23 July 2015
EMEA/CHMP/448694/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zerbaxa

ceftolozane / tazobactam

On 23 July 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zerbaxa, intended for the treatment of complicated intra-abdominal infections, acute pyelonephritis and complicated urinary tract infections. The applicant for this medicinal product is Merck Sharp & Dohme Limited.

Zerbaxa will be available as a powder for solution for infusion containing 1 g ceftolozane and 0.5 g tazobactam. The active substances of Zerbaxa are ceftolozane / tazobactam, a cephalosporin and a beta-lactamase inhibitor, respectively (ATC code: J01DI54). Ceftolozane exerts bactericidal activity through binding to important penicillin-binding proteins, resulting in inhibition of bacterial cell-wall synthesis and subsequent cell death. Tazobactam does not exert any antibacterial activity but protects ceftolozane against hydrolysis.

Zerbaxa, through its antimicrobial action, has been shown to be effective at treating the above-mentioned infections. The most common side effects are nausea, headache, constipation, diarrhoea and pyrexia which were generally mild or moderate in severity.

The full indication is:

"Zerbaxa is indicated for the treatment of the following infections in adults (see section 5.1):

- Complicated intra-abdominal infections (see section 4.4);
- Acute pyelonephritis;
- Complicated urinary tract infections (see section 4.4).

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

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.