Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
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T: 0300-244-4000
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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

10 May 2023

Dear Healthcare Professional

DRUG ALERT – No. EL (23)A/16 - Action Within 5 Days - Class 3 Medicines Recall: Hikma Farmacêutica Portugal S.A., Gemcitabine 1g/26.3ml & 2g/52.6ml Solution For Infusion Vial

Please see the attached 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 forward this alert 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

Grace Jamieson
Medicines Policy Team

Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 Days
Pharmacy/Wholesaler Level Recall

Date: 10 May 2023 EL (23)A/16 Our Ref: MDR 002-05/23

Dear Healthcare Professional,

Hikma Farmacêutica Portugal S.A.

Gemcitabine 1g/26.3ml Solution For Infusion Vial

PL 15413/0093

SNOMED Code 326910007

Batch Number	Expiry Date	Pack Size	First Distributed
CB0013	12/2024	1 vial	20/02/2023

Gemcitabine 2g/52.6ml Solution For Infusion Vial

PL 15413/0093

SNOMED Code 17844811000001107

Batch Number	Expiry Date	Pack Size	First Distributed
CB0014	12/2024	1 vial	20/02/2023

Active Pharmaceutical Ingredient: gemcitabine

Brief description of the problem
Hikma Farmacêutica Portugal S.A has informed the MHRA of a potential issue impacting the batches listed in this notification. Due to a limited number of complaints received regarding loose caps, Hikma Farmacêutica Portugal S.A is recalling the batches as a precautionary measure from pharmacies and wholesalers. The complaints relate to the entire cap being removed when healthcare professionals attempt to remove the flip-off portion of the cap.

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.

As for all medicines, 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 more information or medical information queries, please contact: Portugalcomplaints@hikma.com or Portugaleupharmacovigilance@hikma.com

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

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