31 May 2018
EMA/304289/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Translarna

ataluren

On 31 May 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 Translarna. The marketing authorisation holder for this medicinal product is PTC Therapeutics International Limited.

The CHMP adopted an extension to the existing indication as follows[2]:

"Translarna is indicated for the treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged ~~5~~ **2** years and older (see section 5.1). Efficacy has not been demonstrated in non-ambulatory patients.

The presence of a nonsense mutation in the dystrophin gene should be determined by genetic testing (see section 4.4)."

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, removed text as strikethrough

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