30 May 2024
EMA/CHMP/250300/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Livmarli

maralixibat

On 30 May 2024, 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 Livmarli. The marketing authorisation holder for this medicinal product is Mirum Pharmaceuticals International B.V.

The CHMP adopted a new indication as follows:

> Livmarli is indicated for the treatment of:
>
> Progressive familial intrahepatic cholestasis (PFIC) in patients 3 months of age and older.

For information, the full indications for LIVMARLI will be as follows:

> Livmarli is indicated for the treatment of:[2]
>
> - Cholestatic pruritus in patients with Alagille syndrome (ALGS) 2 months of age and older,
> - **Progressive familial intrahepatic cholestasis (PFIC) in patients 3 months of age and older.**

Treatment with Livmarli should be initiated under the supervision of a physician experienced in the management of patients with cholestatic liver diseases. 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 made 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] 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