

# DRUG ALERT

## CLASS 2 MEDICINES RECALL

Action Within 48 Hours  
Pharmacy, Clinic and Wholesaler Level Recall

Date: 11 July 2013

EL (13)A/20

Our Ref: MDR 46-04/13

Dear Healthcare Professional,

### Pinewood Laboratories Limited

**Erythromycin 125mg/5ml sugar free granules for oral suspension** **PL 04917/0048**

**Erythromycin 250mg/5ml sugar free granules for oral suspension** **PL 04917/0049**

**Erythromycin 500mg/5ml sugar free granules for oral suspension** **PL 04917/0050**

Product	Batch Number	Expiry Date	First Distributed
Erythromycin 500mg/5ml sugar free	DM11748	06/2015	08/05/2013
Erythromycin 250mg/5ml sugar free	DM12089	07/2015	31/05/2013
Erythromycin 125mg/5ml sugar free	DL12462	09/2014	21/06/2013

All remaining stock of the above batches is being recalled as a precautionary measure following a routine inspection of the contract manufacturing site in India. The inspection identified deficiencies in good manufacturing practice (GMP) and the GMP certificate for this site has been withdrawn.

These products have been tested on importation and Qualified Person (QP) released. There is no evidence of a risk to patient safety from products currently in the UK market; however it is considered that the products have not been manufactured in line with GMP requirements.

We do not anticipate that supplies of erythromycin oral suspension will be affected by this recall; the company has confirmed that stocks from an alternative manufacturing site are available.

Remaining stocks of the affected batches should be quarantined and returned to the original supplier for credit. For enquiries relating to stock returns please contact Pinewood Laboratories Ltd Customer services on 00353 52 6186000 or email [international@pinewood.ie](mailto:international@pinewood.ie)

For medical information enquiries please contact Wockhardt UK Ltd Medical Information on 01978 661261 or email [drug.safety@wockhardt.co.uk](mailto:drug.safety@wockhardt.co.uk)

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.

Contd/...

Yours faithfully

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