PACKAGE LEAFLET: INFORMATION FOR THE USER
Primidone SERB 50 mg and 250 mg Tablets

primidone

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 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 phenobarbitone, 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.

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 Primidone works, or Primidone 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, ethosuxamide, 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, digitoxin, 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

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

Taking Primidone with food and drink

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

Driving and using machines

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

■ 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.

Epilepsy

At first, your dose may be as little as 125 mg (half a 250 mg tablet). This will be adjusted by your doctor until your condition is controlled. Typical maintenance doses are as follows:

Age group	Daily dose (milligrams)
Adults and children over 9 years	750 to 1500
Children 6 to 9 years	750 to 1000
Children 2 to 5 years	500 to 750
Children up to 2 years	250 to 500

Elderly / Patients with low physical strength

Lower doses may be prescribed.

Shaking attacks (essential tremor)

Your starting dose may be 50 mg. 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 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.

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 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 PRIMIDONE

Keep out of the reach and sight of children

Keep your tablets below 25°C.

Do not use Primidone after the expiry date which is stated on the carton as {EXP MM/YYYY}. The expiry date refers to the last day of that month.

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 50 mg or 250 mg of primidone. The other ingredients are carmellose calcium, gelatin, magnesium stearate, povidone K30 and stearic acid, which are all typical ingredients used in tablet manufacture.

What Primidone looks like and contents of the pack

Primidone SERB 50 mg Tablets are white uncoated tablets for oral use. One side of the tablet has a single letter 'M'. The other side of the tablet is plain.

Primidone SERB 250 mg Tablets are white uncoated tablets for oral use. One side of the tablet has the letter 'M' either side of a break-line. The other side of the tablet is plain.

Primidone comes in containers of 100 tablets.

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This leaflet was last approved on **May 2017**

Is this leaflet hard to see and read? Phone 0800 198 5000 for help.

If you have any medical enquiry, please email primidoneuk@serb.eu