



28 April 2016  
EMA/CHMP/266959/2016  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Zavicefta

ceftazidime / avibactam

On 28 April 2016 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zavicefta, intended for the treatment of complicated intra-abdominal and urinary tract infections, hospital-acquired pneumonia and infections due to aerobic Gram-negative organisms where treatment options are limited. The applicant for this medicinal product is AstraZeneca AB.

Zavicefta is a fixed dose combination of two active substances, ceftazidime and avibactam, and will be available as a powder for concentrate for solution for infusion (2000 mg / 500 mg). Ceftazidime is a known beta-lactam antibacterial that acts by inhibiting the formation of the peptidoglycan, an important component of the bacterial cell wall. Avibactam is a new beta-lactamase inhibitor that prevents certain classes of beta-lactamases (class A, class C and some class D) from hydrolysing ceftazidime and therefore restores the activity of ceftazidime in many carbapenem-resistant *Enterobacteriaceae*.

Zavicefta, through its antibacterial action, has been shown to be effective at treating the above-mentioned infections. The most common side effects are Coomb's direct test positive, nausea and diarrhoea.

The full indication is:

"Zavicefta is indicated for the treatment of the following infections in adults (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)

Zavicefta 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."  
It is recommended that Zavicefta be prescribed to treat infections due to aerobic Gram-negative

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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



organisms in adult patients with limited treatment options only after consultation with a physician with appropriate experience in the management of infectious diseases.

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.