20 July 2023
EMA/CHMP/283723/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Bylvay

odevixibat

On 20 July 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Bylvay. The marketing authorisation holder for this medicinal product is Albireo AB.

The CHMP adopted a new indication for the treatment of Alagille syndrome. For information, the full indications for Bylvay will therefore be as follows[2]:

> Progressive familial intrahepatic cholestasis (PFIC)
>
> Bylvay is indicated for the treatment of progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older (see sections 4.4 and 5.1).
>
> **Alagille syndrome (ALGS)**
>
> **Bylvay is indicated for the treatment of cholestatic pruritus in Alagille syndrome (ALGS) in patients aged 6 months or older (see sections 4.4 and 5.1).**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] [2] New text in **bold**

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

© European Medicines Agency, 2023. Reproduction is authorised provided the source is acknowledged.