Patient Information Letter

9 December 2013

Important safety information for patients using Jext® solution for injection in pre-filled pen

We would like to alert you to a safety issue concerning some batches of Jext® 150 micrograms adrenaline auto-injector and Jext® 300 micrograms adrenaline auto-injector. The affected batches are listed below.

Routine testing conducted by ALK-Abelló has revealed that during the production process of the batches listed below 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 number, approximately 1 in 2500, of the pens in these batches. Immediate action has been taken to eliminate similar production issues in the future.

What you need to do

Check the batch number printed on the pen or the cardboard box to find out if your Jext® is affected:

If the batch number of your Jext® is not mentioned in the list below you should continue to carry and use your Jext® as normal for the emergency treatment of severe acute allergic reactions (anaphylaxis).

If the batch number of your Jext® is listed below you should obtain a replacement adrenaline auto-injector from your doctor as soon as this is practically possible. Continue to carry and use your Jext® as normal until you are able to obtain a replacement adrenaline auto-injector. You should ensure you understand how to use the replacement auto-injector correctly as it may be different from your Jext®.

If you suffer anaphylaxis before you have obtained a replacement adrenaline auto-injector from your doctor, you should use your Jext® as instructed by the prescribing doctor.

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.

Please report any adverse events to ALK-Abelló on 0118 903 7940 or by e-mail at UKHUDrugSafety@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

Batch number and expiry date of the affected Jext® batches 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

Yours faithfully

Dr Stephen Lombardelli
Medical Director

Further information

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