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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

3 January 2023

Dear Healthcare Professional,

**DRUG ALERT CLASS 4 DRUG ALERT 1 2023 – CLASS 4 MEDICINES DEFECT
INFORMATION – CAUTION IN USE – ALBERIO AB BYLVAY 1200 MICROGRAMS HARD
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 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

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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