

Prescribing Information for Adrenaline (Epinephrine) (1:1000) Injection for Anaphylaxis

See Summary of Product Characteristics (SPC) before prescribing.

Presentation: a clear and colourless solution for injection in a glass prefilled syringe, containing 1mg of adrenaline (as the acid tartrate) per ml of solution. **Indications:** To provide rapid relief for Anaphylaxis or Acute Allergy (Angioedema) both to drugs and other allergens. **Dosage and administration:** The intramuscular (IM) route is recommended by the UK Resuscitation Council as the most appropriate for most individuals who have to give adrenaline to treat an anaphylactic reaction. The subcutaneous route for adrenaline is not recommended for treatment of an anaphylactic reaction as it is less effective. Half doses of adrenaline may be safer for patients who are taking amitriptyline, imipramine or a beta blocker. *Adults:* 500 micrograms (0.5ml). *Elderly:* Use with great caution. *Children:* >12 years: 0.5 mg IM (0.5ml), 6-12 years: 0.3 mg IM (0.3ml), 6 months–6 years: 0.15 mg IM (0.15ml). <6 months: 0.01 mg/kg IM (0.01ml/kg). Repeat the IM adrenaline dose if no improvement in the patient's condition. Further doses can be given at about 5-minute intervals according to the patient's response. Do not give the undiluted 1:1000 adrenaline intravenously. **Method of Administration:** Adrenaline Injection 1/1000 (1mg/ml) may be administered undiluted by IM injection. In the shocked patient, the intramuscular route is recommended as absorption from the intramuscular site is more rapid and reliable. **Contra-Indications:** Hypersensitivity to the active substance or to any of the excipients listed. Adrenaline/epinephrine injection is contraindicated in the following: patients with shock (other than anaphylactic shock); patients with narrow angle glaucoma; use during general anaesthesia with chloroform, trichloroethylene, or cyclopropane, and should be used cautiously, if at all, with other halogenated hydrocarbon anaesthetics. Adrenaline should not be used during labour or, with local anaesthesia of peripheral structures including digits and ear lobe. Use in the presence of ventricular fibrillation, cardiac dilatation, coronary insufficiency, organic brain disease or atherosclerosis, except in emergencies where the potential benefit clearly outweighs the risk. Do not use if solution is discoloured. **Warnings and precautions:** Adrenaline should be used with caution in patients with hyperthyroidism, diabetes mellitus, pheochromocytoma, narrow angle glaucoma, hypokalaemia, hypercalcaemia, severe renal impairment, prostatic adenoma leading to residual urine, cerebrovascular disease, organic brain damage or arteriosclerosis, in elderly patients, in patients with shock (other than anaphylactic shock) and in organic heart disease or cardiac dilatation (severe angina pectoris, obstructive cardiomyopathy, hypertension) as well as most patients with arrhythmias. Repeat administration may produce local necrosis at the sites of injection. Prolonged administration may produce metabolic acidosis, renal necrosis and adrenaline fastness or tachyphylaxis. Adrenaline should be avoided or used with extreme caution in patients undergoing anaesthesia with halothane or other halogenated anaesthetics, in view of the risk of inducing ventricular fibrillation. Do not mix with other agents unless compatibility is known. The patient should be monitored as soon as possible [pulse, blood pressure, ECG (electrocardiogram), pulse oximetry]. 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. 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 1:1000 should not be diluted to 1 in 10,000 for use in cardiac resuscitation. IM injection of adrenaline/epinephrine into the buttocks should be avoided because of the risk of tissue necrosis. This product contains sodium metabisulfite that can cause allergic-type reactions, including anaphylaxis and life-threatening or less severe asthmatic episodes, in certain susceptible individuals. **Interactions:** adrenaline/epinephrine interacts with the following: sympathomimetic agents/oxytocin; alpha-adrenergic and beta-adrenergic blocking agents; general anaesthetics. Other drugs: adrenaline/epinephrine should not be used in patients receiving high dosage of other drugs (e.g. cardiac glycosides); some antihistamines (e.g. diphenhydramine) and thyroid hormones may potentiate the effects of adrenaline/epinephrine; antidepressant agents. Antihypertensive agents. Phenothiazine. 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. **Pregnancy and lactation:** *Pregnancy:* Adrenaline crosses the placenta. Adrenaline should not be used in pregnancy unless clearly necessary. *Breast-feeding:* Adrenaline/epinephrine is distributed into breast milk. Breast-feeding should therefore be avoided in mothers receiving Adrenaline/Epinephrine Injection. **Effects on ability to drive and use machines:** Adrenaline has moderate influence on the ability to drive and use machines. The patients' ability to drive and use machines may be affected by the anaphylactic reaction, as well as by possible

adverse reactions to adrenaline. **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. Anaphylaxis, possibly with severe bronchospasm. Hypokalaemia, metabolic acidosis, inhibition of insulin secretion and hyperglycaemia even with low doses, gluconeogenesis, glycolysis, lipolysis, and ketogenesis. Psychotic states, anxiety, fear, confusion, irritability, and insomnia. Headache, dizziness, tremors, restlessness; 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. Disturbances of cardiac rhythm and rate may result in palpitation and tachycardia. Chest pain/angina may occur; 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; adrenaline causes E.C.G. changes including a decrease in T-Wave amplitude in all leads in normal subjects. Hypertension (with risk of cerebral haemorrhage); coldness of extremities may occur even with small doses of adrenaline. Dyspnoea, pulmonary oedema may occur after excessive doses or in extreme sensitivity. Dry mouth, reduced appetite, nausea, vomiting, hypersalivation. Difficulty in micturition, urinary retention. Sweating, weakness; repeated injections of adrenaline can cause local ischaemic necrosis as a result of vascular constriction at the injection site; tissue necrosis may also occur in the extremities, kidneys and liver. Consult SPC for further information. **Overdose:** See SPC for symptoms and treatment guidance. **Product Licence Number:** PL 12064/0058. **Marketing Authorisation Holder:** Aurum Pharmaceuticals Ltd, Bampton Road, Romford, RM3 8UG. **Basic NHS Price:** £14.47. **Legal Category:** POM. **Further information:** Martindale Pharma, Bampton Road, Romford, RM3 8UG. Tel: 01277266600. **Date of Preparation:** October 2020.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Martindale Pharma, an Ethypharm Group Company. Tel: 01277 266 600. e-mail: drugsafety.uk@ethypharm.com