

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Hospital Pharmacy and Ward Level Recall

Date: 22 July 2014

EL (14)A/11

Our Ref: MDR 43-06/14

Dear Healthcare Professional,

Wockhardt UK Ltd

Amoxicillin Sodium 500mg Powder for Solution for Injection

PL 29831/0012

Batch Number	Expiry Date	Pack Size	First Distributed
1WA4002	31 Jan 2017	10 x 500mg	14 Apr 2014
1WA4003	31 Jan 2017	10 x 500mg	28 Feb 2014
1WA4004	31 Jan 2017	10 x 500mg	15 Apr 2014

Further to the Class 4 'Caution in Use' Alert issued on July 09 2014, ref. EL (14)A/09, Wockhardt UK Ltd has received a small number of additional reports of injection site reactions in both paediatrics and adults. As a precaution, the above batches of the 500mg presentation are now being recalled. The investigation by Wockhardt and its contract manufacturer in Italy is ongoing and at this time, there is no evidence to suggest that these batches are defective.

Remaining stock from the affected batches should be quarantined and returned to the original supplier for credit. For enquiries relating to stock returns please contact Wockhardt UK Ltd Customer Services on 01978 669215 or email customer.services@wockhardt.co.uk.

For medical information enquiries please contact Wockhardt UK Ltd Medical Information on 01978 661261 or email drug.safety@wockhardt.co.uk

Please note, the advice given in EL (14)A/09 still applies. That is, the following products (all batches) should not be administered to neonates or infants (below 1 year old) until further notice:

Amoxicillin Sodium 250mg Powder for Solution for Injection	PL 29831/0010
Amoxicillin Sodium 500mg Powder for Solution for Injection	PL 29831/0012
Amoxicillin Sodium 1G Powder for Solution for Injection	PL 29831/0011

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully

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