26 January 2023
EMA/CHMP/7134/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Wakix

pitolisant

On 26 January 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 Wakix. The marketing authorisation holder for this medicinal product is Bioprojet Pharma.

The CHMP adopted an extension to the existing indication to include treatment of adolescents and children from the age of 6 years old. For information, the full indication for Wakix will be as follows:[2]

> Wakix is indicated in adults, **adolescents and children from the age of 6 years** for the treatment of narcolepsy with or without cataplexy (see also 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.

[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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