



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Hospital Pharmacy and Radiology Department Level Recall

Date: 01 February 2018

EL (18) A/02

Our Ref: MDR 20-12/17

Dear Healthcare Professional,

Bayer plc

Magnevist Solution for Injection, 0.5mmol/ml, intravenous

1 x 5ml, 1 x 10ml, 1 x 15ml, 1 x 20ml vial

PL 00010/0542

5 x 10ml pre-filled syringe

PL 00010/0543

(Gadopentetate Dimeglumine)

Contact details Bayer products:

Medical Information: Bayer UK Medical Information team. Tel: 0118 206 3116

Email: medical.information@bayer.co.uk

Stock enquiries: Bayer UK Customer Services team. Tel: 0118 206 3999.

Email: customerservicemt@bayer.com

GE Healthcare AS

Omniscan Solution for Injection 0.5 mmol/ml

10 x 5ml, 10 x 10ml, 10 x 15ml, 10 x 20ml vials

PL 00637/0015

1 x 10ml, 1 x 15ml 1 x 20ml, 10 x 10ml, 10 x 15ml 10 x 20ml

PL 00637/0030

pre-filled syringe

(Gadodiamide)

Contact details GE Healthcare products:

Medical Information: GE Healthcare Medical Affairs, The Grove Centre, White Lion Road, Buckinghamshire HP7 9LL. Tel: 01494 544000 Email: Medical.Information@ge.com

Stock enquiries: Stephen McLaughlin, Director of Quality Operations, GE Healthcare Ltd, IDA Industrial Park, Carrigtwohill, Cork, Ireland Tel: +353 87 9432162 Email: Stephen.mclaughlin2@ge.com

All unexpired stock of the above products marketed by Bayer plc and GE Healthcare AS is being recalled and should immediately be quarantined. This follows a safety review of the gadolinium



containing contrast media by the European Medicines Agency (EMA) which has resulted in the suspension of the above licences as of 01 February 2018. The review concluded that small amounts of gadolinium are retained in brain tissue after the use of gadolinium contrast agents. More gadolinium retention in the brain has been observed with linear gadolinium agents than with macrocyclic gadolinium agents. Both of the products being recalled are linear agents. There is currently no evidence that gadolinium deposition in the brain has caused any adverse neurological effects in patients. Further information can be found on our website via the following link:

<https://www.gov.uk/drug-safety-update/gadolinium-containing-contrast-agents-removal-of-omniscan-and-iv-magnevist-restrictions-to-the-use-of-other-linear-agents>

Please note, Magnevist 2.0mmol/l solution for injection for intra-articular use is outside the scope of this recall.

For Bayer Products:

Bayer will be writing to all their customers attaching an inventory form for completion and return by 9th February 2018. They will then arrange collection of any quarantined stock and appropriate reimbursement or credit of any quarantined stock.

For GE Healthcare products:

For Northern Ireland, stock should be returned to the local distributor (Synapse). Contact details as follows:

Tel: +353 (0) 1 8624600

Michelle O'Connor: moconnor@synapsemedical.ie

Glenda Hearn: ghearn@synapsemedical.ie

For the rest of the UK, it should be returned to the UK supplier (UPS). Contact details for UPS in the event of a recall:

Ian Evans: Ian.Evans@polarspeed.com Tel: 07890 531246

Ruth Davies: Ruth.Davies@polarspeed.com Tel: 07973 709554

General Quality Inbox: Quality.Department@polarspeed.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully

Alison Bunce

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