Mysoline® 250mg Tablets
(primidone)

This product is available using the above name but will be referred to as Mysoline throughout the following:

Patient Information Leaflet

Read all of this leaflet carefully before you start using this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1) What Mysoline is and what it is used for
2) Before you use Mysoline
3) How to use Mysoline
4) Possible side effects
5) How to store Mysoline
6) Further information

1) What Mysoline is and what it is used for
Mysoline contains primidone as the active ingredient; this belongs to a group of medicines used to treat seizures. Mysoline is used for the treatment of certain types of epilepsy, seizures (fits) or shaking attacks (essential tremor).

2) Before you use Mysoline
Do not take Mysoline if you:
- are allergic (hypersensitive) to primidone, a substance called phenobarbitone, or to any of the other ingredients of Mysoline (these are listed in Section 6: Further information)
- have porphyria (a rare inherited disorder of metabolism) or anyone in your family has it.

Take special care with Mysoline if you:
- have ever had problems with your breathing, kidneys or liver.
- are pregnant or are trying to become pregnant (see beneath for further information)
- if you go into hospital, tell the medical staff that you are taking Mysoline.
A small number of people being treated with anti-epileptics such as primidone have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is important because some medicines may affect the way Mysoline works, or Mysoline may affect the way other medicines work.
In particular, tell your doctor if you are taking any of the following:
- Other medicines used to treat epilepsy and other types of seizures (such as phenytoin, felbamate, sodium valproate, carbamazepine, ethosuximide, oxcarbazepine, tiagabine, topiramate, zonisamide)
- Anticoagulants to prevent blood clots (such as warfarin)
- Barbiturates (such as sleeping tablets)
- Methadone (used to treat severe pain, cough, or as a substitute for morphine addiction)
- Herbal remedies containing St John’s Wort
- Antibiotics (such as chloramphenicol, metronidazole, doxycycline)
- Antiviral medicines (such as nelfinavir)
- Asthma medicines (such as theophylline, montelukast)
- Hormone containing medicines (such as the oral contraceptive pill)
- Medicines used to treat high blood pressure or heart conditions (such as beta-blockers, digoxin, losartan, nimodipine, quinidine)
- Cyclosporin (used to prevent rejection of an organ transplant and also for other diseases of the body’s immune system)
- Medicines used to treat mental health problems or depression (such as clozapine, lamotrigine, mianserin, tricyclic antidepressants)
- Steroid-containing medicines
- Medicines used to treat cancer (such as cyclophosphamide, etoposide)
- Granisetron (used to treat severe nausea and vomiting)
- Medicines used during an anesthetic for surgery (such as rocuronium, vecuronium)
- Medicines containing morphine, or similar medicines called opiates

Mysoline may increase the toxic effect on the liver of an overdose of paracetamol.

Taking Mysoline with food and drink
Alcohol can react with Mysoline. Ask your doctor for advice if you want to drink alcohol.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine.

The use of Mysoline in pregnancy is associated with an increased risk of abnormalities in babies. Therefore, you must tell your doctor if you are pregnant, or trying to become pregnant because Mysoline has the potential to harm your unborn child.

Pregnant women can have reduced folic acid in their blood whilst taking Mysoline. In addition, the new born child may develop withdrawal symptoms if the mother has taken Mysoline in the late stages of pregnancy. Blood clotting problems have occurred occasionally in children born to women who were previously taking anticonvulsant drugs.
Tell your doctor if you are breast-feeding because Mysoline may cause your baby to be very sleepy.

Driving and using machines
Mysoline can make you feel sleepy. If so, do not drive or operate machinery.

3) How to use Mysoline
Always take Mysoline exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
Swallow the tablets whole with a drink of water.

Mysoline is normally taken twice a day. Try to take your tablets at the same time each day.
Epilepsy
At first, your dose may be as little as 125mg (half a 250mg tablet). This will be adjusted by your doctor until your condition is controlled. Typical maintenance doses are as follows:

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<th>Age group</th>
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Elderly / Patients with low physical strength
Lower doses may be prescribed.

Shaking attacks (Essential tremor)
Your starting dose may be 50mg. This will be adjusted by your doctor until your condition is controlled. The maximum daily dose for shaking attacks (essential tremor) is 750 mg.

If you take more Mysoline than you should
If you take more than your normal dose, contact your doctor or nearest hospital.

If you forget to take Mysoline
If you miss a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Mysoline
Do not stop taking your Mysoline, even if you are feeling well, unless your doctor tells you to. You may have become dependent on Mysoline, and therefore you could get a withdrawal reaction if you stop treatment too quickly. Mysoline treatment should be reduced gradually to prevent this.

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

4) Possible side effects
Like all medicines, Mysoline can cause side effects, although not everybody gets them.

When first taking Mysoline, drowsiness and lack of energy may occur; these usually pass.

There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids.

Common side effects (affecting fewer than 1 in every 10 people)
- disturbances of vision
- dizziness
- jerky movements
- rolling of the eyes.

Uncommon side effects (affecting fewer than 1 in every 100 people)
- nausea and vomiting
- headache
- skin rash.

Rare side effects (affecting fewer than 1 in every 1000 people)
- joint or bone pain
- changes in mood or behaviour.
- severe skin reactions affecting large portions of your body including redness, pain, ulcers, blisters, shedding the outer layer of skin or involvement of lips or the lining of the mouth, nostrils or ears (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome)
- a disease called lupus erythematosus which causes inflammation of various parts of the body including the skin, joints, lungs, kidneys, heart, and liver.
- development of Dupuytren’s contracture (a thickening of fibrous tissue in the palm of the hand that causes one or more fingers to draw back)
- abnormalities of the blood cells; if you notice a pale appearance of your skin, abnormal bleeding or tendency to bruising, fever or sore throat, please consult your doctor
- raised levels of enzymes in your liver.

Do not be alarmed by this list of possible events. You may not have any of them.

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). By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Mysoline
- Keep out of the sight and reach of children.
- Do not store above 25°C. Protect from light and moisture.
- If your doctor tells you to stop taking your tablets, take any tablets you have left back to the pharmacy.
- Do not take your tablets after the expiry date on the container. Take any tablets that are out of date back to the pharmacy.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6) Further Information
What Mysoline contains
Each tablet contains 250 mg of primidone as the active ingredient. It also contains the following inactive ingredients that allow it to be made. These are carmellose calcium, gelatin, magnesium stearate, povidone and stearic acid.

What Mysoline looks like and contents of the pack
The tablets are white round, uncoated tablets. One side of the tablet has the letter ‘M’ either side of a break-line. The other side of the tablet is plain.

Mysoline 250mg Tablets comes in a blister pack of 50 tablets in a carton.

PL 10383/2140 Mysoline 250mg Tablets

Who makes and repackages your medicine?
Your medicine is manufactured by Recipharm Limited, Vale of Bardsley, Ashton-Under-Lyne, Lancashire, OL7 9RR, UK. Procured from within the EU and repackaged by the Product Licence Holder: Primecrown Ltd., 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

Leaflet date: 07.09.2015

Mysoline is a registered trademark of SERB, France.
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- Anticoagulants to prevent blood clots (such as warfarin)

3) How to use Primidone
Always take Primidone exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Swallow the tablets whole with a drink of water.

Primidone is normally taken twice a day. Try to take your tablets at the same time each day.

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Alcohol can react with Primidone. Ask your doctor for advice if you want to drink alcohol.

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PL 10383/2140 Primidone Serb 250mg Tablets POM

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