# ABBREVIATED PRESCRIBING INFORMATION

## EpiPen (adrenaline) 300 micrograms solution for injection in pre-filled pen, EpiPen Junior (adrenaline) 150 micrograms solution for injection in pre-filled pen

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

**Indications, Dosage and Administration:** the emergency treatment of severe allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens, as well as idiopathic or exercise induced anaphylaxis.

Posology: Paediatric population: Usual paediatric dose is 0.01 mg/kg body weight. However, the prescribing physician has the option of prescribing more or less than these amounts based on careful assessment of each individual patient and recognizing the life- threatening nature of reactions for which this is being described. A dosage below 150 micrograms cannot be administered with EpiPen adrenaline Auto-Injector. The physician should consider using other forms of injectable adrenaline if lower doses are felt to be necessary for small children.

Children and adolescents over 30 kg in weight: The usual dose is 300 micrograms for intramuscular use. Children between 15 kg and 30 kg in weight: The usual dose is 150 micrograms for intramuscular use. Children below 15 kg in weight: The suitability of EpiPen Junior has to be judged individually. The use in children weighing less than 7.5 kg is not recommended unless in a life-threatening situation and under medical advice. Adults: The usual dose is 300 micrograms for intramuscular use. An initial dose should be administered as soon as symptoms of anaphylaxis are recognized. In the absence of clinical improvement or if deterioration occurs, a second injection with an additional EpiPen or EpiPen Junior Auto-Injector may be administered 5 - 15 minutes after the first injection. It is recommended that patients are prescribed two EpiPen or EpiPen Junior pens which they should carry at all times.

The physician prescribing an EpiPen or EpiPen Junior Auto-Injector must ensure that the patient understands the indications for use and the correct method of application. Therefore, the physician should discuss the patient information leaflet, the correct handling of the Auto-Injector and the possible symptoms of an anaphylactic shock in detail with the patient.

Method of administration: EpiPen Auto-Injectors are intended for immediate administration in patients, who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions. For intramuscular administration into the anterolateral thigh, not the buttock. It is designed to inject through clothing or directly through the skin.

The patient/carer should be informed that following each use of EpiPen or EpiPen Junior

- They should call for immediate medical assistance, ask for an ambulance and state “anaphylaxis” even if symptoms appear to be improving.
- Conscious patients should preferably lie flat with feet elevated but sit up if they have breathing difficulties. Unconscious patients should be placed on their side in the recovery position.
- The patient should if possible remain with another person until medical assistance arrives.

**Presentation:** Solution for injection in pre-filled pen (Auto-Injector). Clear and colourless solution. EpiPen: A single dose (0.3 ml) contains 300 micrograms (0.3 mg) adrenaline (epinephrine). EpiPen Junior: A single dose (0.3 ml) contains 150 microgram (0.15 mg) adrenaline (epinephrine).

**Contraindications:** There are no known absolute contraindications to the use of EpiPen or EpiPen Junior during an allergic emergency.

**Warnings and precautions:** All patients who are prescribed EpiPen or EpiPen Junior should be thoroughly instructed to understand the indications for the use and the correct method of administration. It is strongly advised also to educate the patient’s immediate associates (e.g. parents, caregivers, teachers) for the correct usage of the EpiPen or EpiPen Junior in case support is needed in the emergency situation. The patient should be instructed to dial 112, ask for ambulance, state anaphylaxis to seek emergency medical assistance immediately after administering the first dose in order to have close monitoring of the anaphylactic episode and further treatment as required. The Auto-Injectors should be injected into the anterolateral aspect of the thigh. Patients should be advised not to inject into the buttock. In case of injection performed by a caregiver, immobilization of the patient’s leg should be ensured during injection to minimize the risk of leg laceration, bent needle or other injuries. The product is for single use only and in no case the used pen should be reused. Adrenaline is ordinarily administered with extreme caution to patients who have a heart disease.

Adrenaline should only be prescribed to those patients, but also those suffering from diabetes, hyperthyroidism, hypertension and elderly individuals if the potential benefit justifies the potential risk. There is a risk of adverse reactions following epinephrine 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, epinephrine may be associated with a transient worsening of Parkinson symptoms such as rigidity and tremor. 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. Patients with concomitant asthma may be at increased risk of a severe anaphylactic reaction. Accidental injection into hands or feet resulting in peripheral ischaemia has been reported. Patients may need treatment following the accidental injection.
In patients with 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.
EpiPen and EpiPen Junior contain sodium metabisulfite which may rarely cause severe hypersensitivity reactions including anaphylactic symptoms and bronchospasm in susceptible people, especially those with a history of asthma. Patients with these conditions must be carefully instructed in regard to the circumstances under which EpiPen or EpiPen Junior should be used. This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium -free'. Patients should be warned regarding related allergens and should be investigated whenever possible so that their specific allergens can be characterised.
**Interactions with other medicinal products and other forms of interaction:** Caution is indicated in patients receiving drugs that may sensitise the heart to arrhythmias, including digitalis and quinidine. The effects of adrenaline may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors (MAO-inhibitors) and catechol -O-methyl transferase inhibitors (COMT inhibitors), thyroid hormones, theophylline, oxytocin, parasympatholytics, certain antihistamines (diphenhydramine, chlorpheniramine), levodopa and alcohol. 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. Observe: The ß-stimulating effect can be inhibited by simultaneous treatment with ß -blocking drugs.
**Fertility, pregnancy and lactation:** Pregnancy: Clinical experience in the treatment of pregnancy is limited. Adrenaline should be used during pregnancy only if the potential benefit justifies the potential risk for the foetus. Breast-feeding: Adrenaline is not orally bioavailable; any adrenaline excreted in breast milk would not be expected to have any effect on the nursing infant. Fertility: As adrenaline is a substance that naturally occurs in the body, it is unlikely that this drug would have any detrimental effects on fertility.
**Undesirable effects:**
Side effects associated with adrenaline's alpha and beta receptor activity may include symptoms such as tachycardia and hypertension as well as undesirable effects on the central nervous system.
Very common (≥1/10): None
Common (>1/100, <1/10): None
For details of uncommon, rare and very rarely reported adverse events and those of unknown frequency, see SmPC.
**Reporting of adverse reactions:**
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie. Adverse reactions/events should also be reported to the marketing authorisation holder at the email address: pv.ireland@viatris.com or phone 0044(0)8001218267.
**Legal Category:** Subject to prescription which may be renewed (B)
**Marketing Authorisation Number:** PA23355/011/001 (EpiPen Junior), PA23355/011/002 (EpiPen)
**Marketing Authorisation Holder:** Viatris Healthcare Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN Ireland
**Full prescribing information available on request from:** Viatris, Dublin 17. Email: enquiry.ire@viatris.com

**Date of Revision of Abbreviated Prescribing Information:** 30 Jun 2023
**Reference Number:** IE-AbPI-EpiPen-EpiPenJunior-v003