



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 21 August 2023

EL (23)A/28

Our Ref: MDR 040-07/23

Dear Healthcare Professional

medac GmbH (t/a medac Pharma LLP)

Sodiofolin 50 mg/ml solution for injection/infusion, (100mg/2ml vial)

PL 11587/0005

SNOMED Code 4799711000001101

Batch Number	Expiry Date	Pack Size	First Distributed
D210211C	30/04/2024	1	16/02/2022
D210211D	30/04/2024	1	03/03/2022
D210211F	30/04/2024	1	04/04/2022
D210211G	30/04/2024	1	13/06/2022
D210211H	30/04/2024	1	17/06/2022

Active Pharmaceutical Ingredient: 54.65mg/ml disodium folinate equivalent to 50mg/ml folic acid.

Brief description of the problem

Further to [EL\(23\)/A26](#) medac GmbH (t/a medac Pharma LLP) have identified further batches that are impacted. medac GmbH (t/a medac Pharma LLP) is recalling the products and respective batches in this notification due to particles detected during long-term stability tests. As stated in the Summary of Product Characteristics (SmPC): 'Only clear solutions without visible particles should be used.' These batches are being recalled as a precautionary measure and the root cause analysis investigation remains ongoing.

Advice for healthcare professionals

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

Advice for patients

No further action is required by patients as this is a Pharmacy and Wholesaler level recall. This product is administered by healthcare professionals directly. If you have concerns about a medicine you may be using, please contact your healthcare professional.

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).



Medicines & Healthcare products Regulatory Agency

Further Information

For all medical enquiries, please contact medical information at medac Pharma LLP by email to info@medacpharma.co.uk or by telephone 01786 458086.

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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