13 November 2025
EMADOC-1700519818-2615480
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Xerava

eravacycline

On 13 November 2025, 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 Xerava. The marketing authorisation holder for this medicinal product is Paion Pharma GmbH.

The CHMP adopted an extension to the existing indication, as follows:[2]

> Xerava is indicated **in adolescents from the age of 12 years weighing at least 50 kg, and in adults**, for the treatment of complicated intra-abdominal infections (cIAI) ~~in adults~~ (see sections 4.4 and 5.1).
>
> Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website 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, removed text as strikethrough

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