EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2019
EMA/CHMP/662007/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Recarbrio

imipenem / cilastatin / relebactam

On 12 December 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Recarbrio, intended for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options. The applicant for this medicinal product is Merck Sharp & Dohme B.V.

The active substances of Recarbrio are imipenem, cilastatin and relebactam. It will be available as a 500 mg/500 mg/250 mg powder for solution for infusion. It is a fixed-dose combination (ATC code: J01DH56) of: a carbapenem antibacterial agent that inhibits the formation of peptidoglycan (an important component of the bacterial cell wall); a renal dehydropeptidase inhibitor that limits the renal metabolism of the carbapenem; and a novel beta-lactamase inhibitor that prevents certain classes of beta-lactamases (classes A and C, but not classes B and D) from hydrolysing the carbapenem, thereby restoring its antibacterial activity against certain resistant bacteria.

The benefits with Recarbrio are its ability to treat the above-mentioned infections effectively. The most common side effect is diarrhoea.

The full indication is:

"Recarbrio is 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 Recarbrio be prescribed 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.

[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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