PRESCRIBING INFORMATION

EpiPen® and EpiPen® Jr.
(adrenaline)

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: 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. 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. 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.

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.

Pregnancy and lactation: Adrenaline should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

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 infection, palpitations, tachycardia, hypertension, undesirable effects on the central nervous system, sweating, nausea and vomiting, respiratory difficulty, pallor, dizziness, weakness, tremor, headache, apprehension, nervousness, anxiety and undesirable effects on the CNS. Cardiac arrhythmias may follow administration of adrenaline. Overdoses of adrenaline may cause cerebral haemorrhage or arrhythmias.

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 PL 46302/0171, EpiPen® Jr. Auto-Injector PL 46302/0172 **MAH:** Mylan Products Ltd., Station Close, Potters Bar, EN6 1TL, UK **NHS Price:** EpiPen® and EpiPen® Jr. are available as single unit doses at £53.80 each or as a twin pack of 2 Auto-Injectors at £107.60 **Date of Revision of Prescribing Information:** February 2023 **Veeva Reference:** EPI-2023-0065

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 Mylan 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