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Patient Information Leaflet

Mexitil® Capsules 50 mg & 200 mg

(mexiletine hydrochloride)



Boehringer
Ingelheim

Please read this leaflet carefully. It contains a summary of the information available on your medicine. The information in the leaflet applies to MEXITIL Capsules 50 mg and 200 mg only. If after reading this you have any questions ask your doctor or pharmacist.

What is your medicine called?

The name of your medicine is MEXITIL Capsules 50 mg or MEXITIL Capsules 200 mg.

What does your medicine contain?

There are two strengths of this medicine available:

The 50 mg capsules (coloured red and purple), contain 50 mg of mexiletine hydrochloride (equivalent to 41.5 mg of mexiletine) as the active ingredient.

The 200 mg capsules (coloured red), contain 200 mg of mexiletine hydrochloride (equivalent to 166.2 mg of mexiletine) as the active ingredient.

The capsules also contain the following inactive ingredients:

50 mg capsules: Maize starch, colloidal silica, magnesium stearate, gelatin, erythrosine (E127), indigo carmine (E132), titanium dioxide (E171) and black iron oxide (E172).

200 mg capsules: Maize starch, colloidal silica, magnesium stearate, gelatin, erythrosine (E127), indigo carmine (E132) and titanium dioxide (E171).

This medicine is available in blister packs of 100 capsules.

What are MEXITIL Capsules 50 mg & 200 mg?

These capsules belong to a group of medicines called anti-arrhythmics which help to correct an abnormal heart rhythm.

The Product Licence and Product Authorisation for this medicine are held by:

Boehringer Ingelheim Limited,
Ellesfield Avenue,
Bracknell, Berkshire,
United Kingdom
RG12 8YS

and the capsules are manufactured at:

Boehringer Ingelheim Pharma GmbH & Co. KG
Birkendorfer Strasse 65
88397 Biberach an der Riss
Germany

How MEXITIL Capsules 50 mg & 200 mg help you

This medicine is taken by patients to treat a serious abnormal heart rhythm.

Before taking MEXITIL Capsules 50 mg & 200 mg

Do not take this medicine if:

- You are allergic to the active ingredient mexiletine hydrochloride or any other ingredient in this product
- You have had a heart attack within the past 3 months or you suffer from any other heart problems
- You are allergic to local anaesthetics

Take special care when taking this medicine if:

- You suffer from liver or kidney disease.

Your doctor may monitor your progress whilst on treatment.

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- You suffer from liver or kidney disease.

Your doctor may monitor your progress whilst on treatment.

Pregnancy and breast-feeding

Tell your doctor or pharmacist if you are pregnant, planning to become pregnant or if you are breast-feeding.

Driving and using machinery

This medicine may occasionally cause drowsiness, which can be made worse by alcohol. If affected do not drive or operate machinery and avoid alcohol.

Taking other medicines

As MEXITIL Capsules 50 mg & 200 mg may affect or be affected by other medicines, please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, even those not prescribed, in particular: strong painkillers (e.g. narcotic analgesics), antacids (indigestion remedies), metoclopramide, rifampicin, phenytoin, phenobarbitone, theophylline, warfarin or local anaesthetics.

Your medicine may also be affected by caffeine-containing beverages such as tea or coffee and other medicines which alter the pH (acidity or alkalinity) of the urine, for example antacids (indigestion remedies), citrates and vitamin C preparations (which contain ascorbic acid).

If in doubt ask your doctor or pharmacist.

How to take MEXITIL Capsules 50 mg & 200 mg

Follow your doctor's instructions about when and how to take your medicine and always read the label.

The capsules should be swallowed whole, with a good cupful of water, preferably after food.

The usual recommended dosage is as follows:

A single starting dose of 400 mg followed two hours later by a maintenance dose of 200-250 mg which is then given three to four times daily.

Your doctor will monitor your condition regularly throughout your treatment with this medicine, and will adjust the dose to suit your needs.

If you forget to take a dose, take it as soon as you remember, then carry on as before.

If you accidentally take too many capsules, you should get medical help immediately either by calling your doctor or by going to the nearest hospital accident and emergency department. Always take the labelled medicine container with you whether or not there are any capsules left.

Changing from MEXITIL Capsules 50 mg & 200 mg to MEXITIL PERLONGETS

Take the first PERLONGET in the evening, in place of the last capsule.

Or

Take the first PERLONGET in the morning with the capsule. Do not take any more capsules after this.

After Taking MEXITIL Capsules 50 & 200 mg

All medicines can cause side-effects. This medicine can cause the following side-effects:

1. Side-effects associated with the stomach and intestines:

Nausea (feeling sick), vomiting, indigestion, constipation, diarrhoea, dry mouth, unpleasant taste and hiccoughs. Ulceration of the oesophagus (tube which passes from the mouth to the stomach) may occur if the capsules are swallowed without enough water.

2. Side-effects associated with the central nervous system:

Drowsiness, dizziness, diplopia (double vision), blurred vision, nystagmus (rapid, involuntary movement of the eyes), dysarthria (problems with speech), ataxia (uncoordinated movements affecting posture)

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2. Side-effects associated with the central nervous system:

Drowsiness, dizziness, diplopia (double vision), blurred vision, nystagmus (rapid, involuntary movement of the eyes), dysarthria (problems with speech), ataxia (uncoordinated movements affecting posture), tremor, paraesthesia (pins and needles), convulsion, mental disorders, confusion, insomnia (difficulty sleeping).

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3. Side-effects associated with the heart:

Hypotension (low blood pressure), sinus bradycardia (slowing of the heart rate), atrial fibrillation (irregular heart rate), palpitations, conduction defects (problems with the heart rhythm), worsening of abnormal heart beat, pre-existing heart failure, and torsade de pointes (a heart condition where the heart rate is increased).

4. Other side-effects:

Rash, arthralgia (pain in the joints without swelling), fever, thrombocytopenia (reduction of the number of platelets in the blood sometimes resulting in bruising). Appearance of positive but symptomless antinuclear factor titres (antibodies) have been observed (seen in blood testing). Liver damage and jaundice (yellowing of the skin) have occurred when this medicine has been given.

Rarely, leucopenia (reduction in the white blood cell count seen in blood testing), Stevens-Johnson Syndrome and erythroderma (reddening of the skin) have occurred. Cases of pulmonary infiltrates/interstitial lung disease (inflammation of the lung tissue) and pulmonary fibrosis (thickening and stiffening of the lining of the air sacs of the lungs) have also been reported.

If you experience any of these side-effects and they persist or become troublesome consult your doctor.

If you experience any other side-effects not mentioned above, consult your doctor or pharmacist.

How to store MEXITIL Capsules 50 mg & 200 mg

The capsules should not be used after the expiry date which will be printed on the packaging.

The capsules should be stored below 25°C.

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

This leaflet was written in December 2004.

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