

27th February 2014



Batch Recall
Jext 150mcg Solution for Injection in a
Pre-filled Pen PA1255/6/1
Jext 300mcg Solution for Injection in a
Pre-filled Pen PA1255/6/2

ALK-Abelló Ltd
1 Manor Park
Manor Farm Road
Reading
Berkshire
RG2 0NA
United Kingdom

T +44 (0) 118 903 7940
F +44(0) 118 903 7941
W alk-abello.com/uk

Product	Batch Number	Expiry date
Jext 150mcg	0000884201	31/03/2015
	0000871645	28/02/2015
	0000785382	31/01/2015
Jext 300mcg	0000874584	28/02/2015
	0000816025	31/01/2015
	0000774776	31/01/2015
	0000780783	31/01/2015

Dear Doctor

Following previous communications from the Irish Medicines Board, ALK-Abelló wishes to advise you that the above listed batches of Jext 150mcg and Jext 300mcg auto-injectors are being recalled with immediate effect. The recall can now happen, as replacement, unaffected Jext pens are currently available at wholesalers.

The recall is going to patient level.

This action has been agreed with the Irish Medicines Board.

The reason for the recall is that a small percentage (0.04%) of auto-injectors from the above-listed batches may not function correctly and lead to injection failure.

If you are in possession of pens from the above-listed batches, please return them to your supplier immediately.

Pharmacists have been requested to contact patients to whom they have dispensed Jext pens, so that they may return their pens for replacement. Should you receive queries from patients who have been prescribed Jext, the advice for those patients is as follows:

- Please check your home and other relevant locations, including schools and workplace, to identify all Jext pens in your possession
- Please check the batch number on the pens, labels or outer cartons, to ascertain if you are carrying any pens from the affected batches
- If you are carrying pens from an affected batch, please return them to the pharmacy or clinic from which they were received, where you will be given replacement, unaffected pens

If a patient returns pens from the affected batches to you, please return them to your supplier for credit.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact ALK-Abelló at +44 118 903 7940.

Yours sincerely

Dr Stephen Lombardelli
Medical Director