B. PACKAGE LEAFLET

Package leaflet: Information for the user

Primidone SERB
50mg, 125mg and 250mg Tablets
Primidone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Primidone SERB is and what it is used for
2. What you need to know before you take Primidone SERB
3. How to take Primidone SERB
4. Possible side effects
5. How to store Primidone SERB
6. Contents of the pack and other information

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

2. What you need to know before you take Primidone SERB

Do not take Primidone SERB:
- If you are allergic to primidone, phenobarbital, or to any of the other ingredients of this medicine (these are listed in Section 6: Further information).
- If you have porphyria (a rare inherited disorder of metabolism) or anyone in your family has it.

Warnings and precautions
This medication is not effective in certain forms of epilepsy. Your doctor will assess the need to prescribe you this medicine depending on the form of epilepsy you are suffering from.

Consult your doctor immediately if the frequency of your seizures increases or if seizures of a different type appear.

Talk to your doctor or pharmacist before taking Primidone SERB:
- If you have ever had respiratory, kidneys or liver problems;
- If you 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 SERB.

Your doctor may prescribe you Vitamin D supplementation (in case of long-term treatment).

A small number of people being treated with anti-epileptics such as Primidone SERB have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis or DRESS syndrome) have been reported with the use of Primidone SERB, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).
These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.
The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.
If you have developed Stevens-Johnson syndrome, toxic epidermal necrolysis or DRESS syndrome with the use of Primidone SERB or any other medicine containing phenobarbital, you must not be re-started on these medicines at any time.
If you develop a rash or these skin symptoms, stop using Primidone SERB and seek immediate advice from a doctor and tell him that you are taking this medicine.

Other medicines and Primidone SERB
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is important because some medicines may affect the way Primidone SERB works, or Primidone SERB 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, valproic acid, carbamazepine, perampanel, lamotrigine, oxcarbazepine, stiripentol, tiagabine, zonisamide),
- Anticoagulants to prevent blood clots (such as acenocoumarol, fluindione, phenindione, warfarin),
- Barbiturates or benzodiazepines (such as sleeping tablets),
- Medicines used to treat severe pain, cough, or as a substitute for morphine addiction (such as methadone, oxycodone or fentanyl),
- Antibiotics (such as metronidazole, doxycycline, telithromycine),
- Asthma medicines (such as theophylline, montelukast),
- Hormone containing medicines (such as the oral contraceptive pill, estroprogestatives, progestatives, ulipristal),
- Thyroid hormones,
- Medicines used to treat high blood pressure or heart conditions (such as beta-blockers, nimodipine),
- Cyclosporine (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 lurasidone, tricyclic antidepressants, lamotrigine, mianserin, quetiapine, sertraline),
- Steroid-containing medicines,
- Medicines used to treat cancer (such as cyclophosphamide, etoposide, abiraterone, axitinib, eribuline, ifosfamide, bosutinib, crizotinib, dabrafenib, dasatinib, erlotinib, gefitinib, imatinib, lapatinib, nilotinib, pazopanib, ruxolitinib, sorafenib, sunitinib, vandetanib, regorafenib, vemurafenib, vismodegib, cabozantinib, ceritinib, ibrutinib, olaparib, ponatinib, cabazitaxel, docetaxel, irinotecan, procarbazine),
- St-John's wort,
- Medicines containing morphine or similar medicines called opiates,
- Bedaquiline, delamanid (used to treat tuberculosis),
- Quinine (used to treat malaria),

- Medicines used to treat viral infections such as HIV infection or hepatitis C (such as boceprevir, cobicistat, daclatasvir, dasabuvir, dolutegravir, lopinavir, maraviroc, nelfinavir, ombitasvir+paritaprevir, rilpivirine, ritonavir, simeprevir, sofosbuvir, telaprevir),
- Anti-fungal medicines (voriconazole, albendazole, itraconazole, posaconazole),
- Anticoagulants (such as apixaban, dabigatran, rivaroxaban or ticagrelor),
- Folates (vitamin B9),
- Medicines used to reduce immunity (immune-suppressants, such as cyclosporine, tacrolimus, sirolimus, everolimus),
- Deferasirox (iron-chelator),
- Medicine used to treat cystic fibrosis (ivacaftor),
- Medicines used to treat a heart disease, high blood pressure or to regulate cardiac rhythms (such as class IA antiarythmics, calcium antagonists, bosentan, dronedarone, ivabradine, macitentan, nimodipine, propafenone, ranolazine or betablockers (metoprolol, propranolol)),
- Antiparasite agent (albendazole, praziquantel).

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

Pregnancy, breast-feeding and fertility

Pregnancy
If taken during pregnancy, primidone which is extensively metabolised to phenobarbital can cause serious birth defects and can affect the way in which the child develops as it grows. Birth defects which have been reported in studies include cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth) and heart abnormalities. Other birth defects have also been reported, such as malformation of the penis (hypospadias), smaller than normal head size, facial, nail and finger abnormalities. If you take phenobarbital during pregnancy you have a higher risk than other women of having a child with birth defects that require medical treatment. In the general population, the baseline risk of major malformations is 2-3%. This risk is increased by about 3 times in women taking phenobarbital (main metabolite of primidone).
Primidone SERB should not be used during pregnancy unless nothing else works for you.
Talk to your doctor immediately if you are pregnant. Your doctor should discuss the possible effects of phenobarbital tablets on the unborn child and the risks and benefits of treatment should be considered carefully.
If you have taken Primidone SERB during the last third of the pregnancy, appropriate monitoring should be conducted to detect potential disorders in the newborn, such as seizures, excessive crying, muscle weakness, sucking disorders.

