Medicines & Healthcare products Regulatory Agency

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Pharmacy/Wholesaler Level

Date: 15 May 2024 EL (24)A/15 Our Ref: MDR 082-05/24

Dear Healthcare Professional,

Doncaster Pharma Limited

Keppra 500mg film-coated tablets **PL 56830/0005**

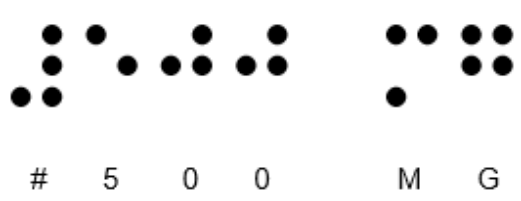
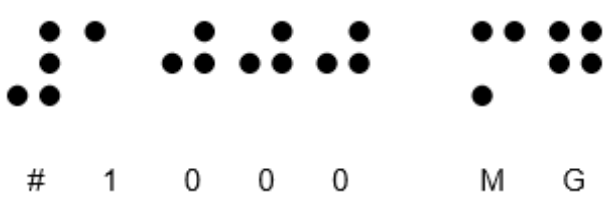
SNOMED Code: N/A

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

Medicines & Healthcare products Regulatory Agency

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	**Incorrect Braille**
The **correct** Braille message should read: 	The **incorrect** Braille message reads as: 

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 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