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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

29 April 2025

Dear Healthcare Professional,

DRUG ALERT CLASS 4 – No 19 2025 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – JUBILANT PHARMACEUTICALS NV – PREGABALIN 25MG, 50MG, 75MG, 100MG, 150MG, 200MG, 225MG, 300MG 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, EL(25)A/19

Caution In Use

Issued 29 April 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Jubilant Pharmaceuticals NV

MEDICINE DETAILS

Pregabalin 25mg capsules

PL19156/0145

Active Ingredient: Pregabalin

SNOMED code: 7888911000001104

GTIN: 089028053339

FOR AFFECTED LOT BATCH NUMBERS – SEE ANNEX 1

Pregabalin 50mg capsules

PL19156/0146

Active Ingredient: Pregabalin

SNOMED code: 7890111000001103

GTIN: 08902805203346

FOR AFFECTED LOT BATCH NUMBERS – SEE ANNEX 2

Pregabalin 75mg capsules

PL19156/0147

Active Ingredient: Pregabalin

SNOMED code: 7890411000001108

GTIN: 08902805203353

FOR AFFECTED LOT BATCH NUMBERS – SEE ANNEX 3

Pregabalin 100mg capsules

PL19156/0148

Active Ingredient: Pregabalin

SNOMED code: 7890711000001102

GTIN: 08902805203360

FOR AFFECTED LOT BATCH NUMBERS – SEE ANNEX 4

Pregabalin 150mg capsules

PL19156/0149

Active Ingredient: Pregabalin

SNOMED code: 7891011000001108

GTIN: 08902805203377

FOR AFFECTED LOT BATCH NUMBERS – SEE ANNEX 5

Pregabalin 200mg capsules

PL19156/0150

Active Ingredient: Pregabalin

SNOMED code: 7891511000001100

GTIN: 08902805203384

FOR AFFECTED LOT BATCH NUMBERS – SEE ANNEX 6

Pregabalin 225mg capsules

PL19156/0151

Active Ingredient: Pregabalin

SNOMED code: 13075911000001106

GTIN: 08902805203391

FOR AFFECTED LOT BATCH NUMBERS – SEE ANNEX 7

Pregabalin 300mg capsules

PL19156/0152

Active Ingredient: Pregabalin

SNOMED code: 7891911000001107

GTIN: 08902805203407

FOR AFFECTED LOT BATCH NUMBERS – SEE ANNEX 8

Background

Jubilant Pharmaceuticals BV has informed the MHRA that the outer carton (box) of the product batches mentioned in this notification are missing the medicines legal classification for a Prescription Only Medicine 'POM'. There is no risk to product quality or safety of the medicines because of this missing information, therefore the affected batches are not being recalled.

The batches listed as 'not yet distributed' have also been packaged with the incorrect outer carton (box) and are missing the medicines legal classification for a Prescription Only Medicine 'POM'. The MHRA, in discussion with the Department of Health and Social Care, considers these products critical for patients, therefore these batches will not be repackaged and continue to be distributed. They are therefore included in the notification and the expected distribution dates for these batches will take place from May 2025.

Advice for Healthcare Professionals:

Healthcare professionals are advised to exercise caution when handling the listed products and ensure that they are stored accordingly and in line with the guidance for the storage of Prescription Only Medicines (POM).

Additionally, healthcare professionals are reminded to only dispense these products when the pharmacy team receives a suitable prescription prescribed by a qualified health professional.

Advice for Healthcare Professionals to Provide to Patients:

This issue is about missing information on the outer carton (box). The medicine itself is not affected and therefore patients do not need to take any action.

These products will have been prescribed and dispensed by the qualified healthcare professional(s) responsible for your care. If you have any concerns, please speak with your pharmacy team in the first instance. If you have concerns about a medicine you may be using, please contact your healthcare professional.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA [Yellow Card scheme](#).

