



**Medicines Authority**  
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## Drug Alert

### CLASS I MEDICINES RECALL

Action Now - including out of hours

Date: 9<sup>th</sup> September 2009

Our Ref: MDR 2\_9/09

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Dear Healthcare Professional,

### **Thymoglobuline® [Anti-thymocyte Globulin (Rabbit)] 25mg/vial**

Batch Number	Expiry Date	Pack Size	First Distributed
TH184-H05	28/2/2010	N/A	23/07/2007

The Inspectorate and Enforcement Directorate within the Medicines Authority have been informed of a Medicinal Defect Report warranting a recall by the Spanish Authorities. This recall is being carried out by Cherubino Ltd. in consultation with the Marketing Authorisation Holder and under the supervision of the Medicines Authority.

It has been classified as a Class I recall up to patient/ward level.

This recall was initiated when Thymoglobulin lot TH189 failed a periodic stability test based upon appearance of the reconstituted product. Another three Thymoglobulin lots **TH184**, TH187 and TH194 are still within specification for appearance. However, these lots are also expected to trend out of specification for appearance on stability before their expiration date.

The local distributor, Cherubino Ltd, has confirmed that batch **TH184-H05** is the only batch effected by this recall on the local market.

Simon Serge

Medicines Inspector