DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 02 May 2013 EL (13)A/14 Our Ref: MDR 63-04/13

Dear Healthcare Professional,

Pfizer Limited

Ativan Injection 4mg/ml PL 00057/1279

(Lorazepam)

Batch Number	Expiry Date	Pack Size	First Distributed
4004	Jul 2013	10 x 1ml	08 Oct 2012
4005	Jul 2013	10 x 1ml	18 Dec 2012
4007	Sep 2013	10 x 1ml	05 Feb 2013
4009	Dec 2013	10 x 1ml	09 Apr 2013

Pfizer Limited has informed us that during routine testing and subsequent investigation of some unreleased batches of Ativan Injection which had been subjected to automated visible inspection during manufacture, a very small number of ampoules containing glass particles were identified. The incidence rate, at <0.01%, is very low. The batches listed in the above table have already been released to the market and whilst there is no evidence to suggest that they are affected by this issue (Pfizer has received no customer complaints or adverse reaction reports related to this matter), it cannot be ruled out.

Since Pfizer is the only UK Marketing Authorisation Holder for this product and there is no alternative stock available, these batches are not at present being recalled. As a precaution in the meantime, however, the following procedures should be followed prior to administration:

- Visually inspect the contents of each ampoule carefully for particulate matter. Reject the ampoule if any particulate matter is discovered. Please report any findings to Pfizer Medical Information on 01304 616161
- Follow all recommended steps for product dilution in accordance with the product information.
- Pre-filter the product prior to administration by using 5 micron filter needles or filter straws when drawing it into the syringe.
- Remove the filter needle or filter straw from the syringe and replace with a new sterile needle for administration.

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For medical information enquiries, please contact Pfizer Medical Information on 01304 616161

For any stock related enquiries, please contact Pfizer's Customer Contact Centre on 0845 608 8866 and select option 2.

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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