

Primidone Cas No. : 125-33-7

Primidone is used to treat epileptic and other seizures. It can be used alone or with other anticonvulsant drugs. It is chemically similar to barbiturates.

Take Primidone exactly as prescribed. Do not change from one manufacturer's product to another without consulting your doctor.

Active Pharmaceuticals Ingredients Manufacturers

Taj Pharmaceuticals Ltd.**Primidone****CAS No. : 125-33-7****Synonyms**

5-ethyl-5-phenyl-hexahydropyrimidine-4,6-dione

Identifiers

CAS number 125-33-7

ATC code N03AA03

PubChem 4909

DrugBank APRD00549

ChemSpider 4740

Chemical dataFormula C₁₂H₁₄N₂O₂

Mol. mass 218.252 g/mol

Pharmacokinetic data

Bioavailability ~100%

Protein binding 25%

Metabolism Hepatic

Half life Primidone: 5-18 hours,

Phenobarbital: 75-120 hours,

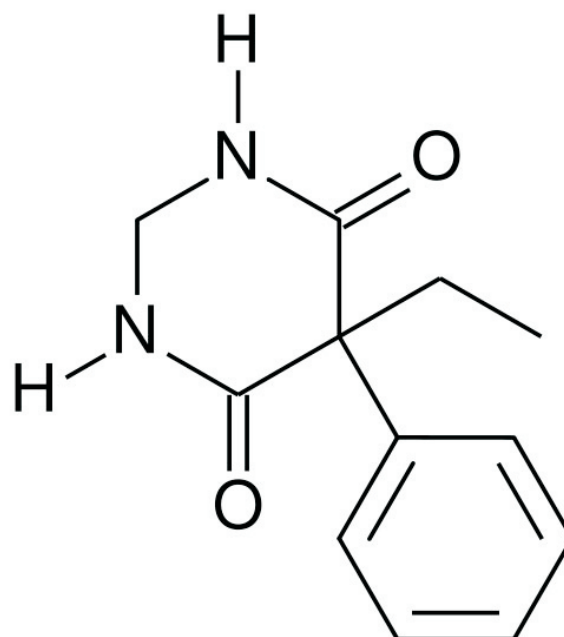
PEMA: 16 hours

Time to reach steady state:

Primidone: 2-3 days,

Phenobarbital&PEMA 1-4weeks

Excretion Renal



Primidone is an anticonvulsant of the pyrimidinedione class whose active metabolites, phenobarbital and phenylethylmalonamide are also anticonvulsants. It is used mainly to treat complex partial, simple partials, generalized tonic-clonic seizures, myoclonic, akinetic seizures and it has been a valuable alternative to propranolol in the treatment of essential tremor. Unlike other anticonvulsants such as carbamazepine and valproic acid, primidone is rarely used in the treatment of bipolar disorder or any other psychiatric problem. It is also not widely used in treatment of neuropathic pain, trigeminal neuralgia, or migraine. Primidone has been occasionally used to treat long QT syndrome, cerebral palsy, and athetosis.

Uses

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How should you take Primidone?

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Primidone

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Side Effects

Side effects cannot be anticipated. If any develop or change in intensity, inform your doctor as soon as possible. Only your doctor can determine if it is safe for you to continue taking Primidone .

* Side effects may include:

Lack of muscle coordination, vertigo or severe dizziness

Special warnings about Primidone

Remember that you must not stop taking Primidone suddenly.

It can take several weeks for the full effectiveness of Primidone to be seen.

Since Primidone is generally given for long periods of time, your doctor will check your blood count every 6 months.

Recommended dosage for Primidone

ADULTS

For people 8 years of age and older who have not been treated before, the doctor will start Primidone as follows, using either 50-milligram or scored 250-milligram Primidone tablets:

Days 1 to 3: 100 to 125 milligrams at bedtime

Days 4 to 6: 100 to 125 milligrams 2 times a day

Days 7 to 9: 100 to 125 milligrams 3 times a day

Day 10 to maintenance: 250 milligrams 3 times a day

For most adults and children 8 years of age and over, the usual maintenance dosage is 250 milligrams 3 or 4 times a day. If you need more, your doctor may increase the dose to five or six 250-milligram tablets. You should not take more than 500 milligrams 4 times a day (2000 milligrams or 2 grams).

In patients already receiving other anticonvulsants, the usual starting dose of Primidone is 100 to 125 milligrams at bedtime; your doctor will gradually increase this dose to a maintenance level as the other drug is gradually decreased. Your doctor will either find a working level for the combination or withdraw the other medication completely. When Primidone is to be used as a single drug, it will take at least 2 weeks to make the transition from two drugs to one.

CHILDREN UNDER AGE 8

Days 1 to 3: 50 milligrams at bedtime

Days 4 to 6: 50 milligrams 2 times a day

Days 7 to 9: 100 milligrams 2 times a day

Day 10 to maintenance: 125 milligrams 3 times a day to 250 milligrams 3 times day

The usual maintenance dosage is 125 to 250 milligrams 3 times daily or 10 to 25 milligrams per 2.2 pounds of body weight per day, divided into smaller doses.

Over dosage

Any medication taken in excess can have serious consequences. If you suspect a Primidone overdose, seek medical attention immediately.

DOSAGE

Primidone comes as a tablet and suspension (liquid) to take by mouth. It usually is taken once a day at bedtime when you first use it, and then the dosage is gradually increased to three or four times a day. It may be taken with food. Shake the suspension well before each use. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take primidone exactly as directed. Do not take more or less of it or take it more often than your doctor tells you to.



This medication must be taken regularly to be effective. Do not skip doses even if you feel that you do not need them. Do not stop taking this drug until your doctor specifically tells you to do so. Stopping the drug abruptly can cause seizures. Your doctor probably will decrease your dose gradually.

Take Primidone exactly as prescribed. Do not change from one manufacturer's product to another without consulting your doctor.

If using Primidone Suspension, shake well before using.

DRUG DESCRIPTION

Chemical name: 5-ethylidihydro- 5-phenyl-4,6 (1H, 5H) pyrimidinedione.primidone

is a white, crystalline, highly stable substance, M.P. 279-284°C. It is poorly soluble in water (60 mg per 100 mL at 37°C) and in most organic solvents. It possesses no acidic properties, in contrast to its barbiturate analog.

Each tablet, for oral administration, contains 250 mg primidone. In addition, each tablet contains the following inactive ingredients: colloidal silicon dioxide, docusate sodium, magnesium stearate, microcrystalline cellulose, sodium benzoate, sodium starch glycolate and stearic acid.

Anticonvulsant; drug used to treat epilepsy and seizures.

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Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

This leaflet was prepared by
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