

Drug Alert
CLASS 2 MEDICINES RECALL
Action Within 48 Hours

Date: 24th October 2013

Our Ref: **MDR 8-10/13-2**

Dear Healthcare Professional,

Wockhardt UK Ltd.

Fluoxetine 20mg capsules

Naproxen 250mg tablets

AA 154/06701

MA 154/02101

Product and Pack size	Batch Number	Expiry Date	First Distributed
Naproxen 250mg tablets x 28 tabs	LM 10421	28 February 2014	22 May 2012
Naproxen 250mg tablets x 28 tabs	LM 10072	30 November 2013	27 March 2012
Naproxen 250mg tablets x 28 tabs	LM 10025	30 November 2013	27 March 2012
Fluoxetine 20mg capsules x 30 caps	LM 11432	31 August 2014	28 November 2012
Fluoxetine 20mg capsules x 30 caps	LM 11884	31 October 2014	6 March 2013

Medicinal products, named above together with their corresponding batch numbers, are being recalled up to pharmacy level by the local distributor under the supervision of the Medicines Authority. This recall is being affected following an inspection held at a second Wockhardt manufacturing site in India. The inspection identified deficiencies in good manufacturing practice (GMP) and as a result the GMP certificate for this site has been withdrawn.

These products have been tested on importation and Qualified Person (QP) released. It is considered that the products in question have not been manufactured in line with GMP requirements.

Thus no further products from the above list are to be supplied and distributed. Remaining stocks of the affected products are to be quarantined immediately and returned to your supplier.

Yours faithfully

Muriel Giglio
Medicines Inspector
Medicines Authority