Prescribing Information (PI): NaMuscla® *(Mexiletine hydrochloride)* 167mg hard capsules. Consult the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Each Namuscla 167mg hard capsule contains mexiletine hydrochloride corresponding to 166.62mg mexiletine. **Indication:** Symptomatic treatment of myotonia in adults with non-dystrophic myotonic disorders. **Dosage & Administration:** Orally with water. In case of digestive intolerance, take with a meal. Recommended starting dose is 167mg daily. Based on clinical response and symptoms; after at least 1 week of treatment, the daily dose can be increased to 333mg daily and after at least 1 further week of treatment, the dose can be increased to 500mg daily. Maintenance dosing is between 167mg–500mg daily, throughout the day. Dose should not exceed 500mg/day. Regular reassessment should be implemented, not to continue long-term in a patient not responding/benefiting. Before starting treatment, a detailed cardiac evaluation should be carried out; throughout treatment cardiac monitoring needs to be continued and adapted. Caution in mild or moderate hepatic impairment; dose should only be increased after at least 2 weeks of treatment. Not recommended in severe hepatic impairment or in severe renal impairment. *Cardiac disorders*: If modifying the mexiletine dose, or if co-administering medicines susceptible to affect cardiac conduction, patients should be monitored by ECG (especially conduction anomalies). **Contraindications:** Hypersensitivity to the active substance, excipients or local anaesthetics. Ventricular tachyarrhythmia. Complete heart block (i.e. third-degree atrioventricular block) or heart block susceptible to evolve to complete heart block (first-degree atrioventricular block with markedly prolonged PR interval (≥240ms) and/or wide QRS complex (≥120ms), second-degree atrioventricular block, bundle branch block, bifascicular and trifascicular block). Myocardial infarction (acute/past), or abnormal Q-waves. Symptomatic coronary artery disease. Heart failure with mid-range (40-49%) and reduced (<40%) ejection fraction. Atrial tachyarrhythmia, fibrillation or flutter. Sinus node dysfunction (including sinus rate< 50bpm). Co-administration with medicines inducing torsades de pointes or a with narrow therapeutic index. **Warnings/Precautions:** *Cardiac arrhythmogenic effects:* May induce an arrhythmia or accentuate a pre-existing arrhythmia, either diagnosed/undiagnosed. Before starting treatment, a detailed cardiac evaluation (ECG, 24-48-hour Holter-monitoring & echocardiography) should be carried out in all patients. A cardiac evaluation is recommended after treatment start (e.g. within 48 hours). Patients without cardiac abnormalities, periodic ECG monitoring is recommended (every 2 years/more frequently). Patients prone to, or with cardiac abnormalities, detailed cardiac evaluation, including ECG, should be carried out before and after a dose increase. During maintenance treatment, detailed cardiac evaluation, including ECG, 24-48 hour Holter-monitoring and echocardiography, is recommended at least annually, or more frequently. Inform patients about symptoms of arrhythmias and advise to immediately contact emergency care. Benefit of treatment needs to be balanced against risk. Stop immediately if cardiac conduction abnormalities or contraindications are detected. Electrolytic imbalance may increase the proarrhythmic effects. Conduct an electrolytic evaluation prior to initiating mexiletine in every patient. Correct electrolyte imbalance before administering and monitor throughout treatment. *Drug reaction with eosinophilia and systemic symptoms (DRESS)*: Hypersensitivity to; mexiletine, excipients or local anaesthetics are at high risk of developing DRESS and should not receive mexiletine. *Cardiac Monitoring, Hepatic & Renal:* Refer to dosage and administration section above. *Epilepsy:* Can increase seizure frequency therefore monitor. *Smoking:* Dose may need to be increased/decreased if a patient starts/stops smoking, respectively. *CYP2D6 polymorphism* At least 7 days before dose increase must be respected to ensure steady-state levels and tolerance, irrespective of CYP450 polymorphism. **Interactions:** *Antiarrhythmics inducing torsades de pointes (class Ia, Ic, III)*: Increases the risk of potentially lethal torsades de pointes and concomitant use is contraindicated. *Antiarrhythmics (class Ib, II, IV):* Co-administration is not recommended, unless exceptionally, due to increased risk of adverse cardiac reactions. *CYP1A2 & CYP2D6 inhibitors:* Significantly increases mexiletine exposure and risk of adverse reactions. Clinical and ECG monitoring, and adaptation of mexiletine dosage may be indicated. *CYP1A2 & CYP2D6 inducers*: Based on clinical response, mexiletine dosage should be adapted. *Other medicines:* Monitor if co-treated with other medicines, especially those with narrow therapeutic windows. *CYP1A2 and OCT2 substrates*. Monitor substrate blood levels when mexiletine dose is changed. Consider dose adjustment of the substrate. *Caffeine*: Reduce during treatment. **Pregnancy & Lactation:** Preferrable to avoid use during pregnancy. Excreted in human milk. A risk/benefit decision must be made whether to discontinue breast-feeding or mexiletine. Effect on human fertility not evaluated. **Driving/Using Machines:** May have minor influence. **Side Effects: Very Common:** Insomnia, abdominal pain. **Common**: Somnolence, headache, paraesthesia, vision blurred, vertigo, tachycardia, flushing, hypotension, nausea, acne, pain in extremities, fatigue, asthenia, chest discomfort, malaise. **Uncommon**: Seizure, speech disorders, bradycardia**. Rare:** Hepatic function abnormal. **Very Rare:** DRESS syndrome, drug-induced liver injury, liver disorder, hepatitis. **Not Known:** Leukopenia, thrombocytopenia, lupus-like syndrome, dermatitis exfoliative, Stevens-Johnson syndrome, hallucinations, confusional state, diplopia, dysgeusia, atrioventricular block, circulatory collapse, hot flush, pulmonary fibrosis, diarrhoea, vomiting, oesophageal ulcers and perforation. Refer to SmPC for full list of side effects. **Price & Quantity:** £5000 per pack of 100 capsules. **Marketing Authorisation (MA) Holder:** Lupin Europe GmbH, Hanauer Landstrasse 139-143, 60314 Frankfurt am Main, Germany. **MA No:** EU/1/18/1325/003 **Legal Category:** POM **PI Last revised:** July 2021. **Further information**: Lupin Healthcare UK Ltd. The Urban Building, Second Floor 3-9 Albert St, Slough, Berkshire, SL1 2BE. Tel: 01565 751378. E-mail: information@lupin.com

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