

Adrenaline (Epinephrine) Injection 1:10,000

Prescribing information

Please refer to Summary of Product Characteristics before prescribing.

Presentation: Sterile aqueous, clear and colourless solution for slow intravenous (IV) injection, presented in a glass pre-filled syringe, containing 0.1mg of adrenaline (as acid tartrate) per 1ml of solution. **Indications:** Cardiopulmonary Resuscitation (CPR) in adults and children over 5kg. Acute anaphylaxis in adults. **Dosage and administration:** **This medicinal product is not intended to deliver volumes of less than 2 mL. Intravenous adrenaline should only be administered by those experienced in the use and titration of vasopressors in their normal clinical practice.** *Cardiopulmonary Resuscitation:* 10 ml of the 1:10,000 solution (1 mg) by the intravenous or intraosseous route, repeated every 3-5 minutes until return of spontaneous circulation. Endotracheal use should only be considered as a last resort if no other route of administration is accessible, at a dose of 20 to 25 ml of the 1:10,000 solution (2 to 2.5 mg). In cardiac arrest following cardiac surgery, Adrenaline should be administered intravenously in doses of 0.5 ml or 1ml of 1:10,000 solution (50 or 100 micrograms) very cautiously and titrated to effect. *Acute Anaphylaxis:* Titrate using IV boluses of 0.5 ml of the 1:10,000 solution (0.05mg) according to response. Adrenaline 1mg/10ml (1:10,000) solution for injection in pre-filled syringe is not recommended for intramuscular use in acute anaphylaxis. For intramuscular administration, a 1mg/ml (1:1000) solution should be used. *Paediatric Population:* This medicinal product is not appropriate to deliver a dose of less than 0.5 ml and should therefore not be used by the intravenous or intraosseous route, in neonates and infants with body weight less than 5 kg. *Cardiac arrest in children:* Intravenous or intraosseous route (above 5 kg only): 0.1 ml/kg of 1:10,000 solution (10 micrograms/kg) to a maximum single dose of 10 ml of 1:10,000 solution (1 mg), repeated every 3-5 minutes until return of spontaneous circulation. Endotracheal use (any body weight) should only be considered as a last resort if no other route of administration is accessible, at a dose of 1 ml/kg of 1:10,000 solution (100 micrograms/kg) to a maximum single dose of 25 ml of 1:10,000 solution (2.5 mg). **Contraindications:** Hypersensitivity to the active substance or to any of the excipients, where an alternative presentation of adrenaline or alternative vasopressor is available. **Warnings and precautions:** Adrenaline 1 mg/10 ml (1:10,000), solution for injection in pre-filled syringe is indicated for emergency treatment. Medical supervision is necessary after administration. For intramuscular administration, a 1 mg/ml (1:1000) solution should be used. In the treatment of anaphylaxis and in other patients with a spontaneous circulation, intravenous adrenaline can cause life-threatening hypertension, tachycardia, arrhythmias and myocardial ischaemia. Intravenous adrenaline should only be used by those experienced in the use and titration of vasopressors in their normal clinical practice. Patients who are given IV adrenaline require continuous monitoring of ECG, pulse oximetry and frequent blood pressure measurements as a minimum. The risk of toxicity is increased if the following conditions are pre-existing: hyperthyroidism; hypertension; structural cardiac disease, cardiac arrhythmias, severe obstructive cardiomyopathy; coronary insufficiency; pheochromocytoma; hypokalaemia; hypercalcaemia; severe renal impairment; cerebrovascular disease, organic brain damage or arteriosclerosis; patients taking Monoamine oxidase (MAO) inhibitors; patients taking concomitant medication which results in additive effects, or sensitizes the myocardium to the actions of sympathomimetic agents. Prolonged use of adrenaline can result in severe metabolic acidosis because of elevated blood concentrations of lactic acid. Adrenaline may increase intra-ocular pressure in patients with narrow angle glaucoma. Adrenaline should be used with caution in patients with prostatic hyperplasia with urinary retention. Adrenaline may cause or exacerbate hyperglycaemia, blood glucose should be monitored, particularly in diabetic patients. Adrenaline should be used with caution in elderly patients. Adrenaline should not be used during the second stage of labour. This medicinal product contains 2.70 mg of sodium per ml of solution for injection: to be taken into consideration by patients on a strict sodium diet. **Interactions:** Adrenaline interacts with several other drugs: volatile halogen anaesthetics; imipramine antidepressants; serotonergic-adrenergic antidepressants; sympathomimetic agents; non-selective MAO inhibitors; selective MAO-A inhibitors, Linezolid (by extrapolation from non-selective MAO inhibitors); alpha and beta adrenergic blocking agents; insulin or oral hypoglycaemic agents. Consult SPC for further information. **Pregnancy and lactation:** Adrenaline should only be used during pregnancy if the potential benefits outweigh the possible risks to the

foetus. If used during pregnancy, adrenaline may cause anoxia to the foetus. 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, adrenaline should not be used during the second stage of labour. Adrenaline is distributed into breast milk; therefore, breast-feeding should be avoided in mothers receiving adrenaline injection. **Effects on ability to drive and use machines:** Not applicable in normal conditions of use. **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. Undesirable effects include: hyperglycaemia, hypokalaemia, metabolic acidosis; anxiety, nervousness, fear, hallucinations; headache, tremors, dizziness, syncope; mydriasis; palpitations, tachycardia, in high dosage or for patients sensitive to adrenaline: cardiac dysrhythmia (sinus tachycardia, ventricular fibrillation/cardiac arrest), acute angina attacks, and risk of acute myocardial infarction; pallor, coldness of the extremities, in high dosage or for patient's sensitive to adrenaline: hypertension (with risk of cerebral haemorrhage), vasoconstriction (for example cutaneous, in the extremities or kidneys); dyspnoea; nausea, vomiting; sweating, weakness. repeated local injections may produce necrosis at sites of injection as a result of vascular constriction. Consult SPC for further information. **Product Licence Number:** PL 12064/0006. **Product Licence Holder:** Aurum Pharmaceuticals Ltd, Bampton Road, Romford, RM3 8UG. **Basic NHS Price:** £7.21. **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.
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