateral aspect of the middle third of the thigh. The needle used for injection needs to be sufficiently long to ensure that the adrenaline is injected into muscle.

The following doses of Adrenaline (Epinephrine) Injection BP

Dose of intramuscular injection of Adrenaline (Epinephrine) Injection BP for a severe anaphylactic reaction		
Age	**Dose**	**Volume of adrenaline**
Under 6 Months	100-150 micrograms IM	0.1
6 Months – 6 Years	150 micrograms	0.15 ml
Child 6- 12 years	300 micrograms	0.3 ml
Adult and Child *>12 years	500 micrograms	0.5 ml

*Give 300 micrograms IM (0.3ml) in a child who is small or prepubertal Repeat the IM adrenaline dose after 5 minutes, if there is no improvement in the patient's condition according to blood pressure, pulse, and respiratory function. If life threatening cardiovascular and respiratory features persist, further doses can be given every 5 minutes until specialist critical care is available. A small volume syringe should be used.

4.3 Contraindications

Hypersensitivity to adrenaline, sodium metabisulfite or to any of the excipients listed.
Adrenaline should not be used in fingers, toes, ears, nose or genitalia owing to the risk of ischaemic tissue necrosis

4.4 Special Warnings and Special Precautions for Use

Adrenaline should be used with caution in patients with:
• hyperthyroidism, psychoneurosis, phaeochromocytoma, narrow angle glaucoma, diabetes mellitus, hypokalaemia or hypercalcaemia.
• severe renal impairment, prostatic hypertrophy or urination difficulty
• cerebrovascular disease, organic brain damage or arteriosclerosis
• autonomic dysreflexia (hyperreflexia), particularly in spinal cord injury (e.g. tetraplegics)
• shock (other than anaphylactic shock)
• organic heart disease or cardiac dilatation (severe angina pectoris, obstructive cardiomyopathy, hypertension) as well as most patients with arrhythmias. Anginal pain may be induced when coronary insufficiency is present.
Adrenaline should be used with caution in older patients
Adrenaline should be used with extreme caution in patients with long-standing bronchial asthma and emphysema who have developed degenerative heart disease.
Adrenaline should be used cautiously, if at all, during general anaesthesia with halogenated hydrocarbon anaesthetics.
Adrenaline should not be used during the second stage of labour.
Accidental intravascular injection may result in cerebral haemorrhage due to the sudden rise in blood pressure.
Adrenaline (Epinephrine) Injection BP 1:1000 (1mg/ml) is not suitable for IV use. The IM route is generally preferred in the initial treatment of anaphylaxis, the IV route is generally more appropriate in the Intensive Care Unit (ICU) or Emergency Department (ED) setting. Adrenaline (Epinephrine) Injection BP 1:1000 (1mg/ml) is not
suitable for IV use. If the epinephrine 1:10,000 (0.1 mg/ml) injection is not available, epinephrine injection 1:1000 must be diluted to 1:10,000 before IV use. The IV route for injection of epinephrine must be used with extreme caution and is best

reserved for specialists familiar with IV use of epinephrine (adrenaline) in an appropriate setting.
Monitor the patient as soon as possible (pulse, blood pressure, ECG, pulse oximetry) in order to assess the response to adrenaline.
Repeated injections of Adrenaline can cause necrosis as a result of vascular constriction at the injection site. Tissue necrosis may also occur in the extremities, kidneys and liver. Intramuscular injections of Adrenaline into the buttocks should be avoided because of the risk of tissue necrosis.
Pallor can occur following adrenaline administration, due to vasoconstriction. This might be misinterpreted as ongoing
cardiovascular compromise or anaphylaxis and thereby can increase the risk of adrenaline overdose. This is a particular concern in small children, who may remain pale following 2–3 doses of adrenaline. A significantly raised blood pressure is a
key indicator of adrenaline overdose.
The subcutaneous route for adrenaline is not recommended for treatment of an anaphylaxis as it is less effective.
Prolonged use of Adrenaline can result in severe metabolic acidosis (because of elevated blood concentrations of lactic acid), renal necrosis and tachyphylaxis.
Adrenaline Injection contains sodium metabisulfite, which can cause allergic-type reactions, including anaphylaxis and life threatening or less severe asthmatic episodes, in certain susceptible individuals.
The presence of sodium metabisulfite in parenteral Adrenaline and the possibility of allergic-type reactions should not deter use of the drug when indicated for the treatment of serious allergic reactions or for other emergency situations.

4.5 Interaction with other medicinal products and other forms of interaction

Sympathomimetic agents:

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

Alpha-adrenergic agents:

The vasoconstrictor and pressor effects of adrenaline, mediated by its alpha-adrenergic action, may be enhanced by concomitant administration of drugs with similar effects, such as ergot alkaloids or oxytocin.

