

Medicines Authority

Inspectorate and Enforcement Division 203 Level 3, Rue d'Argens, Gzira Malta

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DRUG ALERT

CLASS II MEDICINES RECALL ACTION WITHIN 48 HOURS

Date: 7th May 2015

Our Ref: MDR 01 _05/2015

Dear Healthcare Professional,

CLASS II Recall of TRAMADOL 50MG CAPSULES (RELONCHEM)

RelonChem Ltd, through the 126a authorisation holder Cherubino Ltd, is recalling all unexpired packs of Tramadol 50mg capsules (RelonChem) distributed in Malta due to the risk of fungal contamination.

The live batches reported to have been distributed in Malta have a pack size of 100 capsules and are the following:-

- Batch HB2008 Exp. Date 09/ 2016
- Batch HB3001 Exp. Date 12/2016
- Batch HB3015 Exp. Date 02/2017

This recall is being performed to **pharmacy level** under the supervision of the Medicines Authority.

Kind Regards,

S Serge Medicines Inspector