25 January 2024
EMA/CHMP/15483/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

EXBLIFEP

cefepime / enmetazobactam

On 25 January 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Exblifep, intended for the treatment of urinary tract infections and pneumonia in adults. The applicant for this medicinal product is Advanz Pharma Limited.

Exblifep will be available as a 2 g / 0.5 g powder for concentrate for solution for infusion. The active substances of Exblifep are cefepime and enmetazobactam, antibacterials for systemic use (ATC code: J01DE51). Cefepime is a cephalosporin which exerts bactericidal activity by inhibiting peptidoglycan cell wall synthesis, while enmetazobactam binds to β-lactamases and prevents the hydrolysis of cefepime.

The benefit of Exblifep is that it is as effective as piperacillin / tazobactam in the treatment of complicated urinary tract infections, including pyelonephritis, as shown in a phase 3, randomised, double-blind, multi-centre study. The most common side effects are pain and inflammation at the infusion site, diarrhoea, skin rash and headache.

The full indication is:

> EXBLIFEP is indicated for the treatment of the following infections in adults:
>
> - Complicated urinary tract infections (cUTI), including pyelonephritis
> - Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP)
>
> Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.
>
> 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 summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been

[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

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