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Date 20th September 2019

Dear Healthcare Professional

Extended Use Beyond Labelled Expiry Date for Selected Lots of Jext® 150 mcg and 300 mcg Adrenaline Auto-Injectors

This letter is sent in agreement with the UK medicines regulator, Medicines and Healthcare Products Regulatory Agency (MHRA), to inform you of the following:

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 MHRA to extend the use of specific lot (batch) numbers of Jext® 150 mcg and Jext® 300 mcg auto-injectors, beyond the labelled expiry date by four months. The affected lot numbers are listed in the table below and are also available on www.jext.co.uk.

Table 1 Affected lots (batches) for extended use of Jext® auto-injectors

No.	Strength, mcg	Lot (batch) no.	Labelled Expiry Date (end of the month)	Extended Use by Date (end of the month)
1	150	A5263	Sep 2019	Jan 2020
2	150	A5682	Sep 2019	Jan 2020
3	150	A5713	Sep 2019	Jan 2020
4	150	A5848	Sep 2019	Jan 2020
5	150	A5850	Oct 2019	Feb 2020
6	150	A6014	Oct 2019	Feb 2020
7	150	A6244	Nov 2019	Mar 2020
8	150	A6705	Nov 2019	Mar 2020
9	150	A6934	Dec 2019	Apr 2020
10	150	A7052	Nov 2019	Mar 2020
11	150	A7082	Nov 2019	Mar 2020
12	150	A7237	Dec 2019	Apr 2020
13	150	A7317	Dec 2019	Apr 2020
14	150	A7403	Dec 2019	Apr 2020
15	150	A7505	Dec 2019	Apr 2020

No.	Strength, mcg	Lot (batch) no.	Labelled Expiry Date (end of the month)	Extended Use by Date (end of the month)
16	150	B3313	Dec 2019	Apr 2020
17	300	A5198	Aug 2019	Dec 2019
18	300	A5283	Aug 2019	Dec 2019
19	300	A5364	Aug 2019	Dec 2019
20	300	A5501	Sep 2019	Jan 2020
21	300	A5676	Sep 2019	Jan 2020
22	300	A5793	Sep 2019	Jan 2020
23	300	A5994	Sep 2019	Jan 2020
24	300	A5910	Oct 2019	Feb 2020
25	300	A5988	Oct 2019	Feb 2020
26	300	A6074	Oct 2019	Feb 2020
27	300	A6148	Nov 2019	Mar 2020
28	300	A6330	Nov 2019	Mar 2020
29	300	A6569	Nov 2019	Mar 2020
30	300	A6848	Nov 2019	Mar 2020
31	300	A6862	Dec 2019	Apr 2020
32	300	A7095	Dec 2019	Apr 2020
33	300	A7215	Dec 2019	Apr 2020
34	300	A7232	Dec 2019	Apr 2020
35	300	A7329	Dec 2019	Apr 2020
36	300	A7393	Dec 2019	Apr 2020
37	300	A7395	Dec 2019	Apr 2020
38	300	A7511	Dec 2019	Apr 2020
39	300	B3042	Dec 2019	Apr 2020
40	300	B3141	Dec 2019	Apr 2020

Important: the extended use only applies to the lots of Jext® 150 mcg and Jext® 300 mcg auto-injectors listed above. Patients can continue to use the Jext® auto-injectors of these specified lots safely until the extended use by date as stated above.

This extended use does not apply to any other lot number of Jext® auto-injectors not specified. Patients must continue to adhere to the labelled expiry date on any Jext® auto-injector not covered by the lot numbers above.

Further information on the extended use of the listed lots of Jext® autoinjectors

You may be aware of the recent supply issues affecting some brands of adrenaline auto-injectors, which have resulted in increased demands on alternative brands of auto-injectors including Jext®. The overall market supply of adrenaline auto-injectors is being monitored by the Department of Health and Social Care.

ALK is working hard to help address the situation and has significantly increased production of its Jext® 150 mcg and 300 mcg adrenaline auto-injectors at its European manufacturing facility. However, due to the time needed for manufacture and the magnitude of the current deficit, it is not possible for ALK to completely meet the shortfall in supply in the short term.

To further ease the shortfall, the period that 40 specific lots of Jext® 150 mcg and Jext® 300 auto-injectors (listed above) can be used has been extended by 4 months beyond the labelled expiry date on the pack.

Lot numbers and labelled expiry dates are marked on the end-flap of the box and on the auto-injector label itself.

This extended use of 4 months beyond the labelled expiry date for the specific lots is based on supportive stability data for Jext® auto-injectors and has been reviewed by the MHRA. The Jext® auto-injectors of these specific lots will continue to work safely and as intended within the allowed extended use by date. The Jext® auto-injectors should continue to be stored as labelled on the pack.

At the end of the extended use period (the end of the month listed in the right column of the table above), a new auto-injector will still need to be obtained.

Further information on recommendations to healthcare professionals

- Tell patients and caregivers about the extended use by date of the specified lots of Jext® 150 mcg and 300 mcg auto-injectors as listed above. This does not apply to other lots of Jext® auto-injectors not listed.
- Show patients and caregivers where to find the lot numbers on their device (on the end-flap and if necessary, on the device label itself) and encourage them to sign up for the Expiry Alert Service.
- Reassure patients and caregivers that their device will continue to work safely over the extended use period.
- Remind patients and caregivers that they should still obtain a new device near the end of the extended use period.
- 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.

This announcement regarding the extended use of certain batches supersedes any notification that a patient may receive via the expiry alert service from www.jext.co.uk. If you require additional information or have any questions, please contact ALK Customer Services: **0118 903 7940**.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789 or
- by downloading and printing a form from the Yellow Card website (see link above)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

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.

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