



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 01 February 2022

EL (22)A/04

Our Ref: MDR 199-01/22

Dear Healthcare Professional,

Flamingo Pharma UK Ltd

Ibuprofen 400mg Tablets

PL 43461/0005

Batch No	Expiry Date	Pack Size	First Distributed
1403444	12/2025	24	06 September 2021

Active Pharmaceutical Ingredient: Ibuprofen

Brief description of the problem

Flamingo Pharma UK Ltd have identified an error relating to the embossed batch number on some cartons of Ibuprofen 400mg tablets. The batch number is illegible on some cartons and poses a risk to traceability in the event of a future recall or a medical enquiry. The batch numbers on the blisters within the cartons are clear and present. Additionally, the expiry date is still visible and clearly marked on the carton and blister.

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 blisters before dispensing the affected batch to ensure the batch number 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.

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. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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