

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 24th July 2014

Our Ref: MDR 12-06/2014 - 2

Dear Healthcare Professional,

(Bayer plc)

Germoloids suppositories

MA513/01002

Germoloids ointment

MA513/01001

(lidocaine hydrochloride)

Name and Batch Number of product	Expiry Date	Pack Size	First Distributed
Germoloids ointment H357	30 th December 2015	1 x 25ml	17 th June 2013
Germoloids ointment H358	31 st December 2015	1 x 25ml	21 st August 2013
Germoloids ointment H365	30 th April 2016	1 x 25ml	18 th November 2013
Germoloids suppositories J143	30 th October 2015	1 x 12 supp.	30 th September 2013
Germoloids suppositories J145	31 st October 2015	1 x 12 supp.	17 th December 2013

The medicinal products **Germoloids suppositories** and **Germoloids ointment** with the above batch numbers, are being recalled up to pharmacy level by the local distributor under the supervision of the Medicines Authority. This recall is being affected following an inspection held at an active pharmaceutical ingredient (API) manufacturing site in Italy which was found to be GMP non-compliant. As a consequence, all finished products containing active ingredients with specific batch numbers which were being manufactured at the Italian site are being recalled.

Remaining stocks of the affected products are to be quarantined immediately and returned to your supplier.

Yours faithfully

Muriel Giglio
Medicines Inspector