



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 June 2018  
EMA/CHMP/411942/2018  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Jinarc tolvaptan

On 28 June 2018, 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 Jinarc. The marketing authorisation holder for this medicinal product is Otsuka Pharmaceutical Europe Ltd.

The CHMP adopted an extension to the existing indication as follows:<sup>2</sup>

“Jinarc is indicated to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with CKD stage 1 to ~~3~~ **4** at initiation of treatment with evidence of rapidly progressing disease (see section 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.

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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

<sup>2</sup> **New text in bold, removed text as strikethrough**