Additional information:

For medical information enquiries please email safety.uk@lambda-cro.com or telephone 0080089013370

For stock control enquiries please email JPUK.Customerservice@jubl.com, or telephone 01233 552293

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

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU

Telephone +44 (0)20 3080 6574

DMRC@mhra.gov.uk

ANNEX 1 - Pregabalin 25mg capsules PL19156/0145

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PQ124002A	31/01/2026	56	10/01/2025
PQ124003A	31/01/2026	56	03/03/2025
PQ124004A	30/06/2026	56	04/03/2025
PQ125001A	31/12/2026	56	Not yet distributed
PQ125002A	31/12/2026	56	Not yet distributed

ANNEX 2 - Pregabalin 50mg capsules PL19156/0146

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PQ224001A	31/01/2026	84	01/10/2024
PQ224002A	31/01/2026	84	07/11/2024
PQ224003A	31/01/2026	84	07/11/2024
PQ224004A	30/06/2026	84	11/12/2024
PQ224005A	31/10/2026	84	13/02/2025
PQ224006A	31/10/2026	84	03/03/2025
PQ224007A	31/10/2026	84	06/03/2025
PQ224008A	31/10/2026	84	Not yet distributed
PQ225001A	31/12/2026	84	Not yet distributed
PQ225002A	31/12/2026	84	Not yet distributed

ANNEX 3 - Pregabalin 75mg capsules PL19156/0147

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PQ324001A	31/01/2026	56	08/10/2024
PQ324002A	31/01/2026	56	30/10/2024
PQ324003A	31/01/2026	56	26/11/2024
PQ324004A	30/06/2026	56	10/01/2025
PQ324005A	30/11/2026	56	Not yet distributed
PQ324006A	30/11/2026	56	Not yet distributed
PQ325001A	31/12/2026	56	Not yet distributed
PQ325002A	31/12/2026	56	Not yet distributed

ANNEX 4 - Pregabalin 100mg capsules PL19156/0148

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PQ424001A	30/04/2026	84	02/12/2024
PQ424002A	31/05/2026	84	05/12/2024
PQ424003A	31/05/2026	84	02/01/2025
PQ424004A	30/11/2026	84	Not yet distributed
PQ424005A	30/11/2026	84	Not yet distributed
PQ425001A	31/12/2026	84	Not yet distributed
PQ425002A	31/12/2026	84	Not yet distributed

ANNEX 5 - Pregabalin 150mg capsules PL19156/0149

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PQ524001A	28/02/2026	56	23/10/2024
PQ524002A	31/03/2026	56	12/11/2024
PQ524003A	31/03/2026	56	09/12/2024
PQ524004A	30/06/2026	56	Not yet distributed
PQ524005B	30/11/2026	56	Not yet distributed

ANNEX 6 - Pregabalin 200mg capsules PL19156/0150

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PQ624001A	31/01/2026	84	09/10/2024
PQ624002A	31/01/2026	84	07/11/2024
PQ624003A	28/02/2026	84	22/11/2024
PQ624004A	31/07/2026	84	23/12/2024
PQ624005A	31/07/2026	84	06/01/2025

ANNEX 7 - Pregabalin 225mg capsules PL19156/0151

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PQ724001A	31/01/2026	56	08/10/2024
PQ724002A	31/01/2026	56	07/11/2024
PQ724003A	28/02/2026	56	07/11/2024

ANNEX 8 - Pregabalin 300mg capsules PL19156/0152

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PQ823001A	31/10/2025	56	09/10/2024
PQ823002A	31/10/2025	56	30/10/2024
PQ823003A	31/10/2025	56	07/11/2024

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PQ824001A	31/07/2026	56	10/01/2025
PQ824002A	31/07/2026	56	17/01/2025
PQ824003A	31/08/2026	56	21/11/2024
PQ824004A	31/08/2026	56	22/11/2024
PQ824005A	30/09/2026	56	03/12/2024
PQ824006A	30/09/2026	56	05/12/2024
PQ824007A	30/09/2026	56	03/03/2025