**Class 2 Medicines Recall: Jext® 150 micrograms adrenaline (as tartrate) solution for injection in pre-filled pen (PL 10085/0052) and Jext® 300 micrograms adrenaline (as tartrate) solution for injection in pre-filled pen (PL 10085/0053)**

9 December 2013

Dear Pharmacist

ALK-Abelló is recalling certain batches of its adrenaline pen, Jext® 150 microgram (PIP code: 358-7599) and Jext® 300 microgram (PIP code: 358-7607), in the United Kingdom and a number of European countries. In the United Kingdom 66,813 pens produced from March 2013 to October 2013 are affected by the recall.

On 9 December, the MHRA advised a patient level recall of the batches listed below in the UK.

**In line with guidance received from the MHRA:**

- Pharmacies are kindly requested to communicate the recall to all patients who have received a prescription for Jext® after 8 May 2013.
- Patients in possession of a Jext® from an affected batch should be advised to attend their GP practice to obtain a prescription for a replacement adrenaline auto-injector.
- When dispensing an alternative adrenaline auto-injector please ensure the patient is aware how to use the alternative auto-injector as the correct activation method is device specific.
- All patients should continue to carry their Jext® and use it as normal until they obtain a replacement adrenaline auto-injector.
- Pharmacists should return all non-dispensed Jext® from affected batches to their local Alliance Healthcare distribution centre for a full refund.
- Pharmacists should expect an increased number of EpiPen® prescriptions. The MHRA has approved importation of some additional product from the USA to ensure continuity of supply.
- Pharmacists should expect patients to bring unused Jext® to the pharmacy for return to ALK-Abelló via their local Alliance Healthcare distribution centre when collecting their replacement adrenaline auto-injectors.
- Pharmacists are kindly requested to forward all Jext® from affected batches returned by patients to their local Alliance Healthcare distribution centre.
- Pharmacists should provide patients who pay NHS prescription charges with a receipt if they are replacing their Jext® with an alternative adrenaline auto-injector.

- Please report any adverse events to ALK-Abelló on 0118 903 7940 or by e-mail at UKHUDrugSafety@alk-abello.com
- Adverse events should also be reported via the MHRA Yellow Card Reporting Scheme. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

For further information please visit www.jext.co.uk/drugalert or contact ALK-Abelló on 0800 028 3144 or info@uk.alk-abello.com

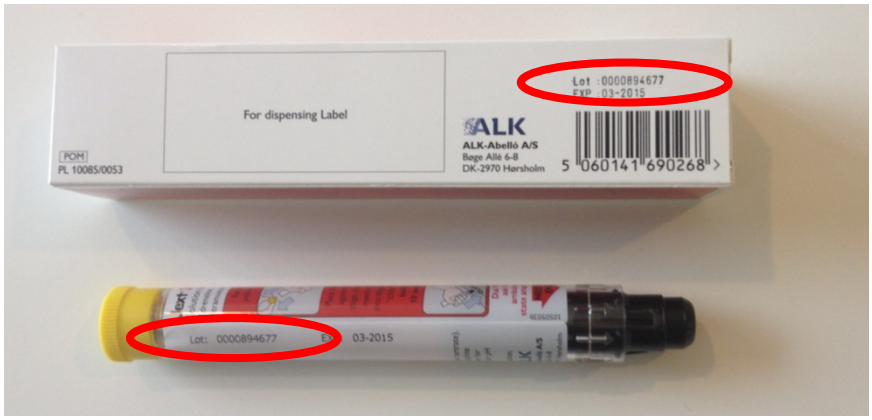
Jext® is a single-use adrenaline auto-injector intended for the emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis.

A routine testing conducted by ALK-Abelló has revealed that during the production process of these batches the needle may have become bent, causing the needle to curl up inside the injector housing upon activation and consequently causing the pen not to deliver the required adrenaline dose. The malfunction only affects a small percentage (0.04%) of the pens in these batches. Immediate action has been taken to eliminate similar production issues in the future.

Batch number and expiry date of the Jext® batches recalled in the United Kingdom:

| Batch Number | Description | Expiry date |
|---|---|---|
| 0000907947 | Jext 150 µg | 30-04-2015 |
| 0000884202 | Jext 150 µg | 31-03-2015 |
| 0000862719 | Jext 150 µg | 28-02-2015 |
| 0000853456 | Jext 150 µg | 28-02-2015 |
| 0000890991 | Jext 150 µg | 28-02-2015 |
| 0000804924 | Jext 150 µg | 31-01-2015 |
| 0000785381 | Jext 150 µg | 31-01-2015 |
| 0000748008 | Jext 150 µg | 31-12-2014 |
| 0000900033 | Jext 300 µg | 30-04-2015 |
| 0000874587 | Jext 300 µg | 28-02-2015 |
| 0000858432 | Jext 300 µg | 28-02-2015 |
| 0000860701 | Jext 300 µg | 28-02-2015 |
| 0000837516 | Jext 300 µg | 28-02-2015 |
| 0000874585 | Jext 300 µg | 28-02-2015 |
| 0000829690 | Jext 300 µg | 31-01-2015 |
| 0000810356 | Jext 300 µg | 31-01-2015 |
| 0000800083 | Jext 300 µg | 31-01-2015 |
| 0000774775 | Jext 300 µg | 31-01-2015 |
| 0000780782 | Jext 300 µg | 31-01-2015 |
| 0000750808 | Jext 300 µg | 31-12-2014 |
| 0000733979 | Jext 300 µg | 31-12-2014 |

Patients can see the batch number printed on the pen and the cardboard box to find out if their Jext® pen is affected by the recall:




Patients carrying a Jext® with a batch number not mentioned above should continue to carry their Jext® for emergency treatment of severe acute allergic reactions (anaphylaxis).

**Advice to patients carrying a Jext® pen with one of the above-mentioned batch numbers**
Patients carrying a Jext® with one of the above-mentioned batch numbers should continue to carry and use their Jext® as normal until they have obtained a replacement adrenaline auto-injector.

If a patient suffers anaphylaxis before they have obtained a replacement adrenaline auto-injector, they are advised to use their Jext® as instructed by the prescribing doctor.

Patients should ensure they understand how to use their replacement auto-injector correctly.

The safety of patients is our priority concern at ALK-Abelló and we are committed to delivering only high-quality products. ALK-Abelló takes the potential malfunction of some our adrenaline pens very seriously and has therefore immediately initiated a dialogue with the authorities regarding a recall. ALK-Abelló has also taken immediate action to eliminate similar production issues in the future.

ALK-Abelló is working with the Department of Health to minimise the financial consequences of this recall.

Yours faithfully

Dr Stephen Lombardelli

Medical Director

**Further information**

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