

Drug Product Recall Notification

Recall of Thymoglobuline® [Anti-thymocyte Globulin (Rabbit)] 25mg/vial
Registration no. Swissmedic 53'588
Lot Number: TH194-H01
Expiration Date: 30.06.2010

This letter is to inform you that Genzyme Corporation, Genzyme Europe B.V., Genzyme Polyclonals, S.A.S. and Genzyme GmbH Switzerland are initiating a worldwide voluntary recall of some Thymoglobuline® finished product lots. This recall was initiated when one Thymoglobuline® lot failed a periodic stability test based upon appearance of the reconstituted product, while other lots which are still within specification for appearance are also expected to trend out of specification for appearance on stability before their expiration date. One of these affected lots - lot TH194-H01 - has been distributed in Switzerland and is now being recalled.

Our records indicate that you have received some product of lot TH194-H01.
No other Thymoglobuline® lots are involved in this recall.

Genzyme believes that this product problem does not pose any new safety concerns to the patients. Genzyme is not aware of any new safety risk to patients related to this problem.

Required Actions:

- **Immediately discontinue all use of lot TH194-H01 you received.**
- **Check your inventory and return all Thymoglobuline® vials from lot TH194-H01 to Globomedica AG Pharmahandel, Gewerbstrasse 12, 8132 Egg b. Zürich.**
- **Complete the enclosed Recall Reply Form. Return the completed form via fax transmission to Genzyme GmbH Switzerland (Fax no. 041 727 80 29) as soon as possible.**

Your assistance with this product recall is greatly appreciated.
Please feel free to call Genzyme at 041 727 80 20 if you require additional information.

Thank you.

Sincerely,

GENZYME GmbH

Dr. Maria Heimgartner
General Manager Switzerland

Dr. pharm. Philippe Karl
Head of Quality Assurance and Regulatory Affairs,
QP