Jext® Prescribing Information

Refer to the Summary of Product Characteristics (SmPC) before prescribing

Please refer to the Summary of Product Characteristics before prescribing. **Name** Jext 150 micrograms solution for injection in pre-filled pen Jext 300 micrograms solution for injection in pre-filled pen **Active Ingredients** Jext 150 micrograms: One pre-filled pen delivers one dose of 0.15ml solution for injection containing 150 micrograms of adrenaline (as tartrate). Jext 300 micrograms: One pre-filled pen delivers one dose of 0.30ml solution for injection containing 300 micrograms of adrenaline (as tartrate). **Indication** Jext is indicated in the emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis. **Dose** Patients between 15 kg and 30 kg in weight – The usual dose is 150 micrograms. Patients over 30 kg in weight – The usual dose is 300 micrograms. **Administration** For single use. Jext is for intramuscular administration into the anterolateral thigh. It is designed to inject through clothing or directly through the skin. Massage around the injection area is advised to accelerate absorption. Please refer to the Summary of Product Characteristics for detailed instructions for use. In the absence of clinical improvement or if deterioration occurs, a second injection with an additional Jext may be administered 5 – 15 minutes after the first injection. It is recommended that patients should carry two Jext pens which they should carry at all times. The patient should seek emergency medical assistance immediately after administering Jext for monitoring of the anaphylactic episode and further treatment as required. **Contraindications** There are no absolute contraindications to the use of Jext during an allergic emergency **Undesirable Effects** The alpha and beta receptor activity of adrenaline may cause undesirable effects on the cardiovascular system, central nervous system and other organ systems including hyperglycaemia, hypokalaemia, metabolic acidosis, headache, dizziness, tremor, syncope, tachycardia, arrhythmia, palpitations, angina pectoris, stress cardiomyopathy, hypertension, vasoconstriction, peripheral ischaemia, bronchospasm, nausea, vomiting, hyperhidrosis or asthenia. Please consult the Summary of Product Characteristics in relation to side- effects. **Warnings** Do not inject Jext into the buttocks due to risk of accidental injection into a vein. Accidental injection into hands or feet may cause peripheral ischaemia due to vasoconstriction. In patients with thick subcutaneous fat layer, there is a risk of adrenaline not reaching the muscle tissue resulting in suboptimal effect. Precautions Special caution should be taken in patients with cardiovascular diseases, hyperthyroidism, phaeochromocytoma, narrow angle glaucoma, severe renal impairment, prostatic adenoma leading to residual urine, hypercalcaemia, hypokalaemia and diabetes. 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. Caution should also be taken in elderly and pregnant patients. Jext contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions in susceptible people. Susceptible people must be carefully instructed in regard to the circumstances under which Jext should be used. All patients who are prescribed Jext should be thoroughly instructed to understand the indications for use and the correct method of administration. It is strongly advised also to educate the patient's immediate associates (e.g. parents, caregivers, and teachers) for the correct usage of Jext® in case support is needed in the emergency situation. Patients should be advised to regularly check Jext and ensure it is replaced within the expiry period. **Legal Category: POM Marketing Authorisation Numbers: PA1255/006/001, PA1255/006/002 Marketing Authorisation holder: ALK Abelló A/S, Bøge Alle 6-8, DK-2970 Hørsholm. Date of last revision: July 2023. IE-JXT-2300019**

Adverse events should be reported. Reporting forms and information can be found using the HPRA Pharmacovigilance website at www.hpra.ie. Adverse events should also be reported to ALK-Abelló Ltd at drugsafetyie@alk.net