

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 22 July 2013

Our Ref: MDR/ 04-07/13 - 2

Dear Healthcare Professional,

Aciclovir 800mg tablets
WOCKHARDT UK LTD. (000154)

MA154/00101

Batch Number	Expiry Date	Pack Size	First Distributed
DK11832	31 OCT 13	35 tablets	22/02/2011
DL10794	28 FEB 14	35 tablets	19/09/2011
DM10044	31 DEC 14	35 tablets	02/05/2012
DM10470	28 FEB 15	35 tablets	25/07/2012
DM11777	30 JUN 15	35 tablets	24/10/2012

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inspection identified deficiencies in good manufacturing practice (GMP) and the GMP certificate for this site has been withdrawn.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