Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 29 July 2013 Our Ref: MDR/ 04-07/13 - 4

Dear Healthcare Professional,

Totamol 25mg, 50mg & 100mg tablets

MA154/03001, MA154/03002, MA154/03003

WOCKHARDT UK LTD. (000154)

Product & Pack Size	Batch Number	Expiry Date	First Distributed
Totamol 25mg x 28 tabs.	DK11446	30 AUG 13	31 JAN 11
Totamol 25mg x 28 tabs.	DK11858	31 OCT 13	12 APR 2011
Totamol 25mg x 28 tabs.	DL10373	31 JAN 14	20 MAY 2011
Totamol 25mg x 28 tabs.	DL10627	28 FEB 14	27 JAN 2011
Totamol 25mg x 28 tabs.	DL11349	30 APR 14	30 NOV 2011
Totamol 25mg x 28 tabs.	DL12730	31 OCT 14	14 MAY 2012
Totamol 25mg x 28 tabs.	DM10703	28 FEB 15	25 JUL 2012
Totamol 25mg x 28 tabs.	DM12307	31 JUL 15	16 APR 13
Totamol 25mg x 28 tabs.	DM12734	31 AUG 15	29 MAY 2013
Totamol 50mg x 28 tabs.	DK11644	30 SEP 13	3 FEB 2013
Totamol 50mg x 28 tabs.	DK11703	30 SEP 13	12 APR 2011
Totamol 50mg x 28 tabs.	DL11672	31 MAY 14	14 FEB 2012
Totamol 50mg x 28 tabs.	DL12012	31 AUG 14	15 DEC 2011
Totamol 50mg x 28 tabs.	DL12176	31 AUG 14	14 MAR 2012
Totamol 50mg x 28 tabs.	DM10110	30 NOV 14	27 JUL 2012
Totamol 50mg x 28 tabs.	DM10448	31 DEC 15	10 SEP 2012
Totamol 50mg x 28 tabs.	DM10449	31 JAN 15	10 SEP 2012
Totamol 50mg x 28 tabs.	DM11191	30 APR 15	20 FEB 2013
Totamol 50mg x 28 tabs.	DM11684	30 JUN 15	16 APR 2013
Totamol 100mg x 28 tabs.	DK11561	31 JUL 13	3 FEB 2011
Totamol 100mg x 28 tabs.	DK11915	31 OCT 13	27 JUN 2011
Totamol 100mg x 28 tabs.	DL10137	31 DEC 13	9 JAN 2012
Totamol 100mg x 28 tabs.	DL10139	30 NOV 13	14 FEB 2012
Totamol 100mg x 28 tabs.	DL12660	31 OCT 14	20 FEB 2013
Totamol 100mg x 28 tabs.	DL12661	31 OCT 14	25 JUL 2012
Totamol 100mg x 28 tabs.	DL12817	31 OCT 14	14 MAR 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inspection identified deficiencies in good manufacturing practice (GMP) and the GMP certificate for this site has been withdrawn.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