Alpha-adrenergic blocking agents:

Alpha-blockers such as phentolamine antagonise the vasoconstriction and hypertension effects of adrenaline. This effect may be beneficial in adrenaline overdose. Adrenaline specifically reverses the antihypertensive effects of adrenergic neurone blockers such as guanethidine with the risk of severe hypertension.

Beta-adrenergic blocking agents:

Severe hypertension and reflex bradycardia may occur with non-cardioselective beta-blocking agents such as propranolol, due to alpha-mediated vasoconstriction.

Beta-blockers, especially non-cardioselective agents, also antagonise the cardiac and bronchodilator effects of adrenaline.

Patients with severe anaphylaxis who are taking non-cardioselective beta-blockers may not respond to adrenaline treatment.

General Anaesthetics:

Administration of Adrenaline in patients receiving halogenated hydrocarbon general anaesthetics that increase cardiac

irritability and seem to sensitise the myocardium to Adrenaline may result in arrhythmias including ventricular premature contractions, tachycardia or fibrillation.

Antihypertensive agents:

Adrenaline specifically reverses the antihypertensive effects of adrenergic neurone blockers such as guanethidine, with the risk of severe hypertension. Adrenaline increases blood pressure and may antagonise the effects of antihypertensive drugs.

Antidepressant agents:

Tricyclic antidepressants such as imipramine inhibit reuptake of directly acting sympathomimetic agents, and may potentiate the effect of adrenaline, increasing the risk of development of hypertension and cardiac arrhythmias.

Concurrent use or use within 2 weeks of a monoamine oxidase inhibitor increases the risk of adverse events.

Phenothiazines:

Phenothiazines block alpha-adrenergic receptors.

Adrenaline should not be used to counteract circulatory collapse or hypotension caused by phenothiazines; a reversal of the pressor effects of Adrenaline may result in further lowering of blood pressure.

Other drugs:

Adrenaline should not be used in patients receiving high dosage of other drugs (e.g. cardiac glycosides) that can sensitise the heart to arrhythmias. Some antihistamines (e.g. diphenhydramine) and thyroid hormones may potentiate the effects of

Adrenaline, especially on heart rhythm and rate. Adrenaline increases the risk of cardiac adverse effects of levodopa. Use of Entacapone may potentiate the chronotropic and arrhythmogenic effects of adrenaline.

Hypokalaemia:

The hypokalaemic effect of adrenaline may be potentiated by other drugs that cause potassium loss, including corticosteroids,

potassium-depleting diuretics, aminophylline and theophylline.

Hyperglycaemia:

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

4.6 Fertility, pregnancy and lactation

Pregnancy

Adrenaline crosses the placenta. There is some evidence of slightly increased evidence of congenital abnormalities. Injection of adrenaline may cause anoxia to the foetus, foetal tachycardia, cardiac irregularities, extrasystoles and louder heart sounds.
Adrenaline usually inhibits spontaneous or oxytocin induced contractions of the pregnant human uterus and may delay the second stage of labour. In dosage sufficient to reduce uterine contractions, the drug may cause a prolonged period of uterine
atony with haemorrhage. For this reason, parenteral Adrenaline should not be used during the second stage of labour.
Adrenaline should only be used during pregnancy if the potential benefits justify the possible risks to the foetus.

Breast-feeding Adrenaline is distributed into breast milk. Breast-feeding should be avoided in mothers receiving Adrenaline injection.

4.7 Effects on ability to drive and use machines
Patients' ability to drive and use machines may be affected by the anaphylactic reaction, as well as by possible adverse reactions to adrenaline.

4.8 Undesirable effects
The adverse events of adrenaline mainly relate to the stimulation of both alpha- and beta-adrenergic receptors. The occurrence of undesirable effects depends on the sensitivity of the individual patient and the dose involved.

Immune system disorders:
Anaphylaxis, possibly with severe bronchospasm

Metabolism and nutrition disorders:
Hypokalaemia, metabolic acidosis.

Inhibition of insulin secretion and hyperglycaemia even with low doses, gluconeogenesis, glycolysis, lipolysis and ketogenesis.

Psychiatric disorders:
Psychotic states, anxiety, fear, confusion, irritability, insomnia, restlessness

Nervous system disorders:
Headache, dizziness, tremors
In patients with Parkinsonian Syndrome, Adrenaline increases rigidity and tremor.
Subarachnoid haemorrhage and hemiplegia have resulted from hypertension, even following subcutaneous administration of usual doses of Adrenaline.

Cardiac disorders:
Disturbances of cardiac rhythm and rate may result in palpitation and tachycardia. Adrenaline can cause potentially fatal ventricular arrhythmias including fibrillation, especially in patients with organic heart disease or those receiving other drugs that sensitise the heart to arrhythmias. Myocardial ischaemia and myocardial infarction have been reported.

