12 November 2020
EMA/CHMP/602260/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Xyrem

sodium oxybate

On 12 November 2020, 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 Xyrem. The marketing authorisation holder for this medicinal product is UCB Pharma S.A.

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

> Treatment of narcolepsy with cataplexy in adult patients, **adolescents and children from the age of 7 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 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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