Mysoline® 250mg Tablets
(primidone)

Your medicine is available using the name Mysoline 250mg Tablets but will be referred to as Mysoline throughout this leaflet. Mysoline Tablets are also available as 50mg strength.

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 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 Mysoline have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

3. How to use Mysoline
Before you 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:

<table>
<thead>
<tr>
<th>Age group</th>
<th>Daily dose (milligrams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults and children over 9 years</td>
<td>750 to 1500</td>
</tr>
<tr>
<td>Children 6 to 9 years</td>
<td>750 to 1000</td>
</tr>
<tr>
<td>Children 2 to 5 years</td>
<td>500 to 750</td>
</tr>
<tr>
<td>Children up to 2 years</td>
<td>250 to 500</td>
</tr>
</tbody>
</table>

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 750mg.

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 anti-epileptic medication, have a history of osteoporosis, or take steroids.

**Common side effects**
- disturbances of vision
- dizziness
- jerky movements
- rolling of the eyes.

**Uncommon side effects**
- nausea and vomiting
- headache
- skin rash.

**Rare side effects**
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 use Mysoline after the expiry date (Exp) printed on the carton and blister labels. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

If your medicine appears to be discoloured or shows any other signs of deterioration, please return to your pharmacist.

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**

The active substance is primidone.

Each tablet contains 250mg of primidone.

The other ingredients are: carmellose calcium, gelatin, magnesium stearate, povidone, stearic acid and purified water.

**What Mysoline looks like and contents of the pack**

Mysoline are white, round, uncoated tablets embossed with a ‘M’ on each side of a break line on one side and plain on the reverse. The tablet can be divided into equal halves.

Mysoline is available in packs of 60 or 100 tablets.

**Manufacturer:**

Manufactured by: Allphamed PHARBIL Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Gottingen, Germany.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster DN3 1QR.

Product Licence holder: Landmark Pharma Ltd., 7 Regents Drive, Prudhoe, Northumberland, NE42 6PX

PL No: 21828/0552 POM

Leaflet revision and issue date (Ref): 09.06.16

Mysoline® is a registered trademark of SERB.

To listen to or request a copy of this leaflet in Braille, large print or audio, please call 01302 365000 and ask for the Regulatory Department.
Your medicine is available using the name Primidone Serb 250mg Tablets but will be referred to as Primidone throughout this leaflet. Primidone Tablets are also available as 50mg strength.

Read all of this leaflet carefully before you start using this medicine.

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your doctor or pharmacist.
3. 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.
4. 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 Primidone is and what it is used for
2. Before you use Primidone
3. How to use Primidone
4. Possible side effects
5. How to store Primidone
6. Further information

1. What Primidone is and what it is used for

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

2. Before you use Primidone

Do not take Primidone if you:

- are allergic (hypersensitive) to primidone, a substance called phenobarbital, or to any of the other ingredients of Primidone (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 Primidone 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 Primidone.

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.

3. How to use Primidone

Before using Primidone, read the information leaflet that comes with your medicine or talk to your doctor or pharmacist. It contains information which is specific for your condition. If you are pregnant or planning to become pregnant, you should ask your doctor or pharmacist for further information.

Primidone contains primidone as the active ingredient; this belongs to a group of medicines used to treat seizures. Primidone is normally taken twice a day. Try to take your tablets at the same time each day.

4. Possible side effects

Some side effects are more common than others but, if you notice any of them, tell your doctor or pharmacist.

Driving and using machines

Primidone can make you feel sleepy. If so, do not drive or operate machinery.

5. How to store Primidone

Keep this leaflet. You may need to read it again.

6. Further information

If you have any further questions, ask your doctor or pharmacist.

Tell your doctor if you are breast-feeding because Primidone may cause your baby to be very sleepy.

Methadone (used to treat severe pain, cough, or as a substitute for morphine addiction)

Antiviral medicines (such as nelfinavir)

Antibiotics (such as chloramphenicol, metronidazole, doxycycline)

Antihistamines (such as chlorphenamine, promethazine, terfenadine)

Asthma medicines (such as theophylline, montelukast)

Driving and using machines

Primidone can make you feel sleepy. If so, do not drive or operate machinery.

7. Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

The use of Primidone 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 Primidone has the potential to harm your unborn child.

Pregnant women can have reduced folic acid in their blood whilst taking Primidone. In addition, the new born child may develop withdrawal symptoms if the mother has taken Primidone in the late stages of pregnancy. Blood clotting problems have occurred occasionally in children born to women who were previously taking anticonvulsant drugs.

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

Tell your doctor if you are breast-feeding because Primidone may cause your baby to be very sleepy.

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.

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:

<table>
<thead>
<tr>
<th>Age group</th>
<th>Daily dose (milligrams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults and children over 9 years</td>
<td>750 to 1500</td>
</tr>
<tr>
<td>Children 6 to 9 years</td>
<td>750 to 1000</td>
</tr>
<tr>
<td>Children 2 to 5 years</td>
<td>500 to 750</td>
</tr>
<tr>
<td>Children up to 2 years</td>
<td>250 to 500</td>
</tr>
</tbody>
</table>

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 750mg.

If you take more Primidone than you should

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

If you forget to take Primidone

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 Primidone

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

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

The use of Primidone 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 Primidone has the potential to harm your unborn child.

Pregnant women can have reduced folic acid in their blood whilst taking Primidone. In addition, the new born child may develop withdrawal symptoms if the mother has taken Primidone in the late stages of pregnancy. Blood clotting problems have occurred occasionally in children born to women who were previously taking anticonvulsant drugs.

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

Like all medicines, Primidone can cause side effects, although not everybody gets them.

When first taking Primidone, 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 anti-epileptic 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Primidone

Keep out of the sight and reach of children.

Do not use Primidone after the expiry date (Exp) printed on the carton and blister labels. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

If your medicine appears to be discoloured or shows any other signs of deterioration, please return to your pharmacist.

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 Primidone contains
The active substance is primidone.
Each tablet contains 250mg of primidone.

The other ingredients are: carmellose calcium, gelatin, magnesium stearate, povidone, stearic acid and purified water.

What Primidone looks like and contents of the pack
Primidone are white, round, uncoated tablets embossed with a 'M' on each side of a break line on one side and plain on the reverse. The tablet can be divided into equal halves.

Primidone is available in packs of 60 or 100 tablets.

Manufacturer:
Manufactured by: Allphamed PHARBIL Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Gottingen, Germany.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster DN3 1QR.

Product Licence holder: Landmark Pharma Ltd., 7 Regents Drive, Prudhoe, Northumberland, NE42 6PX

PL No: 21828/0552 POM

Leaflet revision and issue date (Ref): 09.06.16

To listen to or request a copy of this leaflet in Braille, large print or audio, please call 01302 365000 and ask for the Regulatory Department.