Via e-mail

29 December 2022

Dear Healthcare Professional

Incorrectly labelled bottles of Bylvay (odevixibat) 1200 mcg Hard Capsules (PLGB 36216/0004) batch W067208E – Caution in Use

Summary

- Albireo is the Marketing Authorization Holder for Bylvay® (odevixibat), which is indicated for the treatment of progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older.
- Following our communication to healthcare professionals dated 23 December 2022 in which we confirmed an error on the bottle labels for Bylvay (odevixibat) 1200 mcg Hard Capsules (batch W067208E), we wish to inform you that we have reported this defect to the Medicines and Healthcare products Regulatory Agency and that we will continue to supply the batch above.
- This will avoid a disruption in supply to the UK market, and prevent any confusion that could arise as a result of asking patients to switch to taking 3 x 400 mcg capsules in lieu of the 1200 mcg capsules.
- Healthcare professionals should exercise caution when dispensing or supplying this product. Please refer to the correct information on the main panel of the bottle label and the outer carton of the pack.
- The content of the active ingredient is correctly reflected in the patient information leaflet (PIL).
- There is no risk to product quality and efficacy, therefore the affected batch is not being recalled.

Background on the safety concern

An error has been identified on the GB label for the 1200 mcg strength of Bylvay (odevixibat) capsules. While the carton information is correct, the label on the bottles states that each capsule contains 400 mcg of odevixibat as the active ingredient, which is inconsistent with the strength of the product. We are working with the MHRA to issue a Class 4 Caution In Use Medicines Defect Notification. This will also inform healthcare professionals to exercise caution when dispensing the affected batch of medicine.

As advised in our previous communication, please ensure that your patients understand that packs from the affected batch do contain the correct amount of active ingredient (odevixibat 1200 mcg). The error identified relates to the label on the immediate packaging (bottle), as shown in Appendix 1 below.

The Marketing Authorisation Holder will take steps to ensure that this labelling error is rectified in future batches supplied to the UK market.

Yours sincerely,

Nicole Reichman

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Appendix 1

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Call for reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

You can report via:

- the Yellow Card website – https://yellowcard.mhra.gov.uk/
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Company contact point
If you have any questions about this letter or require more information about Bylvay®, please contact Albireo Medical Information: medinfo@Albireopharma.com

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