



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

27 February 2020  
EMA/CHMP/73102/2020  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Fetcroja cefiderocol

On 27 February 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fetcroja, 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 Shionogi B.V.

Fetcroja will be available as a 1 g powder for concentrate for solution for infusion. The active substance of Fetcroja is cefiderocol, an antibacterial for systemic use (ATC code: J01DI04). It is a siderophore cephalosporin which acts by inhibiting the formation of the peptidoglycan, an important component of the bacterial cell wall.

The benefits with Fetcroja are its ability to treat aerobic Gram-negative infections effectively. The most common side effects are diarrhoea, vomiting, nausea and cough.

The full indication is:

“Fetcroja 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 Fetcroja 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.

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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

