

**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/22/2024  
Date: 10<sup>th</sup> June 2024

# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

**Caution in Use**

**Distribute to Pharmacy / Wholesaler Level**

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Limited has informed the MHRA that the above specified batches listed in this notification have been packed with an outdated Patient Information Leaflet (PIL).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:

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 Drugrus Limited (distributor) on 020 8423 3800 or email [info@drugrus.co.uk](mailto:info@drugrus.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**