Package leaflet: Information for the patient

Namuscla 167 mg hard capsules
mexiletine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

There is an **Alert Card** distributed with Namuscla, to remind you and medical staff of the risk of cardiac arrythmias. **Read the Alert Card in conjunction with this leaflet and keep the card with you at all times**.

What is in this leaflet

1. What Namuscla is and what it is used for
2. What you need to know before you take Namuscla
3. How to take Namuscla
4. Possible side effects
5. How to store Namuscla
6. Contents of the pack and other information

1. What Namuscla is and what it is used for

Namuscla is a medicine that contains the active substance mexiletine.

Namuscla is used to treat the symptoms of myotonia (when muscles relax slowly and with difficulty after they are used) in children aged 6 to 11 years weighing at least 20 kg, adolescents aged 12 to 17 years and adult patients ages 18 years and above with non-dystrophic myotonic disorders, which are caused by genetic defects that affect muscle function. Namuscla improves the symptoms of muscle stiffness and helps the patient to perform their daily activities.

2. What you need to know before you take Namuscla

Do not take Namuscla
- if you are allergic to mexiletine or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to any local anaesthetic
- if you have had a heart attack
- if your heart does not work well enough
- if you have a heart condition that makes it beat irregularly
- if your heart beats too fast
- if the blood vessels of your heart are damaged
- if you also take certain medicines to treat heart rhythm disorders (see Other medicines and Namuscla)
- if you also take certain medicines which have a narrow therapeutic window (see Other medicines and Namuscla).

If you have any doubt, ask your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Namuscla if you have:
- heart problems
- liver problems
- kidney problems
- low or high potassium blood levels
- low magnesium blood levels
- epilepsy

Heart function
Before starting treatment with Namuscla, you will have tests to check how well your heart is working, including ECG (Electrocardiogram). These tests will also be performed regularly during treatment with Namuscla, and before and after your dose of Namuscla is modified. How often these tests will be performed depends on your heart function.
If you or your doctor detects any heart rhythm disturbances or any of the conditions stated in section "Do not take Namuscla", your doctor will stop your treatment with Namuscla.

If you notice that the rhythm of your heart changes (the heart beats faster or slower), if you feel fluttering or pain in your chest, if you have difficulty breathing, if you feel dizzy, if you sweat or if you faint, you have to **contact an emergency centre immediately**.

Some patients may have higher blood levels of Namuscla because of slower break down in the liver and the dose may need to be adjusted accordingly.

Your doctor may measure your potassium and magnesium levels in the blood before starting and during treatment with Namuscla.

Drug reaction with eosinophilia and systemic symptoms (DRESS)
If you are hypersensitive to mexiletine or any other ingredients of this medicine or to any local anaesthetic do not take Namuscla and contact your doctor immediately. Symptoms of hypersensitivity and DRESS include fever, skin rash and blisters, swollen face and swollen lymph glands.

Children under 6 years of age
Namuscla should not be used in children under 6 years of age or weighing below 20 kg since no clinical studies have been carried out in this age group.

Other medicines and Namuscla
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Namuscla with certain medicines for treating heart rhythm disorders (quinidine, procainamide, disopyramide, ajmaline, encainide, flecainide, propafenone, moricizine, amiodarone, sotalol, ibutilide, dofetilide, dronedarone, vernakalant). See section "Do not take Namuscla". Taking Namuscla together with any of these medicines increases the risk of a serious heart rhythm disturbance called torsades de pointes.

Do not take Namuscla with certain medicines which have a so called narrow therapeutic window (these are medicines where small differences in dose or blood concentration may impact the effect of the medicine or side effects). Examples of such medicines are digoxin (for heart problems), lithium (mood stabiliser), phenytoin (for treating epilepsy), theophylline (for asthma) and warfarin (to prevent blood clots).

Tell your doctor or pharmacist if you are taking any of the following as these medicines may affect or be affected by Namuscla:
- medicines for heart problems (lidocaine, tocainide, propranolol, esmolol, metoprolol, atenolol, carvedilol, bisoprolol, nebivolol, verapamil, diltiazem),
- certain other medicines:
    - timolol for treating high pressure in the eye (glaucoma),

- certain antibiotics (ciprofloxacin, rifampicin),
- certain antidepressants (fluvoxamine),
- tizanidine (used to relax the muscles),
- metformin (used against diabetes)
- omeprazole (to treat stomach ulcer and gastric acid reflux).

Smoking and Namuscla
Tell your doctor or pharmacist if you start to smoke or quit smoking while taking Namuscla. This is because smoking impacts the Namuscla blood levels and your dose may need to be adjusted accordingly.

Namuscla with drink
It is recommended to reduce your caffeine intake by half while on treatment with mexiletine because the medicine can increase caffeine levels in your blood.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. If you become pregnant while taking Namuscla, see your doctor immediately as it is preferable not to take Namuscla while you are pregnant.

Mexiletine passes into human milk. You should talk to your doctor about this. Together you will make a decision whether to abstain breast-feeding or to discontinue/abstain from mexiletine therapy.

Driving and using machines

Namuscla may cause tiredness, confusion and blurred vision. If you have these effects do not drive, cycle and use machines.

