

# **DRUG ALERT**

## **CLASS 2 MEDICINES RECALL**

**Action Within 48 Hours**  
**Pharmacy, Clinic and Wholesaler Level Recall**

Date: 11 July 2013

EL (13)A/19

Our Ref: MDR 46-04/13

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Dear Healthcare Professional,

### **Wockhardt UK Limited**

<b>Aciclovir 200mg Tablets</b>	<b>PL 29831/0002</b>
<b>Aciclovir 400mg Tablets</b>	<b>PL 29831/0001</b>
<b>Aciclovir 800mg Tablets</b>	<b>PL 29831/0003</b>
<b>Atenolol 25mg Tablets</b>	<b>PL 29831/0020</b>
<b>Atenolol 50mg Film-Coated Tablets</b>	<b>PL 29831/0018</b>
<b>Atenolol 100mg Film-Coated Tablets</b>	<b>PL 29831/0019</b>
<b>Clopidogrel 75mg Film-Coated Tablets</b>	<b>PL 29831/0415</b>
<b>Donepezil Hydrochloride 10mg Film-Coated Tablets</b>	<b>PL 29831/0441</b>
<b>Donepezil Hydrochloride 5mg Film-Coated Tablets</b>	<b>PL 29831/0440</b>
<b>Entacapone 200mg Film-Coated Tablets</b>	<b>PL 29831/0471</b>
<b>Levetiracetam 250mg Film-Coated Tablets</b>	<b>PL 29831/0360</b>
<b>Levetiracetam 500mg Film-Coated Tablets</b>	<b>PL 29831/0361</b>
<b>Levetiracetam 750mg Film-Coated Tablets</b>	<b>PL 29831/0362</b>
<b>Levetiracetam 1000mg Film-Coated Tablets</b>	<b>PL 29831/0363</b>
<b>Losartan 25mg Film-Coated Tablets</b>	<b>PL 29831/0378</b>
<b>Losartan 50mg Film-Coated Tablets</b>	<b>PL 29831/0379</b>
<b>Losartan 100mg Film-Coated Tablets</b>	<b>PL 29831/0380</b>
<b>Metformin 500mg Film-Coated Tablets</b>	<b>PL 29831/0133</b>
<b>Metformin 850mg Film-Coated Tablets</b>	<b>PL 29831/0134</b>
<b>Pantoprazole 20mg Gastro-Resistant Tablets</b>	<b>PL 29831/0372</b>
<b>Pantoprazole 40mg Gastro-Resistant Tablets</b>	<b>PL 29831/0373</b>

<b>Pramipexole 88mcg Tablets</b>	<b>PL 29831/0472</b>
<b>Pramipexole 180mcg Tablets</b>	<b>PL 29831/0473</b>
<b>Pramipexole 350mcg Tablets</b>	<b>PL 29831/0474</b>
<b>Pramipexole 700mcg Tablets</b>	<b>PL 29831/0475</b>
<b>Propylthiouracil 50mg Tablets</b>	<b>PL 29831/0179</b>
<b>Risperidone 0.5mg Film-Coated Tablets</b>	<b>PL 29831/0343</b>
<b>Risperidone 1mg Film-Coated Tablets</b>	<b>PL 29831/0344</b>
<b>Risperidone 2mg Film-Coated Tablets</b>	<b>PL 29831/0345</b>
<b>Risperidone 3mg Film-Coated Tablets</b>	<b>PL 29831/0346</b>
<b>Risperidone 4mg Film-Coated Tablets</b>	<b>PL 29831/0347</b>
<b>Risperidone 6mg Film-Coated Tablets</b>	<b>PL 29831/0348</b>
<b>Ropinirole 1mg Film-Coated Tablets</b>	<b>PL 29831/0414</b>
<b>Sertraline 50mg Film-Coated Tablets</b>	<b>PL 29831/0184</b>
<b>Sertraline 100mg Film Coated Tablets</b>	<b>PL 29831/0183</b>
<b>Ursodeoxycholic Acid 300mg Film-Coated Tablets</b>	<b>PL 29831/0198</b>

All unexpired stock of the above products is being recalled to pharmacy, clinic and wholesaler level, irrespective of pack configuration, batch number and expiry date.

This is a precautionary recall following a routine inspection of the 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.

No further products 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](mailto: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](mailto:drug.safety@wockhardt.co.uk)

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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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