

EPIPEN® EPIPEN® Jr

(Adrenaline) Auto-Injectors 0.3/0.15mg

EpiPen® and EpiPen® Jr. (adrenaline) Prescribing Information

Presentation: EpiPen delivers a single dose of 0.3mg of adrenaline BP 1:1000 (0.3ml) in a sterile solution. EpiPen Jr. delivers a single dose of 0.15mg adrenaline BP 1:2000 (0.3ml) in a sterile solution. 1.7ml of adrenaline remains in the auto-injector after activation.

Indications: For immediate self administration in the emergency treatment of allergic anaphylactic reactions. Anaphylaxis may be caused by insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise-induced anaphylaxis.

Dosage and administration: ADULTS: Self administration of 0.3mg adrenaline (EpiPen) intramuscularly. CHILDREN: The appropriate dosage may be 0.15mg (EpiPen Jr.) for children 7.5–25kg body weight and 0.3mg (EpiPen) adrenaline for children >25kg body weight, or at the discretion of the physician. EpiPen should only be injected into the anterolateral aspect of the thigh through clothing if necessary. An initial dose should be administered as soon as symptoms of anaphylaxis are recognised. A second injection with an additional EpiPen may be administered 5-15 minutes after the first injection, if indicated. It is recommended that patients are prescribed two EpiPen auto-injectors which they should carry at all times. As EpiPen is designed for emergency treatment, the patient should always seek immediate medical attention even if symptoms have disappeared.

Contra-indications: There are no absolute contra-indications to the use of adrenaline in a life threatening situation.

Precautions: Avoid the risk of inadvertent intravascular injection.

DO NOT INJECT INTO THE BUTTOCKS. Accidental injection into the hands or feet may result in loss of blood flow to the affected areas. If there is an accidental injection into these areas, advise the patient to go immediately to the nearest A & E or hospital casualty department for treatment. All patients who are prescribed EpiPen should be thoroughly instructed to understand the indications for use and the correct method of administration. It is strongly advised to educate the patient's parents, caregivers, teachers, for the correct usage, in case support is needed in the emergency situation. In patients with a thick sub-cutaneous fat layer, there is a risk for adrenaline not reaching the muscle tissue resulting in a suboptimal effect. Use with extreme caution in patients with heart disease and those taking digitalis, mercurial diuretic or quinidine. Adrenaline should only be prescribed to these patients and the elderly if the potential benefit justifies the potential risk. There is a risk of adverse reactions following adrenaline administration in patients with high intraocular

pressure, severe renal impairment, prostatic adenoma leading to residual urine, hypercalcaemia and hypokalaemia. In patients with Parkinson's disease, adrenaline may be associated with a transient worsening of Parkinson's symptoms such as rigidity and tremor.

The effects of adrenaline may be potentiated by tricyclic antidepressants and monoamine oxidase inhibitors. Adrenaline should be used in pregnancy only if the potential benefit justifies any potential risk to the foetus. The patient/carer should be informed about the possibility of biphasic anaphylaxis which is characterised by initial resolution followed by recurrence of symptoms some hours later. Asthmatic patients may be at increased risk of severe anaphylactic reaction. Patients should be warned regarding related allergens and investigated so that their specific allergens can be characterised.

Undesirable effects: Frequency not known: May include palpitations, tachycardia, hypertension, sweating, nausea and vomiting, respiratory difficulty, pallor, dizziness, nervousness, anxiety and undesirable effects on the CNS. Cardiac arrhythmias may follow administration of adrenaline. Overdoses of adrenaline may cause cerebral haemorrhage or arrhythmias. Rare: Stress cardiomyopathy.

For a complete list of warnings and adverse reactions, you should consult the Summary of Product Characteristics.

Package quantity and basic NHS price: EpiPen and EpiPen Jr. are available as single unit doses at £26.45 each or as a twin pack of 2 Auto-Injectors at £52.90

Product licence numbers: EpiPen Auto-Injector PL 15142/0245. EpiPen Jr. Auto-Injector PL 15142/0246

Legal category: POM

Marketing Authorisation Holder: Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishops Stortford, CM22 6PU.

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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 Meda's Medical Information line on 01748 828 810

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