



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

**Caution in Use**  
**Distribute to Pharmacy / Wholesaler Level**

Date: 26 May 2022

EL (22)A/25

Our Ref: MDR 077-05/22

Dear Healthcare Professional,

### Orifarm UK Ltd

#### Loprazolam 1mg Tablets

**PLPI 46927/0262**

Batch No	Expiry Date	Pack Size	First Distributed
20001T00	31 Oct 2023	30 tablets	Nov 2021
20001T01	31 Oct 2023	30 tablets	Nov 2021

Active Pharmaceutical Ingredient: Loprazolam mesylate

#### Brief description of the problem

Orifarm UK have informed us of an error with the Patient Information Leaflet (PIL) packaged within the packs of the above batches. The product name stated in the heading of the PIL has been spelt incorrectly as "lorazolam", instead of "loprazolam". All other sections of the PIL are unaffected.

#### Advice for healthcare professionals

Healthcare professionals are advised to inform patients of this discrepancy when dispensing packs from this batch. Hard copies of the correct PIL could be provided by the Marketing Authorisation Holder upon request, so that any of the affected packs remaining in the dispensary can be supplemented with the correct PIL.

#### Advice for patients

There is a spelling error in the Patient Information Leaflet that accompanies these batches of loprazolam. The medicine itself is not affected and patients do not need to take any action.

#### Further Information

For medical information and stock control queries please contact: Gowthami Gandhamala at [GOGAN@Orifarm.com](mailto:GOGAN@Orifarm.com)

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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