



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 27 November 2024

EL (24)A/57

Our Ref: DMRC-33916753

Dear Healthcare Professional,

Morningside Healthcare Limited

**Tramadol Hydrochloride Morningside 50 mg
Prolonged-Release capsules**

PL 20117/0384

SNOMED Code: 40589011000001102

Batch No	Expiry Date	Pack Size	First Distributed
MRA2303	05/2026	60	30/01/2024

Tramadol Hydrochloride 50 mg capsules

PL 20117/0086

SNOMED Code: 24136911000001105

Batch No	Expiry Date	Pack Size	First Distributed
MRF2301	11/2027	30	06/08/2024

Active Pharmaceutical Ingredient: tramadol hydrochloride

Brief description of the problem:

Morningside Healthcare Limited has informed the MHRA of a packaging issue identified in batch MRA2303 of Tramadol Hydrochloride Morningside 50 mg Prolonged-Release Capsules and batch MRF2301 of Tramadol Hydrochloride 50 mg Capsules. There have been reports of missing capsules within sealed blister strips. Each blister strip for the affected batches should contain 10 capsules. The missing capsules in the sealed blisters has occurred due to a manufacturing issue on the packaging line. The batches in the table are the only batches believed to be impacted.

Wholesalers and Healthcare professionals are advised that there is no risk to the product's quality or efficacy; therefore, the affected batches are not being recalled.

Advice for healthcare professionals:

Caution should be exercised when dispensing Tramadol Hydrochloride Morningside 50 mg Prolonged-Release Capsules from these batches. Cartons should be opened and each blister strip inspected to confirm the presence of 10 capsules per strip before dispensing.

If missing capsules are identified, this should be reported to Morningside Healthcare Limited via the contact details below and the packs returned through your supplier's approved process. Morningside will reimburse the wholesaler accordingly.



Medicines & Healthcare products Regulatory Agency

Advice for patients:

Patients are advised that some packs may contain missing capsules. This issue affects packs with the batch numbers specified in the table. If you find missing capsules in your pack, please speak to your medicine provider immediately for further advice. The medicine itself is not affected, there are no concerns about the quality or efficacy of the capsules that are present.

If you experience any unexpected side effects or adverse reactions, these should be reported via the MHRA Yellow Card Scheme at <https://yellowcard.mhra.gov.uk>.

Further Information:

For medical information enquiries and reports of missing capsules or blister strips, please email medinfo@aspirepharma.co.uk or telephone 01730231148.

For all stock enquiries, please email mpcustomerservices@morningsidepharm.com or telephone 01730231148.

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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