Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
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**IMMEDIATE MESSAGE TO:**

1. Directors of Pharmacy
2. Medical Directors NHS Boards

27 November 2024

Dear Healthcare Professional,

**DRUG ALERT CLASS 4 – No 57 2024 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – MORNINGSIDE HEALTHCARE LTD – TRAMADOL HYDROCHLORIDE MORNINGSIDE 50MG PROLONGED-RELEASE CAPSULES**

Please see 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 arrange to forward this alert on 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

**IRENE FAZAKERLEY**
**Medicines Policy Team**

Medicines & Healthcare products Regulatory Agency

# M E D I C I N E S  N O T I F I C A T I O N

## 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 mplcustomerservices@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

**Defective Medicines Report Centre**
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**Canary Wharf**
**London**
**E14 4PU**
**Telephone +44 (0)20 3080 6574**
**DMRC@mhra.gov.uk**