23 July 2026
EMADOC-1829012207-56940
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lynavoy

linerixibat

On 23 July 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lynavoy[2], intended for the treatment of cholestatic pruritus in adult patients with primary biliary cholangitis.

The applicant for this medicinal product is Glaxosmithkline Trading Services Limited.

Lynavoy will be available as 40 mg film-coated tablets. The active substance in Lynavoy is linerixibat, a bile and liver therapy (ATC code: A05AX08). Linerixibat is an inhibitor of the ileal bile acid transporter (IBAT) that decreases the reabsorption of bile acids from the gut, thereby improving cholestatic pruritus.

The benefits of Lynavoy were demonstrated in a double-blind, placebo-controlled, multicentre, global phase 3 study. Lynavoy treatment led to improvement in the Monthly Itch Score over 24 weeks when compared with placebo, with a least squares mean difference of -0.68 (95 % CI: -1.14 to -0.23; p = 0.003). These findings were corroborated by improvements in pruritus-related sleep interference.

The most common side effects are diarrhoea, abdominal pain and transaminase elevations.

The full indication is:

> Lynavoy is indicated for the treatment of cholestatic pruritus in adult patients with primary biliary cholangitis (PBC).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after 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] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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