

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(26)A/14

Caution In Use

Issued 17 March 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Baxter Healthcare Corporation

MEDICINE DETAILS

Onkotrone Injection 2mg/ml concentrate for solution for infusion in 10 ml vials

PL: 00116/0398

Active Ingredient: mitoxantrone hydrochloride

SNOMED code: 4466011000001103

Carton GTIN Number: 55413760208829,
Unit (vial) GTIN Number: 05413760208824

Onkotrone Injection 2mg/ml concentrate for solution for infusion in 12.5 ml vials

PL: 00116/0398

Active Ingredient: mitoxantrone hydrochloride

SNOMED code: 4467411000001109

Carton GTIN Number: 55413760208843,
Unit (vial) GTIN Number: 05413760208848

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
3L048A	30-Nov-2026	1 x 10 mL vial	16-Oct-2024
3L048I	30-Nov-2026	1 x 10 mL vial	30-Dec-2024
4E049Q	30-Apr-2027	1 x 10 mL vial	20-Feb-2025
4J050J	30-Sep-2027	1 x 10 mL vial	14-Apr-2025
4J050Q	30-Sep-2027	1 x 10 mL vial	10-Jun-2025

4J050V	30-Sep-2027	1 x 10 mL vial	7-Aug-2025
5B051B	31-Jan-2028	1 x 10 mL vial	2-Oct-2025
3C045AA	28-Feb-2026	1 x 12.5 mL vial	10-Feb-2025
3C045Y	28-Feb-2026	1 x 12.5 mL vial	29-Jul-2024
3C045Z	28-Feb-2026	1 x 12.5 mL vial	21-Oct-2024
5B051A	31-Jan-2028	1 x 12.5 mL vial	12-Jun-2025

Background

Baxter Healthcare Corporation have informed the MHRA that the Patient Information Leaflet (PIL) packed in the above batches does not contain up to date information relating to the duration of contraception required for females after stopping taking this medication

The PIL for Onkotrone Injection 2mg/ml concentrate for solution for infusion, was updated regarding the duration of contraception for females and extended from four to nine months as follows: *use effective contraception during therapy and for at least 9 months after cessation of therapy (PIL section 2)*. The specific batches listed in the table above do not contain this updated information in the PIL.

Future batches will contain the correct PIL.

Advice for Healthcare Professionals:

Inform female patients of the necessity to use contraception and not become pregnant for at least 9 months after stopping this medication.

The updated PIL can be accessed on the Electronic Medicines Compendium (eMC):

[Onkotrone Injection 2 mg/ml concentrate for solution for infusion - Patient Information Leaflet \(PIL\) - \(emc\) | 1844](#)

Upon request, Baxter Healthcare Corporation will provide hard copies of the updated PIL to wholesalers/pharmacies so that any remaining stock can be supplemented with the correct PIL information. To request hard copies of the PIL, please contact shs_regulatory_uk@baxter.com with your details, i.e. address, product with batch details, required number of leaflets.

Advice for Healthcare Professionals to Provide to Patients:

It is important for female patients to use contraception for a period of at least 9 months after stopping taking this medication. It is important that you do not become pregnant during this period. If you have any questions about this issue, please contact your healthcare professional in the first instance.

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

Additional information:

For all medical information enquiries regarding this communication, contact Baxter at MedInfo_UK1@baxter.com or telephone 0800 0260516

For stock control enquiries please contact Baxter at servicecs@baxter.com or telephone 0800 028 9881

Recipients of this Medicines Notification 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

Defective Medicines Report Centre

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