

PACKAGE LEAFLET

Package leaflet: Information for the patient

Mexiletine hydrochloride 100 mg hard capsules Mexiletine hydrochloride 200 mg hard capsules mexiletine hydrochloride

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.

The name of your product is Mexiletine hydrochloride 100 mg or 200 mg hard capsules, but it will be referred to as Mexiletine hard capsules throughout this leaflet.

There is an **Alert Card** distributed with Mexiletine hard capsules, to remind you and medical staff of the risk of cardiac arrhythmias. **Read the Alert Card and keep the card with you at all times.**

What is in this leaflet

1. What Mexiletine hard capsules are and what they are used for
2. What you need to know before you take Mexiletine hard capsules
3. How to take Mexiletine hard capsules
4. Possible side effects
5. How to store Mexiletine hard capsules
6. Contents of the pack and other Information

1. What Mexiletine hard capsules are and what they are used for

Mexiletine hard capsules is a medicine that contains the active substance mexiletine hydrochloride. Mexiletine hard capsules are indicated for the documented irregular heartbeat which, in the judgement of the physician, is considered as life-threatening.

2. What you need to know before you take Mexiletine hard capsules

Do not take Mexiletine hard capsules

- If you are allergic to mexiletine hydrochloride or any of the other ingredients of this medicine (listed in Section 6).
- If you are allergic to any local anaesthetics (drugs or agents used to decrease the feeling of pain or by numbing an area of your body, without putting you to sleep).
- If you have a heart rhythm disorder called “sinus syndrome” (unless you have a pacemaker fitted).
- If you have any other heart problems which may cause slow heartbeat and do **not** have a pacemaker fitted.
- If you suffer from severe heart failure (including cardiac shock, which can cause shortness of breath, ankle swelling, or sudden heart rhythm disorders).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Mexiletine hard capsules:

- If you have heart problems
- If you have liver problems
- If you have kidney problems
- If you know you have low or high electrolyte blood levels

- If you suffer from seizures (fits)
- If you know you have abnormal blood counts
- If you have been told that you have a genetic problem with an enzyme in your body called CYP2D6 which breaks down (metabolizes) certain medicines in your body too slowly, because a different dose may be applicable to you.

Children and adolescents

Mexiletine hard capsules should not be used in children and adolescents younger than 18 years old.

Other medicines and Mexiletine hard capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor or pharmacist if you are taking any of the following since these medicines may affect or be affected by Mexiletine hard capsules:

- Medicines for heart problems (quinidine, procainamide, disopyramide, ajmaline, encainide, flecainide, propafenone, moricizine, amiodarone, sotalol, ibutilide, dofetilide, dronedarone, vernakalant, lidocaine, tocainide, propranolol, esmolol, timolol, metoprolol, atenolol, carvedilol, bisoprolol, nebivolol, verapamil, diltiazem, propafenone, quinidine, dofetilide)
- Certain other medicines
 - Opioids (for the treatment of severe pain)
 - Antacids (for the relief of the symptoms of gastroesophageal reflux disease)
 - Atropine (to treat certain types of nerve agent and pesticide poisonings)
 - Metoclopramide (to prevent and treat nausea and vomiting)
 - Drugs that make urine more or less acid
 - Ciprofloxacin (for bacterial infections)
 - Fluvoxamine (antidepressant)
 - Omeprazole (for the treatment of stomach ulcer and gastric acid reflux)
 - Phenytoin (used to treat fits)
 - Rifampicin (for several types of bacterial infections)
 - Theophylline (for treating asthma)
 - Caffeine
 - Tizanidine (muscle relaxant)
 - Metformin (used to treat diabetes)
 - Warfarin (used to treat and prevent blood clots)

Mexiletine hard capsules with cigarette smoking

Tell your doctor or pharmacist if you start to smoke or quit smoking while taking Mexiletine hard capsules because smoking impacts the Mexiletine blood levels and your dose may need to be adjusted accordingly.

Mexiletine hard capsules with food, drink and alcohol

It is recommended to take mexiletine after food in order to reduce the incidence of gastrointestinal adverse effects.

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.

Limit the amount of alcohol you drink while taking this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking any medicine.

As a precautionary measure, it is preferable to avoid the use of mexiletine during pregnancy.

Mexiletine appears in human milk, if your doctor decides to give you mexiletine you will need to consider an alternative method of feeding your baby.

The effects of mexiletine on fertility in humans have not been studied.

Driving and using machines

This medicine can affect your ability to drive and operate machinery. Do not drive or operate machinery while taking this medicine, until you know how it affects you. Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Mexiletine hard capsules contain sodium

These medicines contain less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Mexiletine hard capsules

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

Your doctor may ask you to start therapy with a dose of 400 mg (2 capsules of 200 mg).

The maintenance dose is 150 mg (1 capsule of 50 mg plus 1 capsule of 100 mg) to 300 mg (1 capsule of 100 mg plus 1 capsule of 200 mg) given two to three times daily.

If necessary, dose may be adjusted in 50 or 100 mg increments. A minimum of two to three days between dose adjustments is recommended.

The dose should not exceed 1200 mg per day (6 capsules of 200 mg).

In some cases, your doctor may then decide to either increase or lower the amount you take each day. This will depend on how you react to this medicine.

Use in children and adolescents

Mexiletine hard capsules should not be given to children and adolescents.

Use in patients with liver problems

Mexiletine should be used with caution in patients with mild or moderate liver dysfunction. In those patients, a minimum of two weeks between dose adjustments is recommended. Mexiletine should not be used in patients with severe liver disease.

