

Phenobarbital sodium Cas No. : 57-30-7

This medication is used to cause calm and sleep. It is used when these effects are desirable (e.g., for the relief of severe anxiety, to cause calm before/after surgery, to treat trouble sleeping). Phenobarbital belongs to a class of drugs known as barbiturate anticonvulsants/hypnotics. It works by affecting certain parts of the brain to cause calming, drowsiness, and sleep.

Active Pharmaceuticals Ingredients Manufacturers



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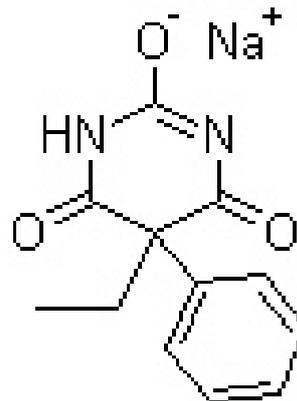


Molecular Formula C₁₂H₁₁N₂NaO₃
Molecular Weight 254.22
CAS Registry Number 57-30-7

Chemistry

Phenobarbital, a barbiturate, occurs as white, glistening, odorless, small crystals or as a white, crystalline powder with a melting point of 174°-178°C and a pKa of 7.41. One gram is soluble in approximately 1000 ml of water, and 10 ml of alcohol. Compared to other barbiturates it has a low lipid solubility.

Phenobarbital sodium occurs as bitter-tasting, white, odorless, flaky crystals or crystalline granules or powder. It is very soluble in water, soluble in alcohol, and freely soluble in propylene glycol. The injectable product has a pH of 8.5-10.5.

**DOSAGE**

Dosage is based on your age, medical condition, phenobarbital blood levels, and response to treatment.

If you are using this medication for calming/sleep problems, use it only when needed to get the most benefit from it. Phenobarbital will not work as well for anxiety or sleep problems if used regularly for more than 2 weeks. Do not use more of this medication than prescribed. Doing so may increase side effects. When used to treat anxiety for an extended period, this medication may not work as well and may require different dosing. Talk with your doctor if this medication stops working well.

This medication may cause dependence when used for anxiety or sleeping problems, especially if it has been used regularly for an extended time and if it has been used in high doses. In such cases, withdrawal reactions (e.g., anxiousness, muscle twitching, shakiness, dizziness, worsening weakness, nausea, vomiting) may occur if you suddenly stop this drug. Withdrawal from phenobarbital can be severe and may include seizures and (rarely) death. To prevent withdrawal reactions when stopping extended, high-dose, regular treatment with this drug, gradually reduce the dosage as directed. Consult your doctor or pharmacist for more details, and report any withdrawal reactions immediately.

This medication works best for severe seizures when the amount of drug in your body is kept at a constant level. Therefore, your health care professional will give you this medication at evenly spaced intervals until your seizures are controlled.

Though very unlikely, abnormal drug-seeking behavior (addiction) is possible with this medication. Do not increase your dose, use it more frequently, or use it for a longer time than prescribed. Properly stop the medication when so directed.

SIDE EFFECTS

Dizziness, unwanted drowsiness, tiredness, loss of appetite, nausea, vomiting, or staggering walk/clumsiness may occur when you first start using the medication but tend to disappear over time (usually in a few weeks). Less common side effects may include headache, constipation, nightmares, and increased dreaming. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. To prevent constipation, maintain a diet adequate in fiber, and drink plenty of water. If you become constipated while using this drug, consult your pharmacist for help with selecting a laxative (e.g., stimulant-type with stool softener).



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serious side effects occur: mental/mood changes (e.g., confusion, agitation, hallucinations, anxiety, inability to think clearly/quickly), slow heartbeat, fainting. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

PRECAUTIONS

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: sleep apnea, severe lung problems (e.g., severe asthma, chronic obstructive pulmonary disease-COPD), porphyria, severe liver disease, alcoholism. Before using this medication, tell your doctor or pharmacist your medical history, especially of: illegal drug use, persistent pain problems, liver problems, mental/mood changes (e.g., depression, thoughts of suicide), certain kidney problems (e.g., nephritis, decreased kidney function), extremely overactive thyroid (thyrotoxicosis).

