



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

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

Date: 03 January 2023

EL (23)A/01

Our Ref: MDR 135-12/22

Dear Healthcare Professional,

### Albireo AB

**Bylvay 1200 micrograms Hard Capsules**

**PLGB 36216/0004**

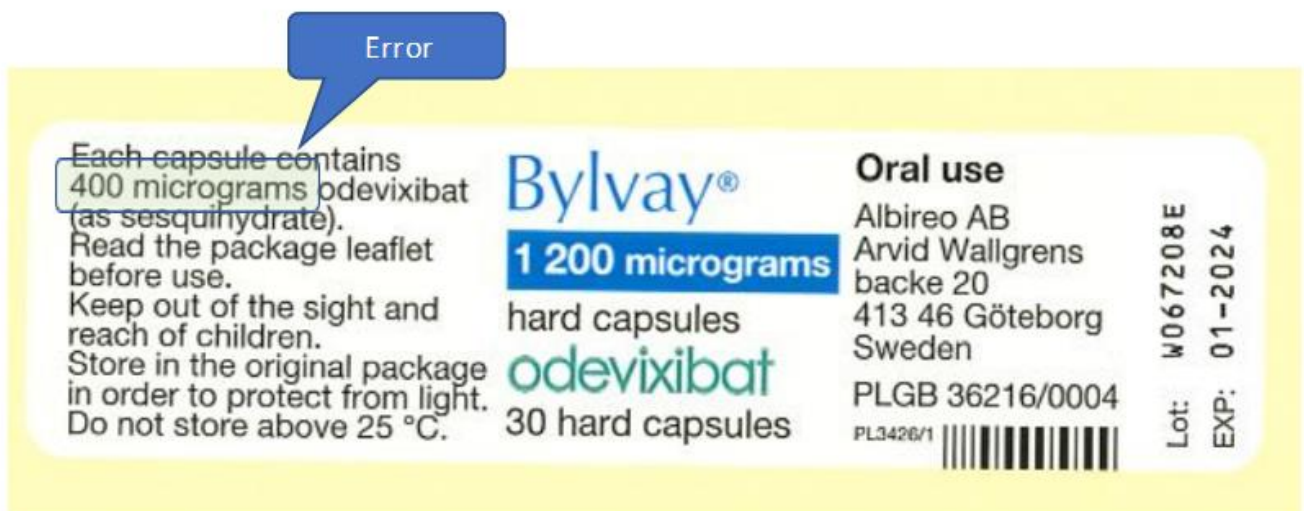
Batch No	Expiry Date	Pack Size	First Distributed
W067208E	01-2024	30 capsules	17 October 2022

**Active Pharmaceutical Ingredient:** Odevixibat

#### Brief description of the problem

Albireo AB has informed the MHRA that the side panel of the bottle label of the above batch of Bylvay 1200 micrograms Hard Capsules erroneously reflected the content of the active ingredient as 400 micrograms odevixibat (as sesquihydrate).

This should state: "Each capsule contains **1200 micrograms** odevixibat (as sesquihydrate)".



The labelling on the main panel of the bottle label and the outer carton are printed correctly to reflect the capsule content as 1200 micrograms odevixibat. The patient information leaflet (PIL) also states that each Bylvay 1200 micrograms Hard Capsule contains 1200 micrograms odevixibat.



Medicines & Healthcare products  
Regulatory Agency

**Advice for healthcare professionals**

Healthcare professionals should note that there is no risk to product quality and efficacy, therefore the affected batch is not being recalled.

Healthcare professionals should exercise caution when dispensing or supplying this product. Please refer to the correct information on the content of the active ingredient as stated on the main panel of the bottle label and the outer carton of the pack.

**Advice for patients**

This notification relates to a typographical error on the label of the bottle for one affected batch of product. 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: [medinfo@Albireopharma.com](mailto:medinfo@Albireopharma.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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