19 September 2024
EMA/CHMP/429747/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zavicefta

ceftazidime / avibactam

On 19 September 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 Zavicefta. The marketing authorisation holder for this medicinal product is Pfizer Ireland Pharmaceuticals.

The CHMP adopted an extension to the existing indications to include treatment of infants from birth. For information, the full indications will be as follows:[2]

> Zavicefta is indicated in adults and paediatric patients ~~aged 3 months and older~~ **from birth** for the treatment of the following infections (see sections 4.4 and 5.1):
>
> - Complicated intra-abdominal infection (cIAI)
> - Complicated urinary tract infection (cUTI), including pyelonephritis
> - Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP)
>
> Treatment of adult patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.
>
> Zavicefta is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adults and paediatric patients ~~aged 3 months and older~~ **from birth** 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.

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, removed text as strikethrough

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