This drug causes drowsiness. Do not drive, use machinery, or perform any activity that requires alertness. Do not use alcoholic beverages while using this medication. Doing so increases serious side effects (inability to wake up, slowed breathing) and may cause death.

A preservative (benzyl alcohol) which might be found in this product or in the liquid used to mix this product can infrequently cause serious (sometimes fatal) problems if given in large amounts (more than 100 milligrams per kilogram daily) to an infant during the first months of life. The risk is greater with low-birth-weight infants. Symptoms include sudden gasping, low blood pressure, very slow heartbeat. If you notice any of these symptoms in your newborn, report them to the doctor immediately. If possible, a preservative-free product should be used when treating newborns. Phenobarbital should not be used to treat anxiety in the elderly because they are more sensitive to the effects of the drug, especially confusion and dizziness.

This medication is not recommended for use during pregnancy. It may harm an unborn baby. Consult your doctor for more details. Since birth control pills may not be effective if taken with this medication (see also Drug Interactions section), discuss other reliable forms of birth control with your doctor. If you become pregnant while using this medication, tell your doctor immediately.

INTERACTION

This drug should not be used with the following medications because very serious interactions may occur: etravirine, sodium oxybate, delavirdine, darunavir, voriconazole.

Some other drowsiness-causing medications may cause serious (possibly fatal) slowed breathing when taken with higher doses of phenobarbital. Tell your doctor or pharmacist if you also take other drugs that cause drowsiness such as: medicine for sleep or anxiety (e.g., alprazolam, diazepam, zolpidem), muscle relaxants (e.g., methocarbamol), narcotic pain relievers (e.g., codeine), psychiatric medicines (e.g., chlorpromazine, risperidone, amitriptyline, trazodone).

If you are currently using any of these medications listed above, tell your doctor or pharmacist before starting phenobarbital.

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: warfarin, estrogens (e.g., some birth control pills/hormone replacement treatments), corticosteroids (e.g., prednisone, dexamethasone), quinidine, felodipine, certain beta blockers (acebutolol, betaxolol, carteolol, metoprolol, propranolol), metronidazole, doxycycline, certain antifungal medications (griseofulvin, posaconazole), phenytoin, valproic acid, cyclosporine, sunitinib, dasatinib, erlotinib, irinotecan, telithromycin, theophylline, MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranlycypromine).



This medication can speed up the removal of many other drugs from your body by affecting certain liver enzymes. This can affect how well these other drugs work. Tell your doctor or pharmacist of all other drugs you take.

Before using this medication, tell your doctor or pharmacist if you use any other prescription and nonprescription products that cause drowsiness such as certain antihistamines (e.g., diphenhydramine) and anti-seizure drugs (e.g., carbamazepine).

DRUG DESCRIPTION

This medication is used to cause calm and sleep. It is used when these effects are desirable (e.g., for the relief of severe anxiety, to cause calm before/after surgery, to treat trouble sleeping). Phenobarbital belongs to a class of drugs known as barbiturate anticonvulsants/hypnotics. It works by affecting certain parts of the brain to cause calming, drowsiness, and sleep. This medication is also used in the emergency control of severe/persistent seizures in certain conditions (e.g., status epilepticus, eclampsia, meningitis). It works by controlling the abnormal electrical activity in the brain that occurs during a seizure.

This medication is usually given by injection into a muscle or slowly into a vein by a health care professional, usually 1 to 4 times daily or as directed by your doctor. Before giving this medication, learn all directions for preparation and usage. Inspect it visually for particles or discoloration. If either is present, do not use the liquid. Injecting phenobarbital into a vein too quickly can cause severe breathing problems, high blood pressure, or low blood pressure. Your health care professional should observe you while you are receiving all doses injected into a vein.

Dosage is based on your age, medical condition, phenobarbital blood levels, and response to treatment.

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.

Information: The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers. Also that the information on the PTCL Safety web site, where this page was hosted, has been copied onto many other sites, often without permission. If you have any doubts about the veracity of the information that you are viewing, or have any queries, please check the URL that your web browser displays for this page. If the URL begins "www.tajapi.com/www/Denatonium Benzoate.htm/" the page is maintained by the Safety Officer in Physical Chemistry at Oxford University. If not, this page is a copy made by some other person and we have no responsibility for it.

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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