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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

12 March 2024

Dear Healthcare Professional,

DRUG ALERT CLASS 2 DRUG ALERT 8 2024 – CLASS 2 MEDICINES RECALL – ACTION WITHIN 48 HOURS – MEDAC GMBH (T/A MEDAC PHARMA LLP), SODIOFOLIN 50MG/ML SOLUTION FOR INJECTION/INFUSION (FOLINIC ACID 400MG/8ML VIAL)

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team





Medicines & Healthcare products
Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 12 March 2024

EL (24)A/08

Our Ref: MDR 080-03/24

Dear Healthcare Professional

medac GmbH (t/a medac Pharma LLP)

**Sodiofolin 50 mg/ml, solution for injection/infusion (folinic acid
400mg/8ml vial)**

PL 11587/0005

SNOMED Code 4800011000001106

Batch Number	Expiry Date	Pack Size	First Distributed
E230320B	31/10/2025	1	23/08/2023

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

Brief description of the problem

medac GmbH (t/a medac Pharma LLP) is recalling the product for the batch specified 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'. This batch is being recalled as a precautionary measure and the root cause investigation remains ongoing.

Advice for healthcare professionals

Stop supplying the above batch 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](#).

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.



Medicines & Healthcare products Regulatory Agency

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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