



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level

Date: 29 December 2020

EL (20)A/61

Our Ref: MDR 038-11/20

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 EL (20)A/52 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 letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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