

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital Ward Level

Date: 09 July 2014

EL (14)A/09

Our Ref: MDR 43-06/14

Dear Healthcare Professional,

Wockhardt UK Ltd

| | |
|---|----------------------|
| 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 |

Wockhardt UK Ltd has received a number of reports of extravasation and injection site reactions **in neonates and infants (below 1 year old)**. As a precaution Wockhardt UK Ltd are asking all healthcare professionals treating neonates and infants not to use Wockhardt Amoxicillin Sodium Powder for Solution for Injection (all batches) in such patients until further notice, while the company investigates.

MHRA is working with Wockhardt UK Ltd to ensure these reports are investigated as quickly as possible. At this time there is no evidence to suggest that these products are defective.

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

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

Yours faithfully

Adam Burgess
Defective Medicines Report Centre
151 Buckingham Palace Road
London
SW1W 9SZ
Telephone +44 (0)20 3080 6574