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Namuscla (*mexiletine)*

An overview of Namuscla and why it is authorised in the EU

What is Namuscla and what is it used for?

Namuscla is a medicine used to treat symptoms of myotonia (muscle stiffness) in patients with non-dystrophic myotonic disorders, a group of inherited muscle disorders. Non-dystrophic means no muscle wasting occurs in patients affected by the condition.

Patients with non-dystrophic myotonic disorders experience muscle stiffness and pain because their muscles are slow to relax after contraction.

Myotonic disorders are rare, and Namuscla was designated an 'orphan medicine' (a medicine used in rare diseases) on 19 November 2014. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/EU3141353.

How is Namuscla used?

Namuscla is available as capsules to be taken by mouth. The recommended starting dose is 1 capsule a day. The dose can be increased up to 3 capsules a day, depending on the intensity of the symptoms and how the patient responds to treatment. Patients should have tests to check how well their heart is working before beginning treatment and regularly during treatment.

Namuscla can only be obtained with a prescription. For more information about using Namuscla, see the package leaflet or contact your doctor or pharmacist.

How does Namuscla work?

The active substance in Namuscla, mexiletine, works by blocking channels in muscle cells that allow sodium ions (electrically charged particles) to pass in and out. These sodium channels play a role in the contraction and relaxation of muscles and are hyperactive in patients with myotonic disorders, causing excessive contractions and stiffness. By blocking them, the medicine helps to reduce the stiffness that occurs when the contractions are prolonged.

Because it has a similar effect on the heart muscle, mexiletine has also been used for many years in patients with abnormal heart rhythm.

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What benefits of Namuscla have been shown in studies?

In one study involving 25 patients with non-dystrophic myotonia, Namuscla was shown to be more effective than placebo (a dummy treatment) at reducing muscle stiffness.

Muscle stiffness was self-assessed by each patient before and after treatment, and scored on a scale running from 0 to 100 (most severe). After 18 days of treatment, the average score for patients treated with Namuscla decreased from 66 to 24, while the score for patients given placebo went from 75 to 66.

The company also provided supportive data on the effectiveness of Namuscla from the literature.

What are the risks associated with Namuscla?

The most common side effects with Namuscla (which may affect more than 1 in 10 people) are abdominal (belly) pain and insomnia (difficulty sleeping). The most serious side effects reported (which may affect up to 1 in 10,000 people) are arrhythmias (disturbances of heart rhythm) and a severe reaction affecting skin, blood and internal organs, known as drug reaction with eosinophilia and systemic symptoms (DRESS). For the full list of side effects of Namuscla, see the package leaflet.

Namuscla must not be used in patients who are hypersensitive (allergic) to the active substance, mexiletine, to any other ingredients of the medicine, or to local anaesthetics (medicines that block out sensation used to prevent pain in a part of the body). Namuscla must also not be used in patients with various heart problems, or together with certain medicines. For the full list of restrictions, see the package leaflet.

Why is Namuscla authorised in the EU?

Namuscla was shown to be effective at easing the symptoms of myotonia in patients with non-dystrophic myotonic disorders, thus improving their quality of life. The safety profile of Namuscla is well known and its side effects affecting the heart are considered to be manageable with restrictions in use and monitoring during treatment.

The European Medicines Agency therefore decided that Namuscla's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Namuscla?

The company that markets Namuscla will provide educational material for doctors and a 'patient alert card' with important information about the risks associated with the medicine, in particular the risk of arrhythmias.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Namuscla have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Namuscla are continuously monitored. Side effects reported with Namuscla are carefully evaluated and any necessary action taken to protect patients.

Other information about Namuscla

Namuscla received a marketing authorisation valid throughout the EU on 18 December 2018.

Further information on Namuscla can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Namuscla.

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