Use in patients with kidney problems

In patients with mild-to-moderate kidney disease no adjustment of the starting dose is required. Mexiletine should not be used in patients with severe kidney disease.

Use in patients with poor metabolism (poor CYP2D6 metabolisers)

Dose adjustments may be needed if you have a genetic problem with an enzyme in your body called CYP2D6. A minimum of one week between dose adjustments is recommended.

If you take more Mexiletine hard capsules than you should

Contact your doctor if you take more than the recommended dose of Mexiletine hard capsules. This could be very harmful to your health. You or your companion should contact the doctor immediately if you have nausea, hypotension (low blood pressure), bradycardia (slow heartbeat), paraesthesia (tingling of the extremities), if you have hallucinations (seeing or hearing something that is not present), convulsions (fits), if you feel that your heart beats irregularly (slower or faster), if you collapse or if your heart stops beating.

If you forget to take Mexiletine hard capsules

Take the next dose as soon as you remember unless it is almost time for your next dose.

Do not take a double dose to make up for a forgotten dose.

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

If you stop taking Mexiletine hard capsules

If you suddenly stop taking Mexiletine you may experience side effects. Speak to your doctor first before stopping this medicine. If you have any 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:

- 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 (with symptoms such as: faster or slower heart beats, feeling fluttering or pain in your chest, difficulty in breathing, dizziness, sweating or fainting); this is a common side effect, may affect up to 1 in 10 people.

Other side effects that may occur:

Contact your doctor or pharmacist if you experience any of the following side effects:

Very common side effects (may affect more than 1 in 10 people):

- Abdominal (belly) pain
- Dyspepsia (difficulty to digest)
- Insomnia (difficulty sleeping)
- Dizziness
- Involuntary shaking (tremor)

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)
- Numbness
- Ringing in the ears (tinnitus)
- Rapid heart rate
- Palpitations (when you feel your heart beating)
- Chest pain (angina pain)
- Abnormal heart rhythm (atrial fibrillation)
- Flushing
- Low blood pressure (which can cause dizziness and feeling faint)
- Nausea (feeling sick)

- Constipation (decreased number of or difficulty making bowel movements)
- Dry mouth
- Acne
- Pain in the arms and legs
- Tiredness
- Weakness
- Chest discomfort
- Malaise (a feeling of general discomfort and illness)
- Rash
- Ataxia (difficulty in coordinating your movements)

Uncommon side effects (may affect up to 1 in 100 people):

- Convulsions (fits)
- Speech disorders
- Slow heart rate
- Memory loss (amnesia)
- Lost consciousness
- Hiccups
- Loss of hair (alopecia)
- Joint pain (arthralgia)
- Dry skin
- Abnormal liver function tests
- Erectile dysfunction (difficulties in getting or keeping an erection)

Rare side effects (may affect up to 1 in 1,000 people):

- Abnormal functioning of the liver (observed after blood analysis)
- Very low white blood cell count (agranulocytosis and neutropenia)
- Heart failure

Very rare side effects (may affect up to 1 in 10,000 people):

- Liver injury including inflammation (hepatitis)
- Blisters of the skin, malaise and fever in the context of a condition called DRESS

Not known (frequency cannot be estimated from the available data):

- Decrease in white blood cells or in platelets
- Lupus like syndrome (an immune system condition)
- 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
- 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 (severe drop in blood pressure)
- Hot flushes
- Pulmonary fibrosis (scarring of the lungs which causes shortness of breath)
- Diarrhoea
- Vomiting
- Injury of the oesophagus

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 Mexiletine hard capsules

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 bottle after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Use within 50 days of opening.

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 Mexiletine hard capsules contain

Mexiletine hydrochloride 100 mg hard capsules

- Each capsule contains 100 mg of the active substance mexiletine hydrochloride, equivalent to 83.10 mg of mexiletine.
- The other ingredients are pregelatinised starch, colloidal anhydrous silica, magnesium stearate.
- Mexiletine hydrochloride 100 mg capsule shell contains: titanium dioxide, FD & C Blue 1, FD & C Red 3, FD & C Red 40, FD & C Yellow 6, gelatin, purified water, SLS.

Mexiletine hydrochloride 200 mg hard capsules

- Each capsule contains 200 mg of the active substance mexiletine hydrochloride, equivalent to 166.20 mg of mexiletine.
- The other ingredients are pregelatinised starch, colloidal anhydrous silica, magnesium stearate.
- Mexiletine hydrochloride 200 mg capsule shell contains: titanium dioxide, FD & C Yellow 6, gelatin, purified water.

What Mexiletine hard capsules look like and contents of the pack

Mexiletine hydrochloride 100 mg hard capsules are white granular powder in a hard gelatin capsule (6.15 mm x 17.80 mm) with a Scarlet opaque cap and an Orange opaque body, imprinted with "A36" on the cap and "100" on the body in white ink.

Mexiletine hydrochloride 200 mg hard capsules are white granular powder in a hard gelatin capsule (6.80 mm x 19.13 mm) with an Orange opaque cap and an Orange opaque body, imprinted with "A28" on the cap and "200" on the body in black ink.

They are packed in HDPE bottles. Each bottle contains 100 capsules.

Pack sizes: 100 hard capsules.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

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Basildon, Essex SS14 3FR
United Kingdom

Manufacturer

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This leaflet was last revised in August 2025

PL 06464/3133 Mexiletine hydrochloride 100 mg hard capsules

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