Medicines & Healthcare products Regulatory Agency

# 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.

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**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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