



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

18 October 2018  
EMA/CHMP/650838/2018  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Namuscla

mexiletine

On 18 October 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Namuscla, intended for the treatment of myotonia in adults with certain hereditary muscle disorders. Namuscla was designated as an orphan medicinal product on 19 November 2014. The applicant for this medicinal product is Lupin Europe GmbH.

Namuscla will be available as capsules (167 mg). The active substance of Namuscla is mexiletine (ATC code: C01BB02) which reduces skeletal muscle hyperexcitability by blocking sodium channels.

The benefits with Namuscla are its ability to reduce muscle stiffness and improve quality of life in patients with non-dystrophic myotonic disorders (sodium or chloride channelopathies). The most common side effects are abdominal pain, vertigo and insomnia; arrhythmias and DRESS (drug reaction with eosinophilia and systemic symptoms) may occur.

The full indication is: "symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders."

It is proposed that Namuscla be prescribed by physicians experienced in the treatment of non-dystrophic myotonic disorders.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

