EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2022
EMA/CHMP/595935/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zerbaxa

ceftolozane / tazobactam

On 23 June 2022, 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 Zerbaxa. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted an extension to include the treatment of paediatric patients from birth to 18 years of age in three of the existing indications. The full indications for Zerbaxa will therefore be as follows:[2]

> Zerbaxa is indicated for the treatment of the following infections in adult **and paediatric patients** (see sections **4.2** and 5.1):
>
> - Complicated intra-abdominal infections (see section 4.4);
> - Acute pyelonephritis;
> - Complicated urinary tract infections (see section 4.4).
>
> Zerbaxa is also indicated for the treatment of the following infection in adult patients (18 years or older) (see section 5.1):
>
> - Hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP).

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 will be 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

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