



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy and Hospital Ward Level

Date: 10 November 2015

EL(15)A/11

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**

Drug Alert number EL (14)A/09 in connection with the above products was issued on 09 July 2014. In this Alert, healthcare professionals treating neonates and infants (below 1 year old) were asked not to use Wockhardt Amoxicillin Powder for Solution for Injection (all strengths and all batches) in such patients. This was a precautionary measure following receipt of a number of reports of extravasation and injections site reactions.

Since a broader investigation of factors which may have caused this issue is now ongoing within the MHRA, the recommendations in EL (14)A/09 are still applicable. An update will be provided should the situation change. At this time, there is still no evidence to suggest that these products are defective.

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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