

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Patient and Pharmacy Level Recall

Date: 09 December 2013

EL (13)A/28

Our Ref: MDR 12-11/13

Dear Healthcare Professional,

ALK-Abelló A/S

Jext 300 micrograms solution for injection in pre-filled pen **PL 10085/0053**

Jext 150 micrograms solution for injection in pre-filled pen **PL 10085/0052**
(Adrenaline Tartrate)

ALK-Abelló Ltd is recalling the batches listed in the tables on page 2 **to patient level**. This is because a potential problem with delivery of the dosage following activation of the auto injector has been identified. This could result in a failure to deliver any adrenaline tartrate in an emergency situation. The Company has informed us that they have received no defect or ADR reports from the market which may be associated with this issue.

Recipients are asked to contact any patients who may be holding stock from the listed batches, which will have been dispensed after 8th May 2013, and advise them to make an appointment with their GP or clinic as soon as possible to discuss switching to an alternative product and any resulting training requirements. At present, the only alternative product available is Epipen.

In order to ensure continuity of supply of Epipen, MHRA has approved the importation of some units of the product from the USA. These units are manufactured at the same site as and are identical to the UK approved product. They have been re-packaged with a UK carton and patient information leaflet. The label on the device itself is the original US label, however. The most significant difference between the labels is that 'adrenaline' is expressed as 'epinephrine' on the American inner labels. A letter to patients, explaining the situation, will be included in imported packs.

Remaining stocks of the affected batches should be quarantined and returned to the original supplier. For stock return enquiries please contact your local Alliance Healthcare distribution centre.

For medical information or any other enquiries please contact ALK-Abelló Ltd on 0800 0283144.

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Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists for information.

Yours faithfully

Alison Bunce

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London
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Affected batches

Jext 300 mcg solution for injection in pre-filled pen

Batch number	Expiry date	Pack size	Date of first distribution
0000733979	31 Dec 2014	1 x 1	09 May 2013
0000750808	31 Dec 2014	1 x 1	17 May 2013
0000774775	31 Jan 2015	1 x 1	05 Jun 2013
0000780782	31 Jan 2015	1 x 1	05 Jun 2013
0000800083	31 Jan 2015	1 x 1	25 Jun 2015
0000810356	31 Jan 2015	1 x 1	25 Jun 2013
0000829690	31 Jan 2015	1 x 1	15 Jul 2013
0000837516	28 Feb 2015	1 x 1	30 Aug 2013
0000858432	28 Feb 2015	1 x 1	02 Aug 2013
0000860701	28 Feb 2015	1 x 1	26 Jul 2013
0000874585	28 Feb 2015	1 x 1	23 Aug 2013
0000874587	28 Feb 2015	1 x 1	14 Oct 2013
0000900033	30 Apr 2015	1 x 1	16 Sep 2013

Jext 150 mcg solution for injection in pre-filled pen

Batch number	Expiry date	Pack size	Date of first distribution
0000748008	31 Dec 2014	1 x 1	17 May 2013
0000785381	31 Jan 2015	1 x 1	19 Jun 2013
0000804924	31 Jan 2015	1 x 1	21 Jun 2013
0000853456	28 Feb 2015	1 x 1	26 Jul 2013
0000862719	28 Feb 2015	1 x 1	23 Aug 2013
0000884202	31 Mar 2015	1 x 1	06 Sep 2013
0000890991	28 Feb 2015	1 x 1	30 Aug 2013
0000907947	30 Apr 2015	1 x 1	16 Sep 2013