

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 center **immediately** if you experience any of the following side effects:

- 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.
- disorders of heart rhythm, see section “Warnings and precautions” for symptoms and more information; this is a common side effect, may affect up to 1 in 10 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)
- Severe reaction to the medicine (with rash and fever)

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
- Stevens-Johnson syndrome: a severe allergic reaction with skin rashes, often in the form of blisters and sores in the mouth and eyes, and other mucous membranes
- Blisters of the skin, malaise and fever in the context of a condition called DRESS
- 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
- Disorders of heart rhythm
- 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 the Yellow Card Scheme Website: 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. 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 oxide [E 172], titanium dioxide [E 171]).

What Namuscla looks like and contents of the pack

Namuscla hard capsules are reddish hard gelatin capsules filled with white powder. Namuscla is available in blister packs containing 30, 50, 100 or 200 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

Hormosan Pharma GmbH
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Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>.