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**IMMEDIATE MESSAGE TO:**

1. Directors of Pharmacy
2. Medical Directors NHS Boards

4 July 2023

Dear Healthcare Professional,

**DRUG ALERT CLASS 2 DRUG ALERT 22 2023 – CLASS 2 MEDICINES RECALL –  
ACTION WITHIN 48 HOURS – MEDAC GmbH (T/A MEDAC PHARMA LLP) –  
DACARBAZINE 100MG,200MG & 500MG POWDER FOR SOLUTION FOR INJECTION  
VIALS**

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:-

- Dental Practitioners
- 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 RECALL

## CLASS 2 MEDICINES RECALL

Action Within 48 Hours  
Pharmacy/Wholesaler Level Recall

Date: 04 July 2023

EL (23)A/22

Our Ref: MDR 228-06/23

Dear Healthcare Professional

### medac GmbH (t/a medac Pharma LLP)

**Dacarbazine 100mg powder for solution for injection vials**

**PL 11587/0008**

**SNOMED Code** 7323411000001109

Batch Number	Expiry Date	Pack Size	First Distributed
D220154AD	30/04/2025	10	26/02/2023

**Dacarbazine 200mg powder for solution for injection vials**

**PL 11587/0009**

**SNOMED Code** 10277911000001108

Batch Number	Expiry Date	Pack Size	First Distributed
F220255A	31/05/2025	10	06/10/2022
F220288A	30/06/2025	10	08/12/2022

**Dacarbazine 500mg powder for solution for injection vials**

**PL 11587/0010**

**SNOMED Code** 7323511000001108

Batch Number	Expiry Date	Pack Size	First Distributed
G220299AE	30/06/2025	1	09/11/2022

Active Pharmaceutical Ingredient: dacarbazine (as dacarbazine citrate)

#### Brief description of the problem

medac GmbH (t/a medac Pharma LLP) is recalling the products and respective batches in this notification due to pink discolouration of the dacarbazine solution immediately after reconstitution (after correct preparation and storage). As stated in the Summary of Product Characteristics (SmPC), *the diluted solution for infusion should be visually inspected and only clear solutions practically free from particles should be used. Do not use the solution if particles are present.* The pink discolouration is caused by a degradation product of dacarbazine and may cause a venous irritation in the patient when the product is applied.



# Medicines & Healthcare products Regulatory Agency

## **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](#).

## **Further Information**

For all medical enquiries, please contact medical information at medac Pharma LLP by email to [info@medacpharma.co.uk](mailto: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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