20 September 2018
EMA/CHMP/635393/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vabomere

meropenem / vaborbactam

On 20 September 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vabomere, intended for the treatment of complicated intra-abdominal and urinary tract infections, hospital-acquired pneumonia, bacteraemia that occurs in association with any of these infections and infections due to aerobic Gram-negative organisms where treatment options are limited. The applicant for this medicinal product is Rempex London Ltd.

Vabomere is a fixed dose combination of two active substances, meropenem and vaborbactam (ATC code: J01DH52), and will be available as a powder for concentrate for solution for infusion (1 g/1 g). Meropenem is a known beta-lactam (belonging to the class of carbapenems) which acts by inhibiting the formation of the peptidoglycan, an important component of the bacterial cell wall. Vaborbactam, a beta-lactamase inhibitor of a new class (cyclic boronates), prevents certain classes of beta-lactamases (class A and class C) from hydrolysing meropenem and therefore restores its activity in many infections due to carbapenem-resistant *Enterobacteriaceae*.

Vabomere, through its antibacterial action, has been shown to be effective at treating the above-mentioned infections. The most common side effects are headache, diarrhoea, infusion site phlebitis and nausea.

The full indication is:

> "Vabomere is indicated for the treatment of the following infections in adults (see sections 4.4 and 5.1):
>
> - Complicated urinary tract infection (cUTI), including pyelonephritis
> - Complicated intra-abdominal infection (cIAI)
> - 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.

[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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Vabomere is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adults 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 proposed that Vabomere be prescribed to treat infections due to aerobic Gram-negative 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.