Medicines & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/43

Caution In Use

Issued 4 September 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Hikma Farmacêutica (Portugal) S.A.

MEDICINE DETAILS

Gemcitabine 2g/52.6ml concentrate for solution for infusion

PL: 15413/0093

Active Ingredient: gemcitabine

SNOMED code: 17844811000001107

GTIN: 5391512 456702

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
CB0033II	01/05/2026	1	05 August 2025

Background

Hikma Farmacêutica (Portugal) S.A has informed the MHRA that the Patient Information Leaflet (PIL) contained within batch CB0033 of Gemcitabine 2g/52.6ml concentrate for solution for infusion does not contain the side effects of serious skin reactions.

Gemcitabine 2g/52.6ml concentrate for solution for infusion is administered by Healthcare Professionals within a hospital setting, and most healthcare professionals will already be aware of these serious skin reactions.

The missing information is:

PIL Section 2

Talk to your doctor, nurse or hospital pharmacist before using gemcitabine:

If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using gemcitabine.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalized exanthematous pustulosis (AGEP) have been reported in association with gemcitabine treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

PIL Section 4

You must contact your doctor immediately if you notice any of the following:
A red, scaly widespread rash with bumps under the swollen skin (including your skin folds, trunk, and upper extremities) and blisters accompanied by fever (Acute Generalized Exanthematous Pustulosis (AGEP) (frequency not known).

Advice for Healthcare Professionals:

Healthcare professionals are advised to review the information contained within this notification and take this into account when prescribing and dispensing this product, where possible.

Please see copies of the correct Patient Information Leaflet: GEMCITABINE PIL.

To request hard copies of the PIL, please contact customerserviceuk@hikma.com with your details, i.e. contact point, address, required number of leaflets.

Advice for Patients:

This medicine is administered under the supervision of a healthcare professional who will be aware of the missing information in the Patient Information Leaflet (PIL).

Please see copies of the correct Patient Information Leaflet: GEMCITABINE PIL.

Patients who experience adverse reaction or have any questions about their medicine should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card Scheme

Additional information:

For medical information queries please telephone +351 21 960 8410, or email portugaleupharmacovigilance@hikma.com.

For all stock control enquiries please telephone +44 020 7399 2760, or email customerserviceuk@hikma.com

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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