30 March 2023
EMA/CHMP/150406/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Tenkasi

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On 30 March 2023, 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 Tenkasi. The marketing authorisation holder for this medicinal product is Menarini International Operations Luxembourg S.A.

The CHMP adopted an extension to the existing indication to include treatment of paediatric patients. For information, the full indication will be as follows:[2]

> Tenkasi is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults and **paediatric patients aged 3 months and older** (see sections **4.2,** 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 in bold

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