



T: 0300-244-4000

E: [medicines.policy@gov.scot](mailto:medicines.policy@gov.scot)

**IMMEDIATE MESSAGE TO:**

1. Directors of Pharmacy
2. Medical Directors NHS Boards

12 October 2022

Dear Healthcare Professional

**DRUG ALERT – No. EL (22)A/43 - Caution in Use – Class 4 Medicines Defect:  
Flamingo Pharma UK Ltd, Ibuprofen 400mg Tablets, Paracetamol 500mg Tablets  
(Caplets),**

Please see the attached 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 forward this alert 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

**Grace Jamieson**  
**Medicines Policy Team**





Medicines & Healthcare products  
Regulatory Agency

# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

**Caution in Use**  
**Distribute to Pharmacy / Wholesaler Level**

Date: 12 October 2022

EL (22)A/43

Our Ref: MDR 019-10/22

Dear Healthcare Professional,

**Flamingo Pharma UK Ltd**

**Ibuprofen 400mg Tablets**

**PL 43461/0005**

Batch no.	Expiry Date	Pack Size	First Distributed
20169	02 / 27	48s	09 Jun 2022
20170	02 / 27	48s	09 Jun 2022
20171	02 / 27	84s	09 Jun 2022
20172	02 / 27	84s	09 Jun 2022
20176	02 / 27	84s	09 Jun 2022
20177	02 / 27	96s	15 Jun 2022
20178	02 / 27	96s	15 Jun 2022
20179	02 / 27	24s	15 Jun 2022
20236	03 / 27	84s	04 Jul 2022
20237	03 / 27	84s	04 Jul 2022
20238	03 / 27	84s	04 Jul 2022
20239	03 / 27	84s	04 Jul 2022
20240	03 / 27	84s	04 Jul 2022
20241	03 / 27	84s	04 Jul 2022
20242	03 / 27	24s	15 Jul 2022
20243	04 / 27	24s	15 Jul 2022
20251	04 / 27	48s	21 Jul 2022
20252	04 / 27	48s	21 Jul 2022
20262	04 / 27	84s	21 Jul 2022
20263	04 / 27	84s	21 Jul 2022
20277	04 / 27	24s	15 Jul 2022



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20278	04 / 27	48s	15 Jul 2022
20265	04 / 27	84s	15 Jul 2022
20266	04 / 27	84s	15 Jul 2022
20264	04 / 27	84s	15 Jul 2022
20279	04 / 27	48s	17 Aug 2022
20303	05 / 27	84s	17 Aug 2022
20304	05 / 27	84s	17 Aug 2022
20305	05 / 27	48s	17 Aug 2022
20306	05 / 27	48s	17 Aug 2022
20307	05 / 27	48s	17 Aug 2022
20314	05 / 27	48s	17 Aug 2022
20315	05 / 27	48s	17 Aug 2022
20316	05 / 27	24s	17 Aug 2022
20317	05 / 27	24s	17 Aug 2022
20318	05 / 27	24s	25 Aug 2022
20322	05 / 27	24s	25 Aug 2022
20323	05 / 27	24s	30 Aug 2022
20329	05 / 27	84s	25 Aug 2022
20355	06 / 27	84s	23 Sep 2022
20356	06 / 27	84s	20 Sep 2022
20357	06 / 27	84s	20 Sep 2022
20358	06 / 27	84s	20 Sep 2022
20359	06 / 27	84s	20 Sep 2022
20360	06 / 27	84s	21 Sep 2022
20361	06 / 27	84s	21 Sep 2022
20362	06 / 27	84s	22 Sep 2022

**Active Pharmaceutical Ingredient:** Ibuprofen

### Paracetamol 500mg Tablets (Caplets)

**PL 43461/0078**

Batch no.	Expiry Date	Pack Size	First Distributed
20103	12 / 26	16s	25 Aug 2022
20112	12 / 26	16s	25 Aug 2022
20257	04 / 27	16s	30 Aug 2022



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20258	04 / 27	16s	30 Aug 2022
20259	04 / 27	16s	25 Aug 2022
20260	04 / 27	16s	25 Aug 2022
20261	04 / 27	16s	25 Aug 2022
20337	05 / 27	16s	25 Aug 2022
20338	05 / 27	16s	06 Sep 2022
20339	05 / 27	16s	06 Sep 2022
20340	06 / 27	16s	06 Sep 2022
20341	06 / 27	16s	06 Sep 2022

**Active Pharmaceutical Ingredient:** Paracetamol

### **Brief description of the problem:**

Flamingo Pharma UK Ltd has identified an error relating to the ink printing of the batch number and expiry date on the carton for three batches of Ibuprofen 400mg tablets. The batches where this defect has been confirmed are batches 20242, 20277 and 20316. The batch number and expiry date are either missing on the carton or the printing is misaligned, which may affect readability. The batch numbers and expiry dates on the blisters within the cartons are clear and present, therefore these impacted batches are not being recalled at this stage.

In addition to the three batches of the ibuprofen product affected (20242, 20277, and 20316), Flamingo Pharma UK Ltd cannot exclude that the other batches of paracetamol and ibuprofen are potentially impacted by this issue. Please see images below highlighting the issue.

**Carton with missing batch no. and expiry**



**Carton with misaligned batch no. and  
expiry date**





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Flamingo Pharma UK Ltd has confirmed that the quality and safety of the product is not impacted, and the batch numbers and expiry dates on the blisters within the cartons are clear and present. See below image for information on where to find this information on the blister.

### Batch number and expiry date found on the edge of blister strips Ibuprofen 400mg tablets:



### Batch number and expiry date found on the edge of blister strips Paracetamol 500mg tablets (caplets):



### Advice for healthcare professionals:

The impacted products are within specification and there is no issue with product quality. Therefore, the affected batches are not being recalled. Healthcare professionals should check the outer carton before dispensing the affected products to ensure the batch number and expiry is present and can be read. In the event of a future recall or medical enquiry, the batch number on the blister should be referred to if the number on the carton cannot be read.

A small proportion of these packs have been overlabelled by Mawdsley Brooks & Co Ltd and they have confirmed they will contact customers directly to inform them of this issue.

Additionally, some batches of Paracetamol 500mg tablets (caplets) have been distributed to retail stores. Staff there are conducting visual checks of the outer carton to ensure that only packs with batch numbers and expiry dates present are available for consumers/patients to purchase.



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### **Advice for patients:**

Patients should note the information relating to missing batch numbers and expiry dates on some packs of Ibuprofen 400mg Tablets marketed by Flamingo Pharma UK Ltd, and the potential for other batches of Ibuprofen 400mg Tablets and Paracetamol 500mg tablets (caplets) to be impacted. There are no concerns about the safety or quality of the medicine. If you find a carton with no batch number or expiry date, please refer to the blister for the correct batch number and expiry date. If you have any additional concerns, please inform your healthcare professional.

### **Further Information:**

For medical information and stock control queries please contact:

#### **Flamingo Pharma**

For medical information [safety@flamingopharma.co.uk](mailto:safety@flamingopharma.co.uk) or general product enquiry [sales@flamingopharma.co.uk](mailto:sales@flamingopharma.co.uk) +44 (0) 7733522465

Or

#### **Mawdsley Brooks & Co Ltd**

[Overlabellingcustomerservices@mawdsleys.co.uk](mailto:Overlabellingcustomerservices@mawdsleys.co.uk) 01302 553064

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](mailto:DMRC@mhra.gov.uk)**