

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 22 August 2013

Our Ref: MDR/ 04-07/13 - 5

Dear Healthcare Professional,

Propylthiouracil 50mg tablets
WOCKHARDT UK LTD. (000154)

MA154/02401

Product & Pack Size	Batch Number	Expiry Date	First Distributed
Propylthiouracil 50mg x 100 tabs.	DL12221	31 AUG 13	15/12/2011
Propylthiouracil 50mg x 100 tabs.	DM12531	31 AUG 14	15/05/2013
Propylthiouracil 50mg x 100 tabs.	DM10800	31 MAR 14	10/09/2012

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inspection identified deficiencies in good manufacturing practice (GMP) and the GMP certificate for this site has been withdrawn.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

Yours faithfully,

S Serge
Medicines Inspector