25 February 2021
EMA/CHMP/99783/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Quofenix

delafloxacin

On 25 February 2021, 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 Quofenix. The marketing authorisation holder for this medicinal product is A. Menarini Industrie Farmaceutiche Riunite s.r.l.

The CHMP adopted a new indication as follows:[2]

Quofenix is indicated for the treatment of **the following infections in adults**:

- acute bacterial skin and skin structure infections (ABSSSI) ~~in adults~~
- **community- acquired pneumonia (CAP)**

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).

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 shown in bold; removed text as strikethrough

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union