23 April 2026
EMADOC-1700519818-3082428
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[11] (post authorisation)

Agamree

vamorolone

On 23 April 2026, 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 Agamree. The marketing authorisation holder for this medicinal product is Santhera Pharmaceuticals (Deutschland) GmbH.

The CHMP adopted a change to the existing indication as follows:[2]

> AGAMREE is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients aged ~~4~~ **2** years and older.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summary 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, removed text as strikethrough

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