DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.
Symptoms of barbiturate dependence are similar to those of chronic alcoholism. If an individual appears to be intoxicated with alcohol to a degree that is radically disproportionate to the amount of alcohol in the blood, the use of barbiturates should be suspected. The lethal dose of a barbiturate is far less if alcohol is also present.

The symptoms of barbiturate withdrawal can be severe and may cause death. Minor withdrawal symptoms may appear 8 to 12 hours after the last dose of a barbiturate. These symptoms usually appear in the following order: muscle twitching, anorexia, diaphoresis, tachycardia, nervousness, irritability, insomnia, and weight loss. Major withdrawal symptoms (convulsions and delirium) may occur within 16 hours and last up to 3 days after abrupt cessation of these drugs. Intensity of withdrawal symptoms gradually declines over a period of approximately 10 days. Individuals susceptible to barbiturate abuse and dependence include alcoholics and opiate abusers as well as other sedative-hypnotic and amphetamine abusers.

Drug dependence to barbiturates arises from repeated administration of a barbiturate or agent with a similar effect on amounts exceeding therapeutic dose levels. The characteristics of drug dependence to barbiturates include: (a) a strong desire or need to continue taking the drug; (b) a tendency to increase the dose; (c) a psychic dependence on the effects of the drug related to subjective and individual appreciation of those effects; and (d) a physical dependence on the effects of the drug requiring its presence for maintenance of homeostasis and resulting in a definite, characteristic, and self-limited abstinence syndrome.

Treatment of barbiturate dependence consists of cautious and gradual withdrawal of the drug. Barbiturate-dependent patients can be withdrawn by using a number of different withdrawal regimens. In all cases withdrawal takes an extended period of time. One method involves substituting a 30% to 50% dose of phenobarbital for each 100 to 200 mg dose of barbiturate that the patient has been taking. The total daily amount of phenobarbital is then administered in 3 to 4 divided doses, not to exceed 600 mg daily. Should signs of withdrawal occur on the first day of treatment, a loading dose of 100 to 200 mg of phenobarbital may be administered intramuscularly, not intravenously. After stabilization on phenobarbital, the total daily dose may be decreased by 30 mg a day as long as withdrawal is proceeding smoothly. A modification of this regimen involves initiating treatment at the patient’s regular dosage level and decreasing the daily dosage by 10 percent if tolerated by the patient.

Infants physically dependent on barbiturates may be given phenobarbital 3 to 10 mg/kg/day. With withdrawal symptoms (hyperactivity, disturbed sleep, tremors, hyperreflexia) are relieved, the dosage of phenobarbital should be gradually decreased and completely withdrawn over a 2-week period.

OVERDOSE

The toxic dose of barbiturates varies considerably. In general, an oral dose of 1 gram of most barbiturates produces serious poisoning in an adult. Death commonly occurs after 2 to 10 grams of ingested barbiturate. The toxic dose of barbiturates in children varies widely depending on age, body weight, and various neurological disorders.

Acute overdosage with barbiturates is manifested by CNS and respiratory depression which may progress to Cheyne-Stokes respiration, areflexia, constriction of the pupils to a slight degree (though in severe cases, the pupils may be dilated). Deep coma. Typical shock syndrome (apnea, circulatory collapse, respiratory arrest, and death) may occur. In children, convulsions may be present. Signs of barbiturate intoxication may include: (a) a decrease in the level of consciousness ranging from sleep to coma, and coma. Tonic-clonic seizures may develop. Respiratory depression is remote when the drug is injected slowly in fractional doses. A commonly used initial dose for the 70 kg adult is 100 mg. Proportional reduction in dosage should be made for patients who are fatigued, debilitated, or elderly. At least one minute is necessary to determine the full effect of intravenous barbiturates. If necessary, additional small increments of the drug may be given up to a total of 150 to 200 mg for adults or 5 to 10 mg/kg for children.

Anticonvulsant use: in convulsive states, dosage of NEMBUTAL Sodium should be kept to a minimum effect. In the more severe convulsions which may follow convulsions. The injection must be made slowly with due regard to the time required for the drug to penetrate the blood-brain barrier. Special patient population: Dosage should be reduced in the elderly or debilitated because these patients may be more sensitive to NEMBUTAL Sodium. Dosage should be reduced for patients with impaired renal function or hepatic disease.

Inspection: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to use. For aqueous solution container systems, Solutions for injection showing evidence of precipitation should not be used.

HOW SUPPLIED

NEMBUTAL Sodium Solution should not be admixed with any other medication section).

NEMBUTAL Sodium Solution is contraindicated in patients sensitive to the effects of the barbiturates and in those with a history of allergic reactions to barbiturates. NEMBUTAL Sodium Solution should be used with caution in patients with hepatic impairment or renal disease.

The barbiturates are nonselective central nervous system depressants which are primarily used as sedative hypnotics and analgesics. They are also useful in the management of epilepsy. Barbiturates are usually administered orally, but they may also be given by injection (intravenous, intramuscular, or subcutaneous), or by inhalation. The barbiturates are reversibly eliminated by the liver, with a half-life of 3 to 6 hours. The liver is the primary site of toxicologically significant metabolism of the barbiturates.
Barbiturates may be habit forming. Tolerance and psychological and physical dependence may occur with chronic administration of barbiturates. Ordinarily, when such dependence occurs, it is of a mild degree and readily controlled by decreasing the dose of the drug or discontinuing its administration gradually. However, patients physically dependent on barbiturates should be cautiously and gradually withdrawn from the drug. Abrupt discontinuation of barbiturates may produce withdrawal symptoms, including: fever, delirium, hypertension, tachycardia, hallucinations, motor excitement, ataxia, convulsions, tremor, rigidity, and delirium tremens. The duration of these symptoms is usually less than 1 week. Preventive measures may be required in patients with a history of barbiturate or alcohol dependence. The physician should be prepared to treat withdrawal symptoms with an adequate dose of other depressant drugs such as diazepam, chloral hydrate, meprobamate, or a combination of these agents. Caution should be exercised when a barbiturate is administered to a nursing woman since small amounts of this drug may appear in breast milk. The patient should be warned against increasing the dose of the drug without consulting a physician.

2. Barbiturates may impair mental and/or physical abilities required for the performance of potentially hazardous tasks (e.g., driving, operating machinery, etc.).

3. Alcohol should not be consumed while taking barbiturates. Concurrent use of the barbiturates with alcohol or other central nervous system depressants may result in excessive and unpredictable intoxication.

4. Most reports of clinically significant drug interactions occurring with the barbiturates have involved phenytoin. However, the administration of other drugs to these barbiturates appears valid and warrants serial blood level determinations of the relevant drugs when there are multiple therapies.

5. Anticonvulsants: Phenytoin, sodium valproate, valproic acid:

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: Phenobarbital has been shown to shorten the half-life of doxycycline for as long as 2 weeks after barbiturate therapy is discontinued.

: Phenobarbital may prolong the half-life of doxycycline by inhibiting its metabolism on therapeutic response has not been established. However, it would be preferable to avoid concomitant administration of these drugs.

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