

Annex 4. Letter to Healthcare Professionals

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:

Summary.

There is currently a shortage of Jext® adrenaline auto-injectors in the UK.

Background to the safety concern.

Due to the recent recall of a competitor product, we have seen an increased demand for JEXT® in all countries, with demand now far exceeding our normal expectations and forecasting. 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 two 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	300	K3984	Dec 2023	Feb 2024
2	300	K4161	Dec 2023	Feb 2024
3	300	K4338	Dec 2023	Feb 2024
4	300	K4160	Dec 2023	Feb 2024
5	300	K4408	Dec 2023	Feb 2024
6	300	K4414	Dec 2023	Feb 2024
7	300	K5311	Jan 2024	Mar 2024
8	300	K4672	Feb 2024	Apr 2024
9	300	K4920	Feb 2024	Apr 2024
10	300	K5183	Feb 2024	Apr 2024
11	300	K5243	Feb 2024	Apr 2024
12	300	K5483	Feb 2024	Apr 2024
13	300	K5619	Feb 2024	Apr 2024
14	300	K5623	Feb 2024	Apr 2024
15	300	K5846	Feb 2024	Apr 2024
16	300	K5806	Feb 2024	Apr 2024
17	300	K6197	Feb 2024	Apr 2024
18	150	K4072	Dec 2023	Feb 2024
19	150	K4558	Dec 2023	Feb 2024
20	150	K4627	Dec 2023	Feb 2024
21	150	K5384	Jan 2024	Mar 2024
22	150	K4938	Feb 2024	Apr 2024
23	150	K5453	Feb 2024	Apr 2024

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® auto-injectors

There is currently a shortage of Jext® adrenaline auto-injectors in the UK. Due to the recent recall of a competitor product, we have seen an increased demand for JEXT® in all countries.

To further ease the shortfall, the period that 23 specific lots of Jext® 150 mcg and Jext® 300 auto-injectors (listed above) can be used has been extended by two 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 two 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 of the box 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** or infouk@alk.net.

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 ▼

You can report via:

- the Yellow Card website <https://yellowcard.mhra.gov.uk/>
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

Yours sincerely

20.11.2023



Emil Stage Olsen

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