19 September 2024
EMA/CHMP/427451/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Buccolam

midazolam

On 19 September 2024, 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 Buccolam. The marketing authorisation holder for this medicinal product is Neuraxpharm Pharmaceuticals, S.L.

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

> Treatment of prolonged, acute, convulsive seizures in infants **from 3 months to adults** ~~toddlers, children and adolescents (from 3 months < 18 years)~~.

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 made 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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