PRESCRIBING INFORMATION

EpiPen® (Adrenaline) Auto-injector 0.3 mg & EpiPen® Jr. (Adrenaline) Auto-injector 0.15 mg

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Indications: EpiPen® auto injectors are automatic injection devices containing adrenaline for allergic emergencies. The auto injectors should be used only by a person with a history or an acknowledged risk of an anaphylactic reaction. The autoinjectors are indicated 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.

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.

Dosage and administration: ADULTS: 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 medical help immediately.

Contra-indications: There are no absolute contra-indications to the use of adrenaline during an allergic emergency.

Warning and precautions: Patients should be advised NOT to inject into the buttocks. Large doses or accidental intravenous injection of adrenaline may result in cerebral haemorrhage due to sharp rise in blood pressure. 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. In case of injection performed by a caregiver, patient's leg should be kept still to reduce risk of injection site injury. The needle should never be reinserted after use.
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. A second injection with an additional EpiPen® may be needed. 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. Anginal pain may be induced by adrenaline in patients with coronary insufficiency. Hyperthyroid individuals (hyperfunction of the thyroid gland), individuals with cardiovascular disease, hypertension (raised blood pressure), or diabetes, elderly individuals, pregnant women, and children under 25 kg body weight using EpiPen® and children under 7.5 kg body weight using EpiPen® Jr. auto injector may theoretically be at greater risk of developing adverse reactions after adrenaline administration. 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. Children under 15 kg in body weight should be carefully monitored for signs of adrenaline overdose (see section 4.9 of SmPC).

Interaction with other medicinal products: Caution is indicated in patients receiving drugs that may sensitise the heart to arrhythmias, including digitalis, mercurial diuretics or quinidine. The effects of adrenaline may be enhanced by tricyclic antidepressants and mono amine oxidase inhibitors (MAO-inhibitors) and catechol-O-methyl transferase inhibitors (COMT-inhibitors), thyroid hormones, theophylline, oxytocin, parasympatholytics, certain antihistamines (diphenhydramine, chlorpheniramine), levodopa and alcohol. Pressor effects of adrenaline may be counteracted by rapidly acting vasodilators or alpha-adrenergic blocking drugs. Adrenaline inhibits the secretion of insulin, thus increasing the blood glucose level. It may be necessary for diabetic patients receiving adrenaline to increase their dosage of insulin or oral hypoglycaemic drugs. The β-stimulating effect can be inhibited by simultaneous treatment with β-blocking drugs.

Pregnancy and lactation: Adrenaline should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Adrenaline not expected to have any effect on the nursing infant.

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

Undesirable effects: *(Rare):* Stress cardiomyopathy. *(Frequency not known):* May include injection site infections such as rare cases of serious skin and soft tissue infections, including necrotizing fasciitis and myonecrosis caused by Clostridia (gas gangrene); Anxiety, apprehension, nervousness, headaches, dizziness, tremor and undesirable effects on the central nervous system, tachycardia, cardiac arrhythmia, palpitations, fatal ventricular fibrillation, angina, hypertension, pallor, peripheral ischaemia following accidental injection of the pens in hands or feet; respiratory difficulties, nausea, vomiting, hyperhidrosis, asthenia, accidental injections can lead to injury at the injection site such as bruising, bleeding, discoloration, erythema or skeletal injury.

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

Legal Category: POM **Marketing Authorisation Number**: EpiPen® Auto-Injector 0.3 mg PL 46302/0171, EpiPen® Jr. Auto-Injector 0.15mg PL 46302/0172 **MAH:** Mylan Products Ltd., Station Close, Potters Bar, EN6 1TL, UK **NHS Price:** EpiPen® 0.3 mg and EpiPen® Jr. 0.15mg are available as single unit doses at £60.69 each or as a twin pack of 2 Auto-Injectors at £121.38 **Date of Revision of Prescribing Information:** July 2024 **Veeva Reference:** UK-EPI-2024-00006

The SmPC for this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/index.htm and from Viatris Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info.uk@viatris.com

Please continue to report suspected adverse drug reactions and device failures with any medicine or vaccine to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report adverse drug reactions and device failures online via the Yellow Card Scheme website: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, you can report via some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) or by calling the Commission on Human Medicines (CHM) free phone line: 0800-731-6789. Adverse reactions/events and device failures should also be reported to MAH at e-mail address: pv.uk@viatris.com