17 October 2019
EMA/CHMP/471384/2019 Corr. [1]
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[2] (initial authorisation)

Quofenix

delafloxacin

On 17 October 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 Quofenix, intended for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults when it is considered inappropriate to use other antibacterial agents commonly recommended for the initial treatment of these infections. The applicant for this medicinal product is A. Menarini Industrie Farmaceutiche Riunite s.r.l.

Quofenix will be available as 300 mg powder for concentrate for solution for infusion and as a 450 mg tablet. The active substance of Quofenix is delafloxacin, an antibacterial for systemic use (ATC code: J01MA23) which inhibits bacterial topoisomerase IV and DNA gyrase (topoisomerase II), which are enzymes required for bacterial DNA replication, transcription, repair, and recombination.

Delafloxacin given intravenously has been shown to be as effective as vancomycin plus aztreonam given intravenously, and delafloxacin given intravenously followed by delafloxacin given by mouth has been shown to be as effective as vancomycin plus aztreonam given intravenously. The most common side effects are fungal infections, headache, diarrhoea, nausea, vomiting, increase in transaminase levels, itching, and injection/infusion site reactions.

The full indication is:

> "Quofenix is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of these infections (see sections 4.4 and 5.1). 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 made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] This document was updated on 21 October 2019 to correct information on the comparison of delafloxacin with vancomycin plus aztreonam

[2] 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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