MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(26)A/23

Caution In Use

Issued 11 May 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Milpharm Limited

MEDICINE DETAILS

Loperamide hydrochloride 2 mg Orodispersible Tablets

PL: 16363/0784

Active Ingredient: Loperamide hydrochloride

SNOMED code: 6 pack: 27980211000001103, 12 pack: 27851511000001108

GTIN: 6 pack: 5060035110667, 12 pack: 5060035110674

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
25882X3	30/11/2029	12 orodispersible tablets	17/12/2025
25882X2	30/11/2029	6 orodispersible tablets	17/12/2025

Background

Milpharm Limited has identified a discrepancy in the Patient Information Leaflet (PIL) approved for Loperamide hydrochloride 2 mg Orodispersible Tablets. There are two errors that have been identified in the current PIL when compared against the appropriate orodispersible reference:

Section 3 (Method of administration): the PIL incorrectly instructs patients to swallow the tablets whole with a drink of water.

- The correct instruction for an orodispersible tablet is to place the tablet on the tongue and allow it to dissolve, without water. The carton (outer packaging) for both

affected batches carries the correct orodispersible method of administration, substantially mitigating this discrepancy at the point of use.

Section 4 (Rare side effects): the PIL omits the entry “Burning or prickling sensation of the tongue” (rare, may affect up to 1 in 1,000 patients), a recognised local effect of the orodispersible formulation that is listed in the Imodium Instants reference PIL.

All other PIL content including indication, dose, dosing frequency, maximum daily dose, contraindications, warnings, precautions, drug interactions, and overdose information — is correctly reflected. No related adverse drug reactions or safety signals have been identified in the company pharmacovigilance database.

Advice for Healthcare Professionals:

Healthcare professionals are asked to note the PIL discrepancies described above for batches 25882X3 and 25882X2 of Loperamide hydrochloride 2 mg Orodispersible Tablets (PL 16363/0784) and share this information with patients, where appropriate.

The correct administration instructions are printed on the carton. Milpharm Limited have confirmed that all future batches will be packed with the corrected PIL.

Healthcare professionals should be aware that “burning or prickling sensation of the tongue” is a recognised rare local adverse effect (frequency up to 1 in 1,000) of the orodispersible formulation, even though it is not currently listed in the affected PIL. Should a patient report this symptom following administration, it should be considered a potential medication-related effect and managed accordingly.

Advice for Healthcare Professionals to Provide to Patients:

If you have been dispensed Loperamide hydrochloride 2 mg Orodispersible Tablets from batch 25882X3 (pack of 12) or batch 25882X2 (pack of 6), please note the following:

- **How to take the tablets:** Place the tablet on your tongue and let it dissolve in your mouth. You do not need water to swallow it. Do not chew the tablet. The leaflet inside the pack may incorrectly tell you to swallow the tablet whole with water — please follow the instructions on the carton (outer pack) and the advice in this notice instead.
- **Possible side effect to be aware of:** A rare side effect (which may affect up to 1 in 1,000 people) of this orodispersible tablet is a burning or prickling sensation of

the tongue. This side effect is not currently listed in the leaflet inside the pack. If you experience this, please speak to your doctor or pharmacist.

- **You do not need to return the medicine.** You can continue to use it as prescribed, following the corrected instructions above.

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 medinfo@aurobindo.com, or telephone 020 8845 8811.

For stock control enquiries please email customerservices.uk@aurobindo.com, or telephone 020 8845 8811.

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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