



For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, HSC Board & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer
Mrs Cathy Harrison
Castle Buildings
Upper Newtownards Road
Belfast BT4 3SQ

Telephone: 028 90 523219
Facsimile: 028 90 522335

E-Mail: cathy.harrison@health-ni.gov.uk

Our Ref: PHC/61/2020
Date: 29 December 2020

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 Hours

Pharmacy and Wholesaler Level Recall

Dear Healthcare Professional

medac GmbH (t/a medac Pharma LLP)

Sodiofolin 50mg/ml Solution for Injection 100mg/2ml

PL 11587/0005

Batch Number	Expiry Date	Pack Size	First Distributed
L180633D	31/10/2021	1 x 1	05/06/2019
L180633L	31/10/2021	1 x 1	08/10/2019
L180633P	31/10/2021	1 x 1	09/02/2020
M190771B	30/11/2022	1 x 1	08/11/2020

Active Pharmaceutical Ingredient: disodium folinate

Brief description of the problem

Further to Drug Alert PHC/52/2020 issued on 11 November 2020, medac Pharma LLP is recalling further batches of products following inspection of vials showing hairline damage to the shoulder of the vials. So far, the company has not received any reports of damage for marketed products. However, as this defect may impact on the sterility of the product, the above batches are being recalled as a precautionary measure.

Advice for healthcare professionals

Stop supplying the batch above immediately. Quarantine all stock and return it to your supplier using your supplier's approved process.

Further Information

For more information or medical information queries, please contact info@medacpharma.co.uk or telephone 01786 458086.

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

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Cathy Harrison', written in a cursive style.

Mrs Cathy Harrison
Chief Pharmaceutical Officer