14 September 2023
EMA/410364/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Voxzogo

vosoritide

On 14 September 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 Voxzogo. The marketing authorisation holder for this medicinal product is BioMarin International Limited.

The CHMP adopted an extension to the existing indication to include treatment of achondroplasia in patients from 4 months of age. For information, the full indication for Voxzogo will be as follows:[2]

> Voxzogo is indicated for the treatment of achondroplasia in patients **4 months** of age and older whose epiphyses are not closed. The diagnosis of achondroplasia should be confirmed by appropriate genetic testing.

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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