Your doctor will talk to you about potential benefit of continuation of the treatment or whether another medication maybe more suitable for you. If you continue treatment,
- During pregnancy: your doctor will adjust your dose to get the minimum effective dose for you.
  Before delivery: you will need to take vitamin K to prevent the bleeding this medicine may cause during the first 24 hours of your baby's life.
- After childbirth: an injection of vitamin K may also be prescribed to your baby, at birth, to avoid any bleeding.

Do not stop taking Primidone SERB until you have discussed this with your doctor, as stopping the medication abruptly may increase the risk of developing seizures, which may have harmful effects on you and the unborn child.

Woman of child-bearing potential/Contraception
If you are a woman of childbearing age you should use effective contraception during treatment with Primidone SERB and for two months after treatment. Primidone SERB may affect how hormonal contraceptives, such as the contraceptive pill, work and make them less effective at preventing pregnancy. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking Primidone SERB.
If you are a woman of childbearing age and are planning a pregnancy, talk to your doctor before you stop contraception and before you become pregnant about switching to other suitable treatments in order to avoid exposing the unborn baby to phenobarbital (primidone is extensively metabolized to phenobarbital).

Effects in the new born
The new born child may develop withdrawal symptoms if the mother has taken Primidone SERB in the late stages of pregnancy. Blood clotting problems have occurred occasionally in children born to women who were previously taking anticonvulsant drugs.
Babies born to mothers using Primidone SERB during pregnancy may also be at increased risk of being smaller than expected.
Neurodevelopmental disorders (delays in development due to disorders in brain development) have been reported among children exposed to phenobarbital (main primidone metabolite) during pregnancy. Studies on the risk of neurodevelopmental disorders remain contradictory.

Breastfeeding
Breast-feeding is not recommended as Primidone is found in breast milk and can make the baby sleepy. Contact your doctor if you are breastfeeding or want to breastfeed.

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

3. How to take Primidone SERB

Always take Primidone SERB exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The dosage will be determined by your doctor and adjusted gradually on individual basis.
Primidone SERB is normally taken twice a day. Try to take your tablets at the same time each day.
Swallow the tablets whole with a drink of water.
The tablet of Primidone SERB 250mg can be divided into equal doses.

Epilepsy
At first, your dose may be as little as 125mg.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

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

Elderly / Patients with renal or liver disease
Lower doses may be prescribed. Please check with your doctor.

If you take more Primidone SERB than you should
If you take more than your normal dose, it may be associated with the following symptoms: coordination disorder of the muscles, unconsciousness, respiratory disorder and even coma.
If you take more than your normal dose, contact your doctor or nearest hospital IMMEDIATELY.

If you forget to take Primidone SERB
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 SERB
Do not stop taking your Primidone SERB, even if you are feeling well, unless your doctor tells you to. You may have become dependent on Primidone SERB, and therefore you could get a withdrawal reaction if you stop treatment too quickly. Primidone SERB 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, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people)
- Lack of energy (apathy), coordination disorders, visual disturbances, rolling of the eyes.
- Nausea.

Uncommon (may affect up to 1 in 100 people)
- Headache, vertigo

- Vomiting
- Allergic skin reaction

Rare (may affect up to 1 in 1,000 people)
- Decreased number of some blood cells (red blood cells or white blood cells or platelets) or development of lymph nodes.
- Changes in mood or behaviour
- Joint or bone pain, Dupuytren's contracture (a thickening of fibrous tissue in the palm of the hand that causes one or more fingers to draw back), osteomalacia (bone softening due to vitamin D deficiency)
- Exfoliative dermatitis (common redness and peeling of the skin)**,** lupus erythematosus (disease which causes inflammation of various parts of the body including the skin, joints, lungs, kidneys, heart and liver
- Raised levels of enzymes in your liver (gamma GT, alkaline phosphatase)

Very rare (may affect up to 1 in 10,000 people)
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2).

Not known (frequency cannot be estimated from the available data)
- Suicidal ideation
- Confusion
- Hallucinations
- Balance issues
- Allergic reactions which may include fever, rash, increased numbers of some blood cells (eosinophils), increased of some liver enzymes
- 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.
- Potentially life-threatening skin rashes (drug rash with eosinophilia and systemic symptoms) have been reported (see section 2).
- Itching (Pruritus)

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Primidone SERB

Keep out of the reach and sight of children
This medicine does not require any special temperature storage conditions.
Do not use Primidone SERB 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. Contents of the pack and other information

What Primidone SERB contains
The active substance is primidone. Each tablet contains either 50 mg, 125 mg or 250 mg of primidone. The other ingredients are carmellose calcium, gelatin, magnesium stearate, povidone and stearic acid.

What Primidone SERB 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 125 mg Tablets are white or virtually white, round, biconvex, uncoated tablets, intagliated with "125" on one side and plain on the reverse.

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 SERB comes in bottles of 100 tablets or blisters containing 10 tablets each.

Not all pack sizes may be marketed.

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