



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2026
EMADOC-1700519818-3015439
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Namuscla mexiletine

On 26 March 2026, 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 Namuscla. The marketing authorisation holder for this medicinal product is Lupin Europe GmbH.

The CHMP adopted two new strengths, 62 mg and 83 mg hard capsules, in addition to the already authorised 167 mg strength. The CHMP also adopted changes to the existing indication as follows:²

Namuscla is indicated for the symptomatic treatment of myotonia in **children aged 6 to 11 years weighing at least 20 kg, adolescents aged 12 to 17 years and adult patients ≥ 18 years** with non-dystrophic myotonic disorders.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summary 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

