

Drug Alert

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Date: 11th July 2014

Our Ref: MDR 06-7/14

Dear Healthcare Professional,

VJ Salomone Pharma Ltd c/o Wockhardt UK Ltd

Wockhardt Amoxicillin Sodium 250mg Powder for Sol for Inj - PL 29831/0010

Wockhardt Amoxicillin Sodium 500mg Powder for Sol for Inj - PL 29831/0012 (AA154/09201)

Wockhardt Amoxicillin Sodium 1g Powder for Sol for Inj - PL 29831/0011

(Amoxicillin Sodium)

Batch Number	Expiry Date	Pack Size	First Distributed
All batches	Not Applicable	Not Applicable	Not Applicable

It has been brought to the attention of the Medicines Authority by VJ Salomone Pharma Ltd (local representatives of Wockhardt UK Ltd) that 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.

At this time there is no evidence to suggest that these products are defective.

For medical information enquiries please contact V.J. Salomone Pharma as the official Wockhardt UK Ltd representative on 22983213 or email josephzammit@vjsalomone.com.

This Caution in Use notification is intended to be distributed up to hospital ward level and should be circulated to the attention of relevant contacts by copy of this letter.

Yours faithfully

Karl De Marco
Medicines Inspector

Medicines Authority Distribution (if applicable):
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Superintendent of Public Health