

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 22nd July 2014

Our Ref: MDR 12-06/2014

Dear Healthcare Professional,

(Bayer plc)

Germoloids HC Spray
(hydrocortisone and lidocaine hydrochloride)

AA 513/01701

Batch Number	Expiry Date	Pack Size	First Distributed
3S13	August 2015	X 30 ml	27 th March 2014
3S12	August 2015	X 30ml	29 th January 2014

The medicinal product **Germoloids HC spray** with the above batch numbers, is 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.

Therefore the supply and distribution of the above product with batch numbers 3S13 and 3S12 is to be discontinued. Remaining stocks of the affected product are to be quarantined immediately and returned to your supplier.

Yours faithfully

Muriel Giglio
Medicines Inspector