

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/52

Caution In Use

Issued 10 December 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Flamingo Pharma UK Ltd

MEDICINE DETAILS

Amitriptyline Hydrochloride 10mg Tablets

PL: 43461/0054

Active Ingredient: amitriptyline hydrochloride

SNOMED code: 40091911000001100

GTIN: 5060464502453

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
1404515	31 Dec 2025	28 Tablets	10/03/2023
1404539	31 Dec 2025	28 Tablets	29/03/2023
1404540	31 Dec 2025	28 Tablets	26/05/2023
1404546	31 Dec 2025	28 Tablets	30/05/2023
1404721	31 Mar 2026	28 Tablets	18/07/2023
1404722	31 Mar 2026	28 Tablets	19/07/2023

MEDICINE DETAILS

Amitriptyline Hydrochloride 25mg Tablets

PL: 43461/0055

Active Ingredient: amitriptyline hydrochloride

SNOMED code: 42543811000001105

GTIN: 5060464502972

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
1404628	28 Feb 2026	28 Tablets	19/05/2023
1404630	28 Feb 2026	28 Tablets	19/05/2023
1404631	28 Feb 2026	28 Tablets	22/05/2023
1404632	28 Feb 2026	28 Tablets	22/05/2023
1404640	28 Feb 2026	28 Tablets	21/06/2023
1404641	28 Feb 2026	28 Tablets	21/06/2023
1404629	28 Feb 2026	28 Tablets	10/08/2023

MEDICINE DETAILS

Amitriptyline Hydrochloride 50mg Tablets

PL: 43461/0056

Active Ingredient: amitriptyline hydrochloride

SNOMED code: 40092111000001108

GTIN: 5060464502446

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
1404615	31 Jan 2026	28 Tablets	17/05/2023
1404616	31 Jan 2026	28 Tablets	17/05/2023
1404626	31 Jan 2026	28 Tablets	15/06/2023
1404627	31 Jan 2026	28 Tablets	15/06/2023

1404724	31 Mar 2026	28 Tablets	10/07/2023
1404723	30 Apr 2026	28 Tablets	10/08/2023

Background

Flamingo Pharma UK Ltd has informed the MHRA that the Patient Information Leaflet (PIL) in the products listed in this notification do not contain all the required safety information. The errors were identified following an MHRA Good Pharmacovigilance Practice (GPvP) inspection and further investigation by the Marketing Authorisation Holder, Flamingo Pharma UK Ltd.

The missing information from the PIL is detailed in this notification:

2. What you need to know before you take Amitriptyline Hydrochloride tablets

In the section, "Warnings and precautions":

The use of Buprenorphine together with Amitriptyline tablets can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Amitriptyline Hydrochloride Tablets").

4. Possible side effects

In the section, "Not known: frequency cannot be estimated from the available data":

Dry eyes

Please see [Amitriptyline HCl 10mg, 25mg, 50mg Film Coated Tablets PIL](#) for the correct information.

Advice for Healthcare Professionals:

The issue impacts all batches of Flamingo Pharma UK Ltd Amitriptyline Hydrochloride 10mg, 25mg and 50mg Film Coated Tablets. The Patient Information Leaflet for these batches contains out of date safety information, i.e. missing safety information concerning the following:

- Serotonin Syndrome
- Dry Eye

There is no risk to product quality or impact to safety of the medicines listed in this notification.

Healthcare professionals are advised to review the information contained within this notification and take this into account when dispensing this product, especially for new patients.

Please note that all further Flamingo Pharma UK Ltd batches of Amitriptyline HCl 10mg, 25mg and 50mg Film Coated Tablets with an expiry date of 31 May 2026 onwards contains the correctly updated safety information in the PIL.

Upon request, Flamingo Pharma UK Ltd will provide hard copies of the updated PIL to pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information. To request hard copies of the PIL, please contact quality@flamingopharma.co.uk with your details, i.e. address, product with batch details, required number of leaflets.

Advice for Healthcare Professionals to Provide to Patients:

Patients should be aware that all batches of Flamingo Pharma UK Ltd Amitriptyline Hydrochloride 10mg, 25mg and 50mg Film Coated Tablets contain an incorrect Patient Information Leaflet (PIL), with missing safety information. The missing safety information is listed in this notification and if you have any additional concerns relating to this information, please contact your pharmacist or prescriber.

The missing information, summarised in this notification, does not change or affect the quality of the product. Patients can continue to safely take this medicine unless they have concerns related to the missing information.

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

Additional information:

For all medical information enquiries and information on this product, please email safety@flamingopharma.co.uk , or telephone +44 (0) 800 0668 348.

For stock control enquiries please email sales@flamingopharma.co.uk , or telephone +44 (0) 7784 240228.

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