Adrenaline causes E.C.G. changes including a decrease in T-Wave amplitude in all leads in normal subjects.
In rare cases stress cardiomyopathy has been seen in patients treated with adrenaline.

Vascular disorders:

Hypertension (with risk of cerebral haemorrhage).

Coldness of extremities may occur even with small doses of Adrenaline.
Bowel necrosis

Respiratory disorders:

Dyspnoea. Pulmonary oedema may occur after excessive doses or in extreme sensitivity.

Gastrointestinal disorders:

Dry mouth, reduced appetite, nausea, vomiting, hypersalivation.

Renal and urinary disorders:

Difficulty in micturition, urinary retention.

General disorders and administrative site conditions:

Sweating, weakness, pallor.
Repeated injections of Adrenaline can cause necrosis as a result of vascular constriction at the injection site. Tissue necrosis may also occur in the extremities, kidneys and liver.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after Authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the National Regulatory Authority via Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose
Symptoms

After overdosage or inadvertent intravenous administration of usual intramuscular subcutaneous doses of Adrenaline, systolic and diastolic blood pressure rise sharply; venous pressure also rises. Cerebrovascular or other haemorrhages and hemiplegia

may result, especially in elderly patients. Pulmonary oedema may occur.

Adrenaline overdosage causes transient bradycardia followed by tachycardia and may cause other potentially fatal cardiac arrhythmias. Kidney failure, metabolic acidosis and cold white skin may also occur.

Treatment

Because Adrenaline is rapidly inactivated in the body, treatment of acute toxicity is mainly supportive.

The pressor effects of Adrenaline may be counteracted by an immediate intravenous injection of a quick-acting alpha adrenoreceptor blocking agent, such as 5-10 mg of phentolamine mesylate, followed by a beta-adrenoreceptor blocking agent, such as 2.5 - 5 mg of propranolol. Arrhythmias, if they occur, may be counteracted by propranolol injection.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: adrenergic and dopaminergic agents, adrenaline.
ATC code: C01 CA 24
Adrenaline is a naturally occurring catecholamine secreted by the adrenal medulla in response to exertion or stress. It is a sympathomimetic amine which is a potent stimulant of both alpha- and beta-adrenergic receptors and its effects on target
organs are therefore complex. It is used to provide rapid relief of hypersensitivity reactions to allergies or to idiopathic or exercise-induced anaphylaxis.
Adrenaline has a strong vasoconstrictor action through alpha- adrenergic stimulation. This activity counteracts the vasodilatation and increased vascular permeability leading to loss of intravascular fluid and subsequent hypotension, which are the major pharmacological features in anaphylactic shock.
Adrenaline stimulates bronchial beta-adrenergic receptors and has a powerful bronchodilator action. Adrenaline also alleviates pruritus, urticaria and angioedema associated with anaphylaxis.

5.2 Pharmacokinetic Properties

There is large inter-individual variability in the response to adrenaline, with peak absorption occurring around 5-10 min after intramuscular injection. Its absorption from the intramuscular site is faster and more reliable than from the subcutaneous site.
Adrenaline is rapidly inactivated in the body, mostly in the liver by the enzymes catechol-O-methyltransferase (COMT) and monoamine oxidase (MAO). Much of a dose of adrenaline is excreted as metabolites in urine. The plasma half-life is about 2-3 minutes. However, when given by subcutaneous or intramuscular injection, local vasoconstriction may delay absorption so that
the effects may last longer than the half-life suggests.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Adrenaline Acid Tartrate

Sodium Metabisulfite
Sodium chloride
Sodium hydroxide
Hydrochloric Acid
Water for injection

6.1 Incompatibilities
Not Applicable

6.2 Shelf life
24 months

6.4 Special precautions for storage
Store at a temperature not exceeding 30^0C. Protect from light.

6.5 Nature and contents of container

1. A Colourless or almost colourless Solution is filled in 1 ml amber ampoule, such 5Ampoules packed in PVC tray & such one PVC tray packed in a carton with leaflet
2. A Colourless or almost colourless Solution is filled in 1 ml amber ampoule, such 10 Ampoules packed in PVC tray & such one PVC tray packed in a carton with leaflet.

7.0 MARKETING AUTHORISATION HOLDER AND MANUFACTURING ADRESS
GOODMED PHARMACY LIMITED
P.O BOX 76337-00508
NAIROBI, KENYA.

MANUFACTURER:
M/S. KAMLA LIFESCIENCES LTD.
Plot No.G-84/1, Tarapur M.I.D.C,
Boisar-401 506, Tal. & Dist. Palghar, Maharashtra, India.

8.0 MARKETING AUTHORIZATION NUMBER:
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9.0 DATE OF FIRST AUTHORIZATION /RENEWAL OF THE AUTHORIZATION
2025 September 17

10.0 DATE OF REVISION OF TEXT

2025 September 17