



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 10 June 2024

EL (24)A/21

Our Ref: MDR 312-04/24

Dear Healthcare Professional,

Dawa Limited

Paracetamol 500mg Film-Coated Tablets

PL 30684/0232

SNOMED Code 41808411000001106

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|-----------|-------------------|
| 220103 | 02/2025 | 32 | 19/12/2023 |
| 220105 | 02/2025 | 32 | 20/10/2023 |

Paracetamol 1000mg Film-Coated Tablets

PL 30684/0233

SNOMED Code 35526411000001100

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|-----------|-------------------|
| 220106 | 02/2025 | 100 | 30/10/2023 |

Active Pharmaceutical Ingredient: Paracetamol

Brief description of the problem

Dawa Limited has informed the MHRA that the above specified batches listed in this notification have been packed with an outdated Patient Information Leaflet (PIL). Section 2 of the PIL does not contain the most up to date information on the use of flucloxacillin as a concomitant medicine, the missing information is in bold below.

Taking other medicines with Paracetamol 500mg/1000mg film coated tablets

Some other medicines may affect or be influenced by Paracetamol 500 mg film coated tablets. Some of these drugs are mentioned below:

“Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.”

Advice for healthcare professionals

There is no risk to product quality because of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when dispensing the products and where possible, provide an updated PIL. The updated leaflet can be accessed via the following links:



Medicines & Healthcare products Regulatory Agency

Paracetamol 500mg Film-Coated Tablets

<https://mhraproducts4853.blob.core.windows.net/docs/03b0d393b1b1c7bf39d7b9b5dfb0fd1420c3f288>

Paracetamol 1000mg Film-Coated Tablets

<https://mhraproducts4853.blob.core.windows.net/docs/64c0bea1e27939866ea2685b87d0c317a6a28b01>

Alternatively, printed copies of the PIL can be requested from Drugsrus Limited (distributor) so that any remaining stock in the dispensary can be supplemented with the correct PIL (see contact details under “further information”).

The Marketing Authorisation Holder has confirmed that undistributed packs of these batches will be repacked with the correct version of the PIL. These packs are identifiable by tamper-evident seals that indicate packs with the updated leaflet.

Advice for patients

The medicine itself is not affected and patients do not need to take any action. Patients should continue to take medicines from these batches as prescribed by your healthcare professional. If you are taking flucloxacillin and have any concerns, please talk to your doctor or pharmacist.

Patients should be aware that the Patient Information Leaflet (PIL) that accompanies the above named batches of Paracetamol 500mg and 1000mg Film-Coated Tablets is missing information in Section 2. The missing information can be found in the background section above.

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

Further Information

For more information, medical information and stock control queries please contact Drugsrus Limited (distributor) on 020 8423 3800 or email info@drugsrus.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

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