

## DRUG ALERT

### CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy/Wholesaler Level

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)".



**Error**

Each capsule contains 400 micrograms odevixibat (as sesquihydrate).  
Read the package leaflet before use.  
Keep out of the sight and reach of children.  
Store in the original package in order to protect from light.  
Do not store above 25 °C.

**Bylvay®**  
**1 200 micrograms**  
hard capsules  
**odevixibat**  
30 hard capsules

**Oral use**  
Albireo AB  
Arvid Wallgrens  
backe 20  
413 46 Göteborg  
Sweden  
PLGB 36216/0004  
PL3426/1

Lot: W067208E  
EXP: 01-2024



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.

**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. RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

**TO ALL CHEMISTS, DOCTORS ON THE LISTS**

Pharmaceutical Services  
2 Franklin Street  
BELFAST  
BT2 8DQ

Telephone No. 028 9536 0333

**3<sup>rd</sup> January 2023**

Pharmaceutical website: <http://www.hscbusiness.hscni.net>