

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 Doctor

ALK-Abelló is recalling certain batches of its adrenaline pen, Jext® 150 microgram and Jext® 300 microgram, 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:

- GP practices are kindly requested to communicate the recall to all patients who have received a prescription for Jext® after 8 May 2013.
- GP practices should contact all such identified patients and advise them to check the batch number(s) of their devices. If the patient has a Jext® from an affected batch they should attend the GP practice to obtain a prescription for a replacement adrenaline auto-injector.
- All patients being changed to an alternative adrenaline auto-injector should be trained 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.
- Please report any adverse events to ALK-Abelló on 0118 903 7940 or by e-mail at UKHDrugSafety@alk-abello.com
- Adverse events should 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

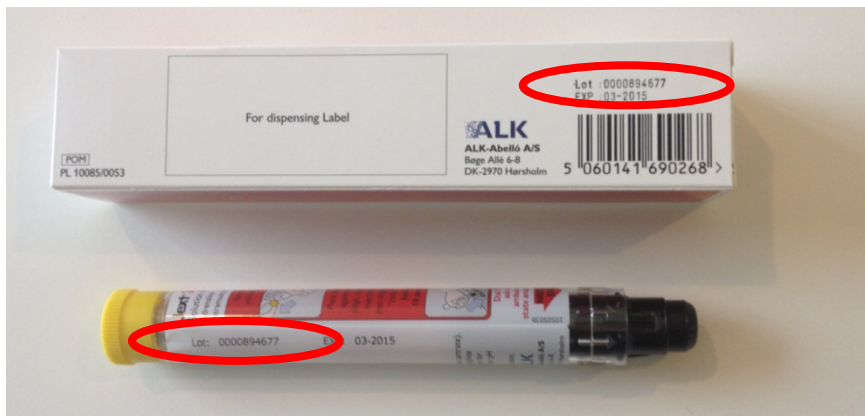
Jext® is a single-use adrenaline auto-injector intended for the emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis.

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® 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 an anaphylactic emergency 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 a priority concern at ALK-Abelló and we are committed to delivering only high-quality products. ALK-Abelló takes the potential malfunction of some of 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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