Primidone Tablets, USP
Anticonvulsant
Rx only

DESCRIPTION
Chemical name: 5-sulphhydrol-5-seryl-6 (1H, 4H)-pyrimidine-4-carboxylic acid.

C₆H₇NO₂S
M.W. 218.25

Primidone is a white, crystalline, highly stable substance, M.P. 279-284°C. It is poorly soluble in water, and freely soluble in alcohol and acetone. It possesses the acidic properties, in contrast to its barbiturate analog.

Forms and strengths: Primidone Tablets USP are available in the following inactive ingredients: lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, stearic acid, and talc.

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

INDICATIONS AND USAGE
Primidone, used alone or concurrently with other anticonvulsants, is indicated in the prophylaxis of seizures. In the treatment of status epilepticus with attendant hypoxia and threat to life. In individual cases where the severity and frequency of the seizures cannot be controlled by any other anticonvulsant drug, or where the use of other anticonvulsants is contraindicated or has failed, primidone may be effective.

CONTRAINDICATIONS
Primidone is contraindicated in: 1) patients with porphyria and 2) those who have active suicidal tendencies, or a history of drug or alcohol dependence.

ADVERSE REACTIONS
The abrupt withdrawal of antiepileptic medication may precipitate status epilepticus. The therapeutic efficacy of a dosage regimen takes several weeks before it can be assessed.

Suicidal Thinking and Behavior
Antiepileptic drugs (AEDs), including primidone, increase the risk of suicidal thoughts or behavior with AEDs was observed as early as

Table 1 shows absolute and relative risk by indication for all evaluated AEDs.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Patients/Incidence</th>
<th>Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primidone Tablets USP</td>
<td>1.8</td>
<td>1.0</td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>3.5</td>
<td>1.0</td>
</tr>
<tr>
<td>Valproate</td>
<td>2.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>1.4</td>
<td>1.0</td>
</tr>
</tbody>
</table>

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as

The relative risk for suicidal thoughts or behavior was higher in clinical trials that employed an effective control (e.g., placebo) than those that did not (i.e., studies comparing primidone to no treatment or to placebo). However, the absolute risk differences were similar for the epilepsy and psychiatric indications.

A mood change should be immediately reported to your healthcare provider so that appropriate monitoring and treatment of mood changes can be initiated. The possibility of precipitating status epilepticus should be reported immediately. The prescriber needs to consider whether the emergence of these thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses can be associated with suicidal thoughts or behavior. If untreated, these illnesses can cause substantial quantities. Since tests for the presence of primidone in biological fluids are too insensitive to be of diagnostic utility, all patients should be monitored adequately for the emergence of these symptoms in any patient who has been prescribed an antidepressant.

ADVERSE REACTIONS

Stopping primidone tablets suddenly can cause serious problems. Taking primidone tablets suddenly can cause serious problems.

MEDIATION GUIDE
Primidone Tablets, USP
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Read this Medication Guide before you start taking primidone tablets and each time you get a refill. 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 talking to your healthcare provider.

Stopping primidone tablets suddenly can cause serious problems.

What are possible side effects of primidone tablets?

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

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worrier:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)•
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

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.

Do not stop taking primidone tablets without first talking to a healthcare provider.

Stopping primidone tablets suddenly can cause serious problems. Taking primidone tablets suddenly can cause serious problems.

Do not take primidone tablets if:

- you have a genetic disorder called porphyria
- you are allergic to phenobarbital

What should I tell my healthcare provider before taking primidone tablets?

Tell your healthcare provider before taking primidone tablets 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. Your healthcare provider will decide if you should take primidone tablets while you are pregnant.

- 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, including prescription and nonprescription medicines, vitamins, and herbal supplements. Taking primidone tablets with other medicines can cause side effects or affect how well they work. Do not start or stop 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.

Rx only
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.

How should I take primidone tablets?

Know the medicines you take. Keep a list of them and show it to your healthcare provider.

Do not start or stop other medicines without talking to your healthcare provider. Taking primidone tablets with certain other medicines can cause side effects or affect how well they work. Do not take primidone tablets with other medicines unless they are approved by your healthcare provider.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. Some side effects may indicate serious problems.

General Information about primidone tablets

Primidone tablets may cause other serious side effects including:

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

• Primidone tablets may rarely cause blood problems. Symptoms may include:
  - Loss of blood from your nose or mouth
  - Trouble urinating
  - Unusual bleeding or bruising
  - Weakness or fatigue

• Primidone tablets may cause allergic reactions. Symptoms may include:
  - Skin rash
  - Hives
  - Sores in your mouth
  - Blistering or peeling skin

The most common side effects of primidone tablets include:

• Problems with walking and moving
• Feeling of dizziness, spinning, or swaying (vertigo)

These are not all the possible side effects of primidone tablets. For more information, ask your healthcare provider or pharmacist.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. 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 light-resistant container.

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

What are the ingredients in primidone tablets?

Active Ingredient: primidone

Inactive ingredients: hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, sodium starch glycolate and talc.

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

Primidone Tablets 250 mg contain FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions including blisters or hives in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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How should I take primidone tablets?

Take primidone tablets exactly as prescribed. Your healthcare provider will tell you how much primidone tablets to take and when to take it.

• Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
• Do not stop taking primidone tablets without first talking to your healthcare provider.
• If you take too much primidone tablets, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking primidone tablets?

• Primidone tablets can 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 talking to your healthcare provider. Using alcohol or taking other drugs that make you sleepy or dizzy while taking primidone tablets without first talking to your healthcare provider can make your sleepiness or dizziness worse. If you feel sleepy or dizzy, do not drive or 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.

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