

# Drug Alert

## CLASS 2 MEDICINES RECALL

### Action Within 48 Hours

Date: 15 July 2013

Our Ref: MDR/ 04-07/13

Dear Healthcare Professional,

**Folic acid 5mg tablets**  
**WOCKHARDT UK LTD. (000154)**

**MA154/01301**

Batch Number	Expiry Date	Pack Size	First Distributed
<b>DL12624</b>	09/2014	28 tablets	March 2012
<b>DM10344</b>	01/2015	28 tablets	July 2012
<b>DL12564</b>	09/2014	28 tablets	May 2012
<b>DM11496</b>	05/2015	28 tablets	February 2013

Medicinal product pertaining to the above product and the above mentioned batches is being recalled up to pharmacy level as a precautionary measure by the local distributor representing the Marketing Authorisation Holder under the supervision of the Malta Medicines Authority. This recall is being affected 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inspection identified deficiencies in good manufacturing practice (GMP) and the GMP certificate for this site has been withdrawn.

The product batches being recalled have been tested on importation into the EU and Qualified Person (QP) released. However it is considered that they have not been manufactured in line with GMP requirements.

All stock of these batches is to be immediately quarantined awaiting collection by the local distributor, who is providing alternative stock to ensure continued availability of the medicinal product.

Yours faithfully,

S Serge  
Medicines Inspector