



Medicine: mexiletine hydrochloride (brand name: Namuscla®)

Resubmission

Lupin Healthcare (UK) Ltd

The Scottish Medicines Consortium (SMC) has assessed mexiletine hydrochloride to treat the symptoms of myotonia (muscle stiffness) in adults with non-dystrophic myotonic disorders (a group of conditions that affect muscle function but do not cause wasting of the muscles). This document summarises the SMC decision and what it means for patients.

What has SMC said?

After careful consideration, SMC has accepted mexiletine hydrochloride to treat the symptoms of myotonia as described above.

This SMC advice takes into account a confidential discount offered by the pharmaceutical company that improves the cost-effectiveness of mexiletine hydrochloride. In addition, SMC was able to apply a more [flexible approach*](#) in the assessment, as it is for a rare condition.

What does SMC's decision mean for patients?

If your healthcare professional thinks that mexiletine hydrochloride for use as described above is the right medicine for you, you should be able to have the treatment on the NHS in Scotland.



What is mexiletine hydrochloride used for?

Mexiletine hydrochloride is for treating the symptoms of myotonia (when muscles relax slowly and with difficulty after they are used) in adult patients who have a non-dystrophic myotonic disorder. Non-dystrophic myotonic disorders are rare, conditions caused by a malfunction of muscle ion channels. They cause muscle stiffness, pain, weakness and fatigue, which can reduce mobility and affect patients' ability to perform daily activities.

How does mexiletine hydrochloride work?

Patients with myotonia have hyperactive sodium channels in their muscle cells, causing excessive contractions and muscle stiffness. Mexiletine hydrochloride works by blocking these channels helping to reduce muscle stiffness and the symptoms that come from it.

*<https://www.scottishmedicines.org.uk/how-we-decide/pace/>

How does SMC make its decision?

SMC carefully considers every new medicine to make sure it benefits patients and is considered to be an acceptable use of the limited resources in NHSScotland.

To do this SMC considers the following:

- Evidence from the company about how well the medicine works compared with current treatments available in Scotland, in relation to how much they will cost to buy and administer.
- Information from patient groups about the potential impact of the medicine on patients and carers.
- Advice from healthcare professionals about any benefits of the new medicine compared to current treatment, along with how the new medicine is likely to be used.

When SMC assesses a medicine it takes account of the needs of all patients in NHSScotland, not just those who may be treated with the medicine under consideration.

You can find more detailed information about the SMC assessment of mexiletine hydrochloride by looking at the SMC Detailed Advice Document (SMC2307).

More information

The organisation below can provide more information and support for people with non-dystrophic myotonic disorders and their families. SMC is not responsible for the content of any information provided by external organisations.

Muscular Dystrophy UK



<https://www.muscular dystrophyuk.org>



0800 652 6352

You can find out more about mexiletine hydrochloride (Namuscla®) in the European public assessment report (EPAR) summary for the public by searching for the medicine name on the European Medicines Agency (EMA) website.



<http://www.ema.europa.eu>