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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

1 February 2024

Dear Healthcare Professional,

**DRUG ALERT CLASS 4 DRUG ALERT 4 2024 – CLASS 4 MEDICINES DEFECT
INFORMATION – CAUTION IN USE – EXELTIS UK LTD GEPRETIX 100MG CAPSULES**

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:-

- 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 NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 01 February 2024

EL (24)A/04

Our Ref: MDR 264-01/24

Dear Healthcare Professional,

Exeltis UK Limited

Gepretix 100mg Capsules

PL 44081/0009

SNOMED Code: 42287211000001104

Batch No	Expiry Date	Pack Size	First Distributed
LF32022A	Jul 2025	30 capsules	27 September 2023
LF32119A	Aug 2025	30 capsules	17 October 2023
LF32120A	Aug 2025	30 capsules	23 November 2023
LF33488A	Nov 2025	30 capsules	04 January 2024
LF33513A	Nov 2025	30 capsules	30 January 2024

Active Pharmaceutical Ingredient: progesterone

Brief description of the problem

Exeltis UK Limited has informed the MHRA regarding an inconsistency in the Patient Information Leaflet (PIL) packaged in cartons of the specified batches of Gepretix 100mg capsules.

The PIL contains the following inconsistency:

- Section 3 states: 'The recommended dose is 200 mg daily at bedtime, for twelve days in the last half of each therapeutic cycle (beginning on Day 15 of the cycle and ending on Day 26). Alternatively, 100 mg can be given at bedtime from Day 1 to Day 25 of each therapeutic cycle.'
- However, in the 'How much to take' subsection below, the PIL states: 'Take one capsule at bedtime on days 15 to 26 of your 28 day cycle.' This section should state 'Take two capsules at bedtime on days 15 to 26 of your 28- day cycle'.

Advice for healthcare professionals

Healthcare professionals are recommended to reiterate the prescribed dosage to their patients and to ensure that patients follow the dispensing advice. The product quality of Gepretix 100mg capsules is not impacted by this issue, therefore the affected batches are not being recalled.

The manufacturer has confirmed that the batch distributed on 30 January 2024 will be accompanied by a note explaining the issue to supplement dispensing at pharmacies. These batches will not be repackaged to avoid any supply concerns. Exeltis UK Limited have confirmed that all future batches of the product will contain the corrected PIL.



Medicines & Healthcare products Regulatory Agency

Advice for patients

No action is needed from patients. The issue is related to inconsistencies contained within the Patient Information Leaflet of the specified batches of Gepretix 100mg capsules. The quality of the medication itself is not affected. Patients should continue to take medicines from these batches as prescribed by their healthcare professional and as per the advice on the dispensing label.

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 medical information enquiries please contact Uk.medinfo@exeltis.com or telephone 01494411775.

For stock control enquiries please contact uk.office@exeltis.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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