

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy, Clinic and Wholesaler Level Recall

Date: 17 October 2013

EL (13)A/24

Our Ref: MDR 56-07/13

Dear Healthcare Professional,

Wockhardt UK Limited

Following Drug Alert EL(13)A/19 a second Wockhardt manufacturing site in India has been inspected. The inspection identified deficiencies in good manufacturing practice (GMP) and the GMP certificate for this site has also been withdrawn.

All unexpired stock of the below products is being recalled to pharmacy, clinic and wholesaler level, for all batches starting with the letter "L", irrespective of pack configuration and expiry date.

Amiloride HCl 5mg Tablets	PL 29831/0006
Clarithromycin 250mg Tablets	PL 29831/0476
Clarithromycin 500mg Tablets	PL 29831/0477
Gliclazide 80mg Tablets	PL 29831/0103
Quinine Sulphate 300mg Tablets	PL 29831/0182
Tamsulosin Pinexel 400mcg Capsules	PL 29831/0366

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.

No further products from the above list should be supplied. Products from alternative suppliers are available in the majority of cases, either in equivalent strengths or varying strengths. Where there are no alternative suppliers therapeutic alternatives should be selected according to clinical practice.

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 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

MHRA is working with Wockhardt UK Ltd to ensure supply is resumed as quickly as possible; at this time there is no indication as to when new stock of these Wockhardt UK Ltd products is likely to be available.

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.

Yours faithfully

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