

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 28 August 2013

Our Ref: MDR/ 04-07/13 - 6

Dear Healthcare Professional,

Aciclovir 200mg tablets
WOCKHARDT UK LTD. (000154)

AA154/06201

Product & Pack Size	Batch Number	Expiry Date	First Distributed
Aciclovir 200mg x 25 tabs.	DK11663	30 SEP 13	03/02/2011
Aciclovir 200mg x 25 tabs.	DK12051	30 NOV 13	12/04/2011
Aciclovir 200mg x 25 tabs.	DL10894	31 MAR 14	05/08/2011
Aciclovir 200mg x 25 tabs.	DL11793	31 JUL 14	28/03/2012
Aciclovir 200mg x 25 tabs.	DL12715	31 OCT 14	24/08/2012
Aciclovir 200mg x 25 tabs.	DM11216	30 APR 15	27/06/2013
Aciclovir 200mg x 25 tabs.	DM12393	31 AUG 15	06/03/2013
Aciclovir 200mg x 25 tabs.	DM12783	30 SEP 15	15/05/2013
Aciclovir 200mg x 25 tabs.	DM13134	30 OCT 15	27/06/2013

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inspection identified deficiencies in good manufacturing practice (GMP) and the GMP certificate for this site has been withdrawn.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

Yours faithfully,

S Serge
Medicines Inspector