3. How to take Namuscla

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults from 18 years of age and above

The recommended starting dose is 1 capsule per day. The doctor will increase the dose gradually depending on how well the medicine is working. The maintenance dose is 1 to 3 capsules daily taken at regular intervals throughout the day, as recommended.

Do not take more than 3 capsules a day.

Children and adolescents (from 6 to 17 years of age)
In children from 6 years of age and adolescents, the recommended dose depends on body weight (Table 1):

Table 1: Recommended doses in paediatric patients

Body weight (kg)	Once daily (morning)	Twice daily (morning and evening)	Three times daily (morning, afternoon and evening)	Maximum total daily dose
20-30 kg	62 mg (1 x 62 mg)	124 mg (2 x 62 mg)	186 mg (3 x 62 mg)	≈187 mg/day

30-40 kg	83 mg (1 x 83 mg)	166 mg (2 x 83 mg)	249 mg (3 x 83 mg) Alternative: 248 mg (4 × 62 mg)	≈250 mg/day
40-60 kg	124 mg (2 x 62 mg)	248 mg (4 x 62 mg)	372 mg (6 x 62 mg)	≈375 mg/day
≥ 60 kg	167 mg (1 x 167 mg or 2 x 83 mg)	334 mg (2 x 167 mg or 4 x 83 mg)	501 mg (3 x 167 mg or 6 x 83 mg)	≈500 mg/day

Your doctor will also regularly reassess your treatment to make sure Namuscla is still the best medicine for you.

Method of administration
Namuscla is for oral use.

Swallow the whole capsule with a glass of water, while standing or sitting up. You may take Namuscla during a meal to avoid belly pain (see section 4 "Possible side effects").

Namuscla capsules should not be opened or administered via feeding tube. Talk to your doctor if you have difficulty swallowing this medicine.

If you take more Namuscla than you should
Contact your doctor if you take more than the recommended dose of Namuscla. This could be very harmful to your health. You or your companion should contact the doctor immediately if you have tingling in the arms and legs, if you feel unable to think clearly or concentrate, if you have hallucinations, convulsions, if you feel that your heart beats slower, if you feel dizzy and faint, if you collapse or if your heart stops beating.

If you forget to take Namuscla
If you have forgotten a dose, do not take a double dose. Just take the next dose at your regular time.

If you have further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most serious side effects are:
Contact your doctor or go to your nearest emergency centre **immediately** if you experience any of the following side effects:

- Stevens-Johnson syndrome (SJS): a severe allergic reaction with skin rashes, often in the form of blisters and sores in the mouth and eyes and other mucous membranes. This side effect has a frequency that is not known (cannot be estimated from available data).
- a condition called DRESS with blisters of the skin and feeling unwell with fever. This is a very rare side effect and may affect up to 1 in 10 000 people.
- arrhythmia and other disorders of the heart rhythm (atrioventricular block, rapid heart rate, ventricular fibrillation). These are common side effects, may affect up to 1 in 10 people, see section "Warnings and precautions" for symptoms and more information.

- severe allergy to mexiletine (with symptoms such as severe rash with fever); this is a very rare side effect, may affect up to 1 in 10 000 people.

Other side effects that may occur:
Very common side effects (may affect more than 1 in 10 people)
- Abdominal (belly) pain
- Insomnia (difficulty sleeping)

Common side effects (may affect up to 1 in 10 people)
- Somnolence (sleepiness)
- Headache
- Tingling in the arms and legs
- Blurred vision
- Vertigo (sensation of feeling off balance)
- Rapid heart rate
- Flushing
- Low blood pressure (which can cause dizziness and feeling faint)
- Nausea (feeling sick)
- Acne
- Pain in the arms and legs
- Tiredness
- Weakness
- Chest discomfort
- Malaise (a feeling of general discomfort and illness)

Uncommon side effects (may affect up to 1 in 100 people)
- Convulsions (fits)
- Speech disorders
- Slow heart rate

Rare side effects (may affect up to 1 in 1 000 people)
- Abnormal functioning of the liver (observed after blood analysis).

Very rare side effects (may affect up to 1 in 10 000 people)
- Liver injury including inflammation (hepatitis)

Not known (frequency cannot be estimated from the available data)
- Decrease in white blood cells or in platelets
- Lupus syndrome (disease of the immune system)
- Redness and peeling of the skin

- Hallucinations (seeing or hearing something that is not present).
- Transient confusion (a temporary inability to think clearly or concentrate)
- Double vision
- Altered sense of taste

- Collapse
- Hot flushes
- Pulmonary fibrosis (disease of the lung)
- Diarrhoea
- Vomiting
- Injury of the oesophagus (food pipe)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Namuscla

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Store below 30 °C. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Namuscla contains
Each hard capsule contains:
- mexiletine hydrochloride corresponding to 166.62 mg of mexiletine (active substance)
- Other ingredients (maize starch, colloidal anhydrous silica, magnesium stearate, gelatin, iron (III) oxide [E 172], titanium dioxide [E 171]).

What Namuscla looks like and contents of the pack
Namuscla hard capsules are reddish orange hard gelatin capsules filled with white powder.
Namuscla is available in blister packs containing 30, 50, 100 or 200 capsules in a carton.

Not all pack sizes may be marketed.

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This leaflet was last revised in July 2026.