



Dear Colleague

MEDICINE SUPPLY ALERT NOTICE

Medicine/Drug in short supply: Adrenalin auto-injectors: Jext[®] 300µg

Priority: Information and further update
Valid until: Ongoing

Issue

1. In October 2019 the Medicines and Healthcare products Regulatory Agency (MHRA) issued a Class 4 drug alert for all strengths of Emerade[®] auto-injectors. This was issued as a Medicines Supply Alert Notice in circular MSAN (2019)3 on 11 October, in which it was advised that the MHRA had approved the extension of expiry dates for specific batches of EpiPen[®] 300 micrograms and Jext[®] 150 micrograms and 300 micrograms by four months beyond the labelled expiry date.

2. The MHRA has now advised that UK-licensed Jext[®] 300 microgram devices are currently unavailable.

3. ALK-Abello Ltd (manufacturers of Jext[®]) has obtained acceptance from the MHRA to import a quantity of Jext[®] 300 microgram from Austria. This stock has an Austrian German language pack, label and patient information leaflet. Although not licensed in the UK, it is equivalent to the UK licensed product. Each device will be supplied in a clear envelope which will also contain a UK Patient Information Leaflet.

4. UK licensed supplies of EpiPen[®] 300 microgram and Emerade[®] 300 microgram remain available.

Advice

5. For patients who require Jext[®] 300 microgram, prescribers may consider prescribing an unlicensed device.

1 November 2019

Addressees:

For action
Community Pharmacy Scotland
Scottish Prescribing Advisor
Network
Medicines Shortage Response
Group (Scotland)

General Enquiries to:

Margaret Syme or Alison Strath
Pharmacy & Medicines Division

Email: PharmacyTeam@gov.scot

www.gov.scot

6. Pharmacies can place orders for unlicensed Jext[®] 300 microgram via Alliance Healthcare using the PIP code: 801-6941. Any handling charge incurred should be included in the electronic claim message.

7. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:

- Prescribing unlicensed medicines, General Medical Council (GMC)
- The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)
- Professional guidance for the procurement and supply of specials, Royal Pharmaceutical Society (RPS)

8. Specific training and advice are required for each brand of adrenaline auto-injector, however, there is no difference in administration between the UK and Austrian Jext[®] 300 microgram devices. Links to the training videos can be found at the following link: <https://hcp.jext.co.uk/>

9. Please see the attached Dear Healthcare Professional letter from ALK-Abello Ltd at Annex A for further information.

Action

10. Healthcare professionals are asked to note the content and actions outlined in this circular and Annex.

Yours sincerely,



Rose Marie Parr
Chief Pharmaceutical Officer/
Deputy Director Pharmacy & Medicines Division



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Date 14th October 2019

Dear Healthcare Professional,

Supply of unlicensed Jext® 300mcg in Austrian packaging

There are supply issues affecting some brands of adrenaline auto-injectors on the UK market. To support and maintain an overall adequate supply, ALK has obtained acceptance from the UK medicines regulator, Medicines and Healthcare Products Regulatory Agency (MHRA) to import a quantity of Jext® 300mcg from Austria. This stock has an Austrian German language pack, label and patient information leaflet. Although not licensed in the UK, it is equivalent to the UK licensed product and is licensed in Austria.

Each device will be supplied in a clear envelope which will also contain a UK Patient Information Leaflet. Patients can also be advised to visit www.jext.co.uk to view training videos and further information as well as order Jext® training devices. Additionally, the Jext® app can be downloaded for iPhone and Android which also contains information on how to use Jext.

This notice only applies to Jext® 300mcg in the following batch numbers: B4509, B4587, B4813, B4722 and B4727.

Further information for Pharmacists

This product has a temporary PIP code which is linked to the original UK product PIP code. If there is no stock of the UK version, you should be linked through to the Austrian stock and vice versa. We anticipate that this stock will only be available for a few weeks.

UK Jext® 300mcg PIP Code : 358-7607
Austrian Jext 300mcg PIP Code : 801-6941

Distribution will be handled by Alcura on behalf of Alliance Healthcare Ltd, the sole distributors of Jext® in the UK. A £20 handling fee will be charged per order for this unlicensed Austrian stock. This fixed fee can be reclaimed in the usual way for unlicensed specials.

Further information on recommendations to healthcare professionals

- Tell patients and caregivers that they should retain the UK Patient information supplied with the product.
- Tell patients and caregivers that they can find additional information on how to use Jext® and order training devices on www.jext.co.uk.
- Reassure patients and caregivers that their device is equivalent to the UK product and will work in exactly the same way.
- Remind patients and caregivers that they should obtain a new device near the end of the month of expiry marked on the box and device. Encourage them to sign up for the Expiry Alert Service.
- Advise patients to continue to check periodically the viewing window in the label of their device to ensure the liquid inside is clear and colourless. Do not use the device if the liquid is discoloured.

If you require additional information or have any questions, please contact ALK Customer Services: **0118 903 7940**.

Yours sincerely



Sean Connor
General Manager
UK, Ireland and Benelux

Jext® Abbreviated Prescribing Information 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, anxiety, hallucination, 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. 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 the adrenaline not reaching the muscle tissue resulting in a 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

Basic NHS Cost: Jext 150 and Jext 300 are available as single unit doses at £23.99 each or as a twin pack of two injectors at £47.98. **Marketing Authorisation Numbers:** PL 10085/0052, PL 10085/0053

Marketing Authorisation holder: ALK Abelló A/S, Bøge Alle 6-8, DK-2970 Hørsholm. **Date of last revision:** June 2018 1238AD

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 ALK-Abelló Ltd.