

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy/Wholesaler Level

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
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)
43461/0078**

PL

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
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



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 overlabeled 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.

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 or general product enquiry sales@flamingopharma.co.uk +44 (0) 7733522465

Or

Mawdsley Brooks & Co Ltd

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.

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.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

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028 9536 0333

12th October 2022

Pharmaceutical website: <http://www.hscbusiness.hscni.net>