

For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, Strategic Planning and Performance Group & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer
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Our Ref: PHC/15/2024
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MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Dear Healthcare Professional,

Doncaster Pharma Limited

Keppra 500mg film-coated tablets

PL 56830/0005

SNOMED Code: N/A

Batch No	Expiry Date	Pack Size	First Distributed
341173/BA	07/2024	60 tablets	21/08/2023
366686/BA	05/2025	60 tablets	21/08/2023
359701/BA	06/2025	60 tablets	21/08/2023
366621/BA	07/2025	60 tablets	21/08/2023
366635/BA	07/2025	60 tablets	21/09/2023
366635/BB	07/2025	60 tablets	21/09/2023
366101/BA	07/2025	60 tablets	06/11/2023
366635/BC	07/2025	60 tablets	06/11/2023
369420/BA	08/2025	60 tablets	01/12/2023
369421/BA	08/2025	60 tablets	01/12/2023
369421/BB	08/2025	60 tablets	25/01/2024
371089/BA	07/2025	60 tablets	01/02/2024

367482/BA	07/2025	60 tablets	01/02/2024
369420/BB	08/2025	60 tablets	01/02/2024
380087/BA	02/2026	60 tablets	05/02/2024
357677/BA	01/2025	60 tablets	12/03/2024
346651/BA	09/2024	60 tablets	02/04/2024
366635/BD	07/2025	60 tablets	08/04/2024
371089/BB	07/2025	60 tablets	11/04/2024
371016/BA	08/2025	60 tablets	11/04/2024
369420/BC	08/2025	60 tablets	11/04/2024
379799/BA	12/2025	60 tablets	11/04/2024
380087/BB	02/2026	60 tablets	11/04/2024
381719/BA	02/2026	60 tablets	11/04/2024
369421/BC	08/2025	60 tablets	23/04/2024
380089/BB	02/2026	60 tablets	23/04/2024
371016/BB	08/2025	60 tablets	24/04/2024
380089/BA	02/2026	60 tablets	24/04/2024

Active Pharmaceutical Ingredient: Levetiracetam

Brief description of the problem

The MA holder, Doncaster Pharma Limited have identified an error relating to the Braille printed on the cartons on above parallel imported packs which have been repackaged by BModesto B.V. Approximately 70% of the packs across the listed batches have been repackaged with the Braille message on the Keppra 500mg film-coated tablets incorrectly stating strength as 1000mg.

Correct Braille

The **correct** Braille message should read:

5 0 0 M G

Incorrect Braille

The **incorrect** Braille message reads as:

1 0 0 0 M G

Advice for healthcare professionals

There is no issue with the quality of the tablets, therefore, the affected batches are not being recalled. We would advise healthcare professionals to check, before dispensing the medication, whether patients or carers handling or taking the medication will be relying on the Braille. Where this is the case, alternative batches should be dispensed to avoid confusion and subsequent underdosing.

Advice for patients

Specific batches of Keppra 500mg film-coated tablets have an incorrect strength printed in Braille on the outer pack, it reads 1000mg instead of 500mg. The pack contains 500mg tablets as prescribed and quality of the medicine itself is not affected by this defect. Patients are reminded to take the tablets as per the instructions from your healthcare professional and those found on the dispensing label. If there are any concerns, consult with your healthcare professional. Never stop taking medicines such as Keppra without medical advice. Suddenly stopping an epilepsy medicine may cause your seizures to start again or happen more often or last longer than before.

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 and stock control enquiries please contact Doncaster Pharma on tel. 01302 365 000, email quality.enquiries@doncasterpharma.co.uk or commercial@doncasterpharma.co.uk

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely

A handwritten signature in black ink, appearing to read "Cathy Harrison". The signature is fluid and cursive, with a long horizontal stroke at the end.

Professor Cathy Harrison
Chief Pharmaceutical Officer