

Phenobarbital acid Cas No. : 50-06-6

This medication is used alone or with other medications to control certain types of seizure problems (e.g., grand mal and partial seizures). Controlling seizures helps prevent injury from falling and allows you to lead a more normal life. Phenobarbital belongs to a class of drugs known as barbiturate anticonvulsants/hypnotics.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.

Phenobarbital acid

CAS No. : 50-06-6

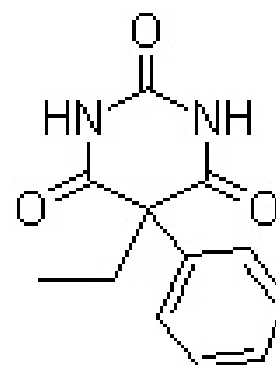


Molecular Formula C₁₂H₁₂N₂O₃
Molecular Weight 232.24
CAS Registry Number 50-06-6

Pharmacokinetic data

Bioavailability >95%
Protein binding 20 to 45%
Metabolism Hepatic (mostly CYP2C19)
Half life 53 to 118 hours
Excretion Renal and fecal

Phenobarbital is indicated in the treatment of all types of seizures except absence seizures. Phenobarbital is no less effective at seizure control than more modern drugs such as phenytoin and carbamazepine. It is, however, significantly less well tolerated.

**DOSAGE**

Phenobarbital comes as a tablet, capsule, and elixir (liquid) to take by mouth. You may obtain a specially marked measuring spoon from your pharmacist to be sure of an accurate dose of the liquid. It usually is taken one to three times a day and may be taken with or without food. If you take phenobarbital once a day, take it at bedtime. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take phenobarbital exactly as directed. If you are taking phenobarbital to control convulsions or seizures, follow the exact schedule prescribed by your doctor.

Phenobarbital can be habit-forming. Do not use phenobarbital for more than 2 weeks if it is being used to help you sleep. Do not take a larger dose, take it more often, or for a longer time than your doctor tells you to. Tolerance may develop with long-term or excessive use, making the drug less effective. This medication must be taken regularly to be effective. Do not skip doses even if you feel that you do not need them. Call your doctor if you have convulsions or seizures while taking phenobarbital. Do not stop taking this drug without talking to your doctor, especially if you have been taking it for a long time. Stopping the drug suddenly can cause withdrawal symptoms (anxiousness, sleeplessness, and irritability). Your doctor probably will decrease your dose gradually.

SIDE EFFECTS

- * drowsiness
- * headache
- * dizziness
- * depression
- * excitement (especially in children)
- * upset stomach
- * vomiting

symptoms are severe or do not go away:



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- * nightmares
- * increased dreaming
- * constipation
- * joint or muscle pain

If you experience any of the following symptoms, call your doctor immediately:

- * seizures
- * mouth sores
- * sore throat
- * easy bruising
- * bloody nose
- * unusual bleeding
- * fever
- * difficulty breathing or swallowing
- * severe skin rash

PRECAUTIONS

Before taking phenobarbital,

- * tell your doctor and pharmacist if you are allergic to phenobarbital or any other drugs.
- * tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially acetaminophen ; anticoagulants such as warfarin ; carbamazepine ; chloramphenicol ; clonazepam ; disulfiram ; doxycycline ; felodipine ; fenoprofen ; griseofulvin ; MAO inhibitors phenelzine or tranylcypromine ; medications for depression, seizures, pain, asthma, colds, or allergies; metoprolol ; metronidazole ; muscle relaxants; phenylbutazone ; propranolol ; quinidine; rifampin ; sedatives; sleeping pills; steroids; theophylline ; tranquilizers; valproic acid ; verapamil ; and vitamins. These medications may add to the drowsiness caused by phenobarbital.
- * tell your doctor if you have or have ever had anemia or seizures, or lung, heart, or liver disease.
- * use a method of birth control other than oral contraceptives while taking this medication. Phenobarbital can decrease the effectiveness of oral contraceptives.
- * tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking phenobarbital, call your doctor immediately.
- * if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking phenobarbital.
- * you should know that this drug may make you drowsy. Do not drive a car or operate machinery until you know how this drug affects you.
- * remember that alcohol can add to the drowsiness caused by this drug.

INTERACTION

Most reports of clinically significant drug interactions occurring with the barbiturates have involved phenobarbital.

1. Anticoagulants: Phenobarbital lowers the plasma levels of dicumarol (name previously used: bishydroxycoumarin) and causes a decrease in anticoagulant activity as measured by the prothrombin time. Phenobarbital can induce hepatic microsomal enzymes resulting in increased metabolism and decreased anticoagulant response of oral anticoagulants (e.g., warfarin, acenocoumarol, dicumarol, and phenprocoumon). Patients stabilized on anticoagulant therapy may require dosage adjustments if phenobarbital is added to or withdrawn from their dosage regimen.

2. Corticosteroids: Phenobarbital appears to enhance the metabolism of exogenous corticosteroids probably through the induction of hepatic microsomal enzymes. Patients stabilized on corticosteroid therapy may require dosage adjustments if phenobarbital is added to or withdrawn from their dosage regimen.





3. Griseofulvin: Phenobarbital appears to interfere with the absorption of orally administered griseofulvin, thus decreasing its blood level. The effect of the resultant decreased blood levels of griseofulvin on therapeutic response has not been established. However, it would be preferable to avoid concomitant administration of these drugs.

4. Doxycycline: Phenobarbital has been shown to shorten the half- life of doxycycline for as long as 2 weeks after barbiturate therapy is discontinued. This mechanism is probably through the induction of hepatic microsomal enzymes that metabolize the antibiotic. If phenobarbital and doxycycline are administered concurrently, the clinical response to doxycycline should be monitored closely.

5. Central nervous system depressants: The concomitant use of other central nervous system depressants including other sedatives or hypnotics, antihistamines, tranquilizers, or alcohol, may produce additive depressant effects.

DRUG DESCRIPTION

Phenobarbital, a barbiturate, is used to control epilepsy (seizures) and as a sedative to relieve anxiety. It is also used for short-term treatment of insomnia to help you fall asleep.

Phenobarbital is a barbiturate, nonselective central nervous system depressant which is primarily used as a sedative hypnotic and also as an anticonvulsant in subhypnotic doses.

Phenobarbital Tablets and Elixir are administered orally and are contained in DEA Schedule IV. Barbiturates are substituted pyrimidine derivatives in which the basic structure common to these drugs is barbituric acid, a substance which has no central nervous system (CNS) activity. CNS activity is obtained by substituting alkyl, alkenyl, or aryl groups on the pyrimidine ring.

Chemically Designated: 5-Ethyl -5-phenylbarbituric acid

Molecular Formula: C₁₂H₁₂N₂O₃

Molecular Weight: 232.24

Inactive Ingredients

Oral Tablets - corn starch, lactose (monohydrate), magnesium stearate and sodium starch glycolate

Oral Elixir - ethyl alcohol, glycerin, oil of orange, sucrose, water, FD& C Red #40 and FD& C Blue #1

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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Mumbai (India).

MPSTJ278

Last revised: 29 August 2009