Namuscla (mexiletine)

IMPORTANT INFORMATION ON CARDIAC MONITORING TO REDUCE THE RISK OF ADVERSE EVENTS

Educational guide for healthcare professionals

Brief introduction

This educational guide is essential to ensure the safe and effective use of Namuscla and manage the risk of cardiac arrhythmia and the risk of adverse reactions in people with reduced mexiletine clearance due to hepatic dysfunction. It aims to educate healthcare professionals (HCPs) to perform cardiac screening procedures in all patients before Namuscla initiation and to exclude those at greater risk of developing cardiac arrhythmias.
The guide aims to support HCPs to be cautious with dosing of patients with hepatic dysfunction and exclude patients with hepatic impairment to reduce the risk of adverse reactions due to reduced mexiletine clearance in those patients.
This educational guide is not promotional but contains important risk minimisation information for HCPs.

General information about Namuscla

The information in this educational material should always be read in conjunction with the Summary of Product Characteristics (SmPC) of Namuscla; please refer to the SmPC before prescribing Namuscla which is available on https://www.medicines.org.uk/emc/product/9838/rmms

Namuscla is indicated for symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders.

Namuscla is not licensed for use in patients with myotonic dystrophy types 1 and 2 (off-label use).

Namuscla is a sodium channel blocking drug that can cause or exacerbate cardiac arrhythmias in some people due to its cardiac effects. All patients should be screened for cardiac and electrolyte disorders before starting Namuscla and cardiac and electrolyte monitoring is also required during treatment, particularly during dose increments.

Cardiac monitoring

Namuscla may cause cardiac effects like increased QRS, decreased QTc, increased PR intervals and tachycardia, which are likely to occur and are related to its pharmacological properties. Electrolytic imbalance such as hypokalaemia, hyperkalaemia or hypomagnesaemia may increase the proarrhythmic effects of Namuscla.

General baseline evaluations:

Cardiac evaluation is required in all patients before treatment (ECG, 24-48 hour Holter-monitoring and echocardiography) and shortly after it is started (e.g. within 48 hours).

Electrolyte tests should be done prior to initiating treatment in every patient. If a patient has an electrolyte imbalance, this should be corrected before administering Namuscla.

Ongoing monitoring:

- In patients without cardiac abnormalities, an electrocardiogram (ECG) monitoring should be performed periodically (every 2 years or more frequently if considered necessary).

- In patients with cardiac abnormalities and in patients prone to such abnormalities, (e.g. patients with history of cardiac disease, patients taking anti-arrhythmic medication), a detailed cardiac evaluation (including ECG) should be carried out before and after any dose increase. During maintenance treatment, a detailed cardiac evaluation (including ECG, 24-48 hour Holter-monitoring and echocardiography) is recommended at least annually, or more frequently if considered necessary as part of routine cardiac assessment.

Caution needs to be exercised while using Namuscla along with other anti-arrhythmic agents, especially those known to induce torsades de pointes and other medicines with interacting potential.

In patients with electrolyte imbalance before treatment, electrolytes should be monitored throughout treatment with personalised periodicity.

Contraindications

Namuscla is contraindicated in patients with any of the following:

- Ventricular tachyarrhythmia
- Complete heart block (i.e. third-degree atrioventricular block) or any heart block susceptible to evolve to complete heart block (first-degree atrioventricular block with markedly prolonged PR interval (≥ 240 ms) and/or wide QRS complex (≥ 120 ms), second-degree atrioventricular block, bundle branch block, bifascicular and trifascicular block)
- Myocardial infarction (acute or 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 < 50 bpm)
- Co-administration with medicinal products inducing torsades de pointes or with a narrow therapeutic index.

When should Namuscla be stopped

HCPs should conduct benefit-risk assessments during treatment and stop Namuscla:

- If a patient (under Namuscla therapy) develops a contraindication or any cardiac conduction abnormalities e.g. an atrioventricular block, a permanent complete heart block, or a sinoatrial block
- If a patient is not responding or experiencing any beneficial effects of Namuscla therapy.

Increased risk of adverse reactions due to reduced mexiletine clearance in those with hepatic dysfunction

Hepatic dysfunction may reduce the metabolism of mexiletine by the liver and increase the risk of adverse reactions.
Namuscla should be used with caution in patients with mild or moderate hepatic impairment; the dose for these patients should only be increased after at least 2 weeks of treatment.
Experience with Namuscla in patients with severe hepatic impairment is limited, hence Namuscla should not be used in patients with severe hepatic impairment.

Patient counselling

Before starting treatment with Namuscla, healthcare professionals should:

- Discuss the risk of cardiac arrhythmias with patients and tell them to seek urgent medical attention if they experience any symptoms of an arrhythmia including palpitations, chest pain, light headedness, shortness of breath and syncope;
- Tell patients to inform their healthcare provider if they develop any new medical problems including hepatic dysfunction and cardiac disease or if they start any new medication;
- Complete their name and contact details on the patient alert card and give it to the patient.

Reporting adverse reactions

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse reactions should also be reported to Lupin via email to: EU-PV@lupin.com or by phone 01565 751378.