Mexitil®

Mexiletine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **Mexitil**.

It does not contain all available information.

It does not take the place of talking to your doctor or pharmacist.

Keep this information with your capsules.

You may want to read it again later.

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any concerns about taking Mexitil.

1. What Mexitil is used for

Mexitil is used in the management of irregular heartbeats, a condition known as ventricular arrhythmia.

Mexitil works by reducing the excitability of the heart. This helps return the heartbeat to normal.

Your doctor will have explained why you are being treated with Mexitil and told you what dose to take. Follow these directions carefully, they may differ from the information contained in this leaflet.

2. Before taking Mexitil

2a) When not to take Mexitil

Only take Mexitil if it has been prescribed for you by a doctor.

Never give it to someone else even if their symptoms seem to be the same as yours.

Do not take **Mexitil** if you are allergic to it or to any of the ingredients. These ingredients are listed in full at the end of this leaflet (see 7b ingredients).

If you are uncertain as to whether you have, or have had, any of these allergies you should raise those concerns with your doctor.

Do not take **Mexitil** if you have experienced the following conditions:

- A heart attack within the last 3 months,
- Reduced heart function, known as decreased cardiac output,
- Serious heart conditions, such as cardiogenic shock or atrio-ventricular block,
- An allergic reaction to local anaesthetics, for example lignocaine.

If you are uncertain as to whether you have, or have had, any of these conditions, you should raise those concerns with your doctor.

You should never use **Mexitil** after the EXPIRY DATE on the carton or blister pack has passed.

You should never use **Mexitil** if the packaging is torn or shows signs of tampering.

2b) Before you start taking Mexitil

It is essential that your doctor knows your medical history before prescribing **Mexitil.**

Before taking **Mexitil**, you must tell your doctor if you have, or have had, any of the following conditions:

- Chronic liver disease (known as cirrhosis) or impaired liver function,
- Severe renal disease,
- Low blood pressure,
- Heart failure,
- A heart condition resulting in a slow heartbeat (known as bradycardia),
- Parkinson's disease
- Convulsions, fits or seizures.

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

Before taking **Mexitil** you must tell your doctor if you are taking any other medicines, obtained with or without a doctor's prescription.

In particular you must tell your doctor if you are taking:

- Opiate analgesics, such as morphine,
- Medicines that acidify or alkalise your urine,
- Other medicines used to treat arrhythmias,
- Medicines which are metabolised by the liver,
- Medicine used to prevent blood clots eg warfarin,
- Medicines used to treat asthma eg theophylline.

These medicines may be affected by **Mexitil** or may affect how well **Mexitil** works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking **Mexitil**.

2c) Pregnancy

You must tell your doctor if you are pregnant, or are likely to become pregnant during the course of your medication.

Your doctor will discuss the risks and benefits of taking **Mexitil** when pregnant.

2d) Breastfeeding

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication.

As **Mexitil** enters the breast milk, your doctor may recommend an alternate method of feeding your child.

3. Taking Mexitil

3a) Recommended dose

The dose of **Mexitil** may be different for each person and their medical condition. Your doctor will tell you how many capsules to take. The number of capsules that you take depends on the strength of the medicine.

The initial dose is 400mg of mexiletine. The maintenance dose is usually 200-250mg of mexiletine 3 times daily, commencing 2 hours after the initial dose. The usual daily dose is between 600-800mg in divided doses.

If your doctor has prescribed a different dose, you should ask for further information from your doctor or pharmacist.

3b) If you forget to take a dose

It is important to take **Mexitil** as directed.

If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time.

Do not take a double dose to make up for the dose that you missed.

3c) If you take too much (overdose)

Contact your doctor, pharmacist or Poisons Information Centre (in Australia telephone 13 11 26; in New Zealand telephone 0800 764 766), immediately if you think that you or anyone else may have taken too much Mexitil, even if there are no signs of discomfort or poisoning.

Go to your doctor or Casualty at the nearest hospital immediately if any signs of overdose are experienced.

In addition to the symptoms listed under **Side effects**, cardiac arrest and convulsions may occur as a result of severe overdose.

4. While you are taking Mexitil

4a) Things to be careful of

Avoid consuming alcohol while taking Mexitil.

In case of doubt, seek medical advice prior to taking this medicine.

4b) Effects on ability to drive or operate machinery

Be careful driving or operating machinery until you know how Mexitil affects you.

Mexitil may cause dizziness or drowsiness. Make sure you know how you react to **Mexitil** before you drive a car, operate machinery, or do anything else that could be dangerous

if you are dizzy or drowsy. If you drink alcohol, dizziness or drowsiness may be worse.

5. Side effects

You should be aware that all prescription medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Your doctor has weighed the risks of you taking **Mexitil** against the benefits they expect it will have for you.

Ask for the advice of your doctor or other medical staff if you have any concerns about the effects of being treated with this medicine.

Tell your doctor immediately if you notice any of the following:

- chest pain
- fast or irregular heart beat,
- shortness of breath
- skin rash associated with any of the above mentioned symptoms and/or fever
- convulsions (seizures).

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Tell your doctor if you notice any of the following side effects and they worry you:

- dizziness or lightheadedness
- heart burn which is a burning sensation in the chest rising up to the throat
- indigestion
- nausea and vomiting
- constipation or diarrhoea
- shaking of the hands
- unsteadiness when walking
- blurred vision
- headache
- numbness or tingling of fingers and toes
- skin rash or skin reactions
- slurred speech
- unpleasant taste
- confusion
- sleepiness
- rapid, uncontrollable movements of the eyes
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- seeing, feeling or hearing things that are not there
- breathlessness, which may be very severe
- hot flush.

Tell your doctor as soon as possible if you experience any side effects during or after treatment with Mexitil, so that these may be properly treated.

In addition, unexpected effects, not listed above, can occur with any medicine.

You should tell your doctor if you notice anything unusual, during or after treatment with Mexitil.

6. After taking Mexitil

6a) Storage

Leave all capsules in the blister pack until it is time to take a dose.

The blister packaging protects the capsules.

Mexitil should be kept in a cool, dry place where the temperature stays below 30°C.

For example, do not leave your capsules in a car or store them in the bathroom. Heat and dampness will damage the capsules.

Keep **Mexitil** capsules where children cannot reach them.

6b) Disposal

If your doctor tells you to stop taking **Mexitil,** the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

7. Product Description

7a) What the capsules look like

Mexitil is the brand name of the capsules prescribed for you by your doctor. There are two different strengths.

Mexitil M 50 Capsules: Red/purple hard gelatin capsule, imprinted with '50mg' and the company symbol. Available in packs of 100 capsules.

Registered in Australia as AUST R 17933.

Mexitil 200mg Capsules: Red/red hard gelatin capsule, imprinted with '200mg' and the company symbol. Available in packs of 100 capsules.

Registered in Australia as AUST R 17931.

7b) Ingredients

The active ingredient in **Mexitil** capsules is mexiletine hydrochloride.

Mexitil M 50 contains maize starch, silica, magnesium stearate, gelatin, indigo carmine CI73015, erythrosine CI45430, iron oxide black CI77499 and titanium dioxide.

Mexitil 200mg contains maize starch, silica, magnesium stearate, gelatin, indigo carmine CI73015, erythrosine CI45430 and titanium dioxide.

7c) Manufacturer

Mexitil is made in Germany and supplied in Australia by:

Boehringer Ingelheim Pty Limited
(ABN 52 000 452 308)
85 Waterloo Road
NORTH RYDE NSW 2113

Mexitil is marketed in New Zealand by:

Boehringer Ingelheim (N.Z.) Limited
Auckland

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