Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 hours Pharmacy/Wholesaler Level Recall

EL (24)A/28

Date: 15 July 2024

Dear Healthcare Professional,

Sun Pharma UK Limited

Gemcitabine PPF 1800mg/180ml Infusion bag

SNOMED Code 33492211000001108

| Batch No | Expiry Date | Pack Size | First Distributed |
|----------|-------------|-----------|-------------------|
| HAD3634A | 30.09.2024 | 1 | 21.02.2023 |

Active Pharmaceutical Ingredient: Gemcitabine

Gemcitabine PPF 1600mg/160ml Infusion bag

SNOMED Code 33491811000001100

| Batch No | Expiry Date | Pack Size | First Distributed |
|----------|-------------|-----------|-------------------|
| HAE1532A | 30.06.2025 | 1 | 20.12.2023 |

Active Pharmaceutical Ingredient: Gemcitabine

Irinotecan PPF 360mg/240ml Infusion bag

SNOMED Code 39293911000001107

| Batch No | Expiry Date | Pack Size | First Distributed |
|----------|-------------|-----------|-------------------|
| HAE1191A | 30.06.2025 | 1 | 20.12.2023 |

Active Pharmaceutical Ingredient: Irinotecan

Brief description of the problem

Sun Pharma UK Ltd is recalling the above batches as a precautionary measure due to a small number of leaks found intermittently in the infusion bags.

Advice for healthcare professionals

Use precaution when handling these products, ensure that the appropriate personal protective equipment is used. Stop supplying the above batches immediately. Quarantine all remaining stock in sealed containers 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. Patients should continue to take medicines provided by your healthcare professional.

PL 31750/0062

PL 31750/0159

Our Ref: DMRC-31113538

PL 31750/0062



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 <u>MHRA Yellow Card</u> <u>scheme</u>.

Further Information

For medical information enquiries please contact, <u>medinfoeurope@sunpharma.com</u>.

For stock control enquiries please contact Sun Pharma Customer Service, <u>Cserv.uk@sunpharma.com</u>.

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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