PRIMIDONE TABLETS, USP
Anticonvulsant
Rx only

DESCRIPTION
Chemical name: 5-ethyl-5-hydroxy-5-phenyl-4,6(1H,5H)-pyrimidinedione. Structural formula:

C₁₂H₁₄N₂O₂ M.W. 218.25

PRIMIDONE Tablets contain primidone, white, crystalline, highly stable substance. MP: 279-284°C (It is poorly soluble in water (0.2 mg per 100 ml at 37°C) and in most organic solvents. It possesses no acid properties and is not hydrolyzed by kauterization or any other usual methods.

Primidone 50 mg and 250 mg tablets contain the following inactive ingredients: hypromellose, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, sodium starch glycolate and lactose.

Primidone 250 mg tablets also contain D&C yellow #10 alumina lake and FD&C yellow #5 alumina lake.

ACTIONS
Primidone causes electro-chemosensory seizure thresholds or seizure patterns in experimental animals. The mechanism(s) of primidone’s antiepileptic action is not known.

INDICATIONS AND USAGE
Primidone is contraindicated in: 1) patients with porphyria and 2) patients who are hypersensitive to phenobarbital (see ACTIONS).

WARNINGS
The abrupt withdrawal of antiepileptic medication may precipitate status epilepticus. The therapeutic efficacy of a dosage regimen takes several weeks before the therapeutic assessment.

Suicidal Behavior and Ideation
Antiepileptic drugs (AEDs), including primidone, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Postmarketing Data
In a pooled analysis of 10 placebo-controlled studies of AEDs (including primidone), the risk of suicidal thoughts or behavior was generally consistent across AED classes. Patients should be closely monitored, with depression and any unusual changes in mood or behavior, treated promptly, and the AED discontinued at the discretion of the physician unless it is clinically warranted.

Pediatric Patients
Pediatric patients have generally been considered more susceptible to the development of suicidal ideation and behavior and, in some cases, to the worsening of pre-existing symptoms. The pooled analysis included 27,863 AED-treated patients, compared to 16,029 placebo-treated patients, representing an increase of approximately one case of suicidal ideation or behavior per 1000 patient years. The risk of suicidal ideation or behavior was similar for all AED classes in the pooled analysis.

Pediatric Patients: Primaquine Tablets USP
Medication Guide provided with the product for more information.

Informative
The following case describes a 5-year-old child who developed suicidal ideation and behavior after starting primidone tablets. The case was reported to the sodium valproate and carbamazepine

Suicidal thoughts or actions could be caused by other things than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

What are primidone tablets?
Primidone tablets are a prescription medicine used alone or with other medicines to treat people with:

- Grand mal seizures
- Complex partial (psychomotor) seizures
- Partial (focal) epileptic seizures

Who should not take primidone tablets?
Do not take primidone tablets if you:

- Have a genetic disorder called porphyria

Who should I tell my healthcare provider before taking primidone tablets?
Before you take primidone tablets, tell your healthcare provider if you:

- Have or have had, depression, mood problems or suicidal thoughts or behavior
- Have any other medical conditions
- Are pregnant or planning to become pregnant. Primidone tablets may harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking primidone tablets. You and your healthcare provider should decide if you will take primidone tablets while you are pregnant.

- If you become pregnant while taking primidone tablets, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. You can enroll online at http://www.naaped.org or call 1-888-233-2334 for information about the safety of antiepileptic drugs during pregnancy.

- Are breastfeeding or plan to breastfeed. Primidone can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take primidone tablets.

Tell your healthcare provider about all the medicines you take (prescription and non-prescription medicines, vitamins, and herbal supplements). Taking primidone tablets with certain other medicines can cause side effects or affect how well they work. Do not stop or start other medicines without talking to your healthcare provider. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist each time you get a new medicine.

Read this Medication Guide before you start taking primidone tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about primidone tablets?
Do not stop taking primidone tablets without first talking to your healthcare provider.

Stopping primidone tablets suddenly can cause serious problems.

PRIMIDONE tablets can cause serious side effects, including:

- Like other antiepileptic drugs, primidone tablets may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.

- Keep all follow-up visits with your healthcare provider as scheduled.

Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

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Tiredness

Hives

Skin rash

Fever, swollen glands, or sore throat that come and go or do not go away

Frequent infections or an infection that does not go away

Skin rash

What should I avoid while taking primidone tablets?

• Primidone tablets may make you sleepy or dizzy. Do not drink alcohol or take other drugs that make you sleepy or dizzy while taking primidone tablets without first discussing this with your healthcare provider. Taking primidone tablets with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.

• Do not drive, operate heavy machinery, or do other dangerous activities until you know how primidone tablets affect you. Primidone tablets can slow your thinking and motor skills.

What are the possible side effects of primidone tablets?

See “What is the most important information I should know about primidone tablets?”

Primidone tablets may cause other serious side effects including:

• Sleepiness that can be severe, especially when you first take primidone tablets.

• Primidone tablets may rarely cause blood problems. Symptoms may include:
  • fever, swollen glands, or sore throat that come and go or do not go away
  • Frequent infections or an infection that does not go away

How can I watch for early symptoms of suicidal thoughts and actions?

• Pay attention to any changes, especially sudden changes, in mood, behavior, thoughts, or feelings.

Tell your healthcare provider if you have any of these symptoms, especially if they are new, or worrisome:

• Feelings of sadness or hopelessness
• Thoughts of suicide or death
• Feelings of restlessness or agitation
• Agitation or pacing
• Having trouble falling asleep or staying asleep
• New or worse aggression or hostility
• New or worse anxiety
• New or worse irritability
• Acting aggressive, being angry, or violent
• Thinking about self-injury or suicide
• Acting on dangerous impulses
• Feeling lonely or hopeless
• Thoughts about suicide or dying
• Acting on plans or intentions to harm yourself
• Attempting suicide

What are primidone tablets?

• Primidone tablets are a prescription medicine used alone or with other medicines to treat people with:
  • Generalized tonic-clonic (grand mal) seizures
  • Partial (focal) epileptic seizures
  • Partial seizures that begin in the back of the brain

Who should not take primidone tablets?

• Do not take primidone tablets if you:
  • have a genetic disorder called prophyria
  • are allergic to phenobarbital

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store primidone tablets?

Store primidone tablets at room temperature between 68°F to 77°F (20°C to 25°C) in a tight, light-resistant container.

Keep primidone tablets and all medicines out of the reach of children.

What is the most important information I should know about primidone tablets?

Let your healthcare provider know if you have any side effect that bothers you or that does not go away.

Stopping primidone tablets suddenly can cause serious problems.

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• Acting on dangerous impulses
• Feeling lonely or hopeless
• Thoughts about suicide or dying
• Acting on plans or intentions to harm yourself
• Attempting suicide

If you become pregnant while taking primidone tablets, talk to your healthcare provider.

What are the possible side effects of primidone tablets?

Frequent infections or an infection that does not go away

Skin rash

Fever, swollen glands, or sore throat that come and go or do not go away

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