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National Stock Exchange of India Limited

Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
Mumbai - 400 051

Symbol: LUPIN

BSE Limited

P. J. Towers, Dalal Street,
Mumbai Samachar Marg,
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Scrip Code: Equity - 500257

Subject: Disclosure pursuant to Regulation 30 of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015

Dear Sir/Madam,

We are pleased to enclose a Press Release titled "Lupin Announces EMA Approval for NaMuscla® Expansion for Pediatric Indication with New Strengths".

The same is for your information and dissemination.

Thanking you,

For LUPIN LIMITED

**AMIT KUMAR GUPTA
COMPANY SECRETARY & COMPLIANCE OFFICER
(ACS -15754)**

Encl.: a/a.

LUPIN LIMITED

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Lupin Announces EMA Approval for NaMuscla® Expansion for Pediatric Indication with New Strengths

NaMuscla is the only approved treatment for myotonia symptoms in NDM in Europe

Mumbai, Zug, July 1, 2026 – Global pharma major Lupin Limited (Lupin) today announced that the European Medicines Agency (EMA) has approved a change to the terms of marketing authorization for NaMuscla, supported by the Pediatric Investigation Plan (PIP). The approval includes two new dosage strengths, 62 mg and 83 mg capsules, in addition to the existing 167 mg, and the revised indications that cover symptomatic treatment of myotonia in children (6–11 years, weighing at least 20 kg), adolescents (12–17 years), and adults (≥ 18 years) with non-dystrophic myotonic disorders¹.

Claus Jepsen, President, Global Specialty, Lupin, said, “This EMA approval for Pediatric Indication of NaMuscla represents a significant step forward for patients and families living with non-dystrophic myotonic disorders—especially children, where options are scarce. At Lupin, we remain committed to broadening access to therapies that improve outcomes across every stage of care.”

Lupin is now working towards making new dosage strengths and expanded pediatric indication available across Europe, subject to local implementation timelines and national reimbursement and access processes.

Notes for Editors

About Myotonic Disorders and Non-Dystrophic Myotonias (NDM)

Myotonic disorders are a group of heterogeneous, inherited, neuromuscular disorders characterized by a shared symptom called myotonia². Myotonia can be described as an inability to relax a contraction of skeletal muscle which originates from a voluntary muscular contraction such as shaking someone’s hand and blinking, or everyday activities such as walking across a street and climbing stairs^{3, 4}.

Non-dystrophic myotonias (NDM) are a sub-set of rare (prevalence of 1:100,000⁵), inherited, myotonic disorders which are caused by mutations within ion channels in the sarcolemma membrane of skeletal muscles. Non-dystrophic myotonias exhibit both sodium and chloride channelopathies which result in altered membrane excitability⁶. For patients with NDM, myotonia is the most prominent symptom and demonstrates different phenotypes in subgroups of NDM disorders, and can affect different parts of the body, such as legs, arms, or facial muscles, more severely³.

Myotonia in NDM patients has an onset in childhood and persists across their lifetime⁷. Patients perceive that myotonia increases in severity over time, impacting daily life³. Myotonia is described by patients in a variety of ways (stiffness, cramps, pain, difficulty releasing a fist, or difficulty swallowing or eating) which can contribute to substantial delays in diagnosis and treatment, leading to decreased patient quality-of-life and often significant disability²⁻⁴.

About NaMuscla (mexiletine)

NaMuscla is the only antimyotonic agent licensed to treat symptomatic myotonia in children aged 6 to 11 years weighing at least 20 kg, adolescents aged 12 to 17 years and adult patients more than 18 years with non-dystrophic myotonic disorders¹. In randomized controlled trials, NaMuscla (167 to 500 mg/day) has been shown to significantly reduce myotonia compared to placebo, reducing skeletal muscle hyperexcitability through its use-dependent, voltage-gated, sodium channel blocking actions which are independent of the cause of channel function. This resulted in an improvement in patient quality-of-life and other functional outcomes, with gastro-intestinal discomfort reported as the most common adverse event, demonstrating NaMuscla to be safe and well tolerated⁶⁻⁹.

References:

1. <https://www.ema.europa.eu/en/medicines/human/EPAR/namuscla>
2. Matthews E, et al. Brain 2010;133:9–22
3. Diaz-Manera J, et al. EMJ. 2021;6[2]:37-46
4. Trivedi JR, et al. Brain 2013; 136:2189-200
5. Emery AEH, Neuromuscular Discord 1991;1:19-29
6. Vicart S, et al. Neuromuscular Discord 2021; 31:1124-1135
7. Matthews E, et al. Pract Neurol 2021;0:1–10
8. Stunnenberg, et al. Muscle Nerve 2020;62(4):430-444
9. NaMuscla®. Summary of Product Characteristics. https://www.ema.europa.eu/en/documents/product-information/namuscla-epar-product-information_en.pdf

About Lupin

Lupin Limited is a global pharmaceutical leader headquartered in Mumbai, India, with products distributed in over 100 markets. Lupin specializes in pharmaceutical products, including branded and generic formulations, complex generics, biotechnology products, and active pharmaceutical ingredients. Trusted by healthcare professionals and consumers globally, the company enjoys a strong position in India and the U.S. across multiple therapy areas, including respiratory, cardiovascular, anti-diabetic, anti-infective, gastrointestinal, central nervous system, and women's health. Lupin has 15 state-of-the-art manufacturing sites and 7 research centers globally, along with a dedicated workforce of over 24,000 professionals. Lupin is committed to improving patient health outcomes through its subsidiaries - Lupin Diagnostics, Lupin Digital Health, and Lupin Manufacturing Solutions.

To know more, visit www.lupin.com or follow us on LinkedIn <https://www.linkedin.com/company/lupin>

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