



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 March 2024  
EMA/CHMP/80600/2024  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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# Emblaveo

aztreonam / avibactam

On 21 March 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 Emblaveo, intended for the treatment of complicated intra-abdominal and urinary tract infections, hospital-acquired pneumonia and infections due to aerobic Gram-negative organisms in patients with limited treatment options. The applicant for this medicinal product is Pfizer Europe MA EEIG.

Emblaveo was reviewed under EMA's accelerated assessment programme.

Emblaveo is a fixed dose combination of two active substances (ATC code: J01DF51 aztreonam and beta-lactamase inhibitor), aztreonam and avibactam, and will be available as a powder for concentrate for solution for infusion. Each vial will contain 1.5 g aztreonam and avibactam sodium equivalent to 0.5 g avibactam.

Aztreonam is a known monocyclic beta-lactam antibacterial agent (monobactam) that inhibits bacterial cell wall synthesis by targeting penicillin-binding proteins (PBPs). Avibactam is a known beta-lactamase inhibitor that prevents certain classes of beta-lactamases (class A, class C and some class D) from hydrolysing aztreonam.

Studies show that Emblaveo is expected to be effective at treating infections for which aztreonam is already used, as well as infections due to aerobic Gram-negative organisms. Microbiology data indicate that aztreonam in combination with avibactam may also have an important utility in infections caused by metallo- $\beta$ -lactamase-producing Enterobacterales and the combination could therefore address an unmet medical need. The most common side effects of Emblaveo are anaemia, serum transaminase elevation and diarrhoea.

The full indication is:

Emblaveo is indicated for the treatment of the following infections in adult patients (see sections 4.4 and 5.1):

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



- Complicated intra-abdominal infection (cIAI)
- Hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP)
- Complicated urinary tract infection (cUTI), including pyelonephritis

Emblaveo is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adult patients with limited treatment options (see sections 4.2, 4.4, and 5.1).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Consultation with a physician with appropriate experience in the management of infectious diseases is recommended before using Emblaveo to treat infections due to aerobic Gram-negative organisms in adult patients with limited treatment options.

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 granted by the European Commission.