Phenobarbital is a substituted pyrimidine derivative in which the basic nucleus is barbituric acid, a substance that has CNS activity. In activity is obtained by a barbituric acid, alkyl, or any group on the pyrimidine ring.

Each 5 mL (Spoon) contains 5 mg Phenobarbital and Alcoholic 3.15%. The oral solution contains Citric Acid, Phenobarbital Sodium, FD&C Red No. 40, Orange Flavor and Purified Water.

**Description**

Phenobarbital is a barbituric acid derivative and occurs as white, odorless, small crystals or crystalline powder that is very slightly soluble in water, soluble in alcohol, in ether, and in soluble of chloroform but is sparingly soluble in alcohol. Phenobarbital is ethyl-phenoxydibuturic acid and has the empirical formula C₁₅H₂₃N₂O₃. Its molecular weight is 232.24. It has the following structural formula:

\[
\text{C}_2\text{H}_5\text{NH}_2\text{C}_2\text{H}_4\text{O}_2\text{C}_2\text{H}_5\text{NH}_2\text{C}_2\text{H}_4\text{O}_2\text{C}_2\text{H}_5\text{NH}_2\text{C}_2\text{H}_4\text{O}_2
\]

Phenobarbital is rapidly absorbed than are the acids. The rate of absorption is increased if the sodium salt is ingested as a dilute solution or taken on an empty stomach. Phenobarbital can pass into the breast milk but does not appear to affect the infant. Phenobarbital is 5-ethyl-5-phenylbarbituric acid and has the empirical formula C₁₅H₂₃N₂O₃. Its molecular weight is 232.24. It has the following structural formula:

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\text{C}_2\text{H}_5\text{NH}_2\text{C}_2\text{H}_4\text{O}_2\text{C}_2\text{H}_5\text{NH}_2\text{C}_2\text{H}_4\text{O}_2\text{C}_2\text{H}_5\text{NH}_2\text{C}_2\text{H}_4\text{O}_2
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**Phenobarbital Oral Solution, USP**

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proceeding smoothly. A modification of this regimen involves

- The concomitant use of other CNS depressants, including other sedatives or hypnotics, antihistamines, tranquilizers, or alcohol, may produce additive depressant effects.

- MAOIs prolong the

Estradiol, Estrone, Progesterone, and other Steroidal Hormones

Pretreatment with or concurrent administration of

Animal Data

In a 29-year epidemiologic study of 9,136 patients who were treated on an anticonvulsant protocol that included Phenobarbital, results indicated a higher than expected frequency of breast cancer in women who received the medication. In this study, breast cancer was diagnosed at a mean of 16 years after the initiation of Phenobarbital treatment. In the general population, breast cancer is diagnosed on average at age 56. Although the results were statistically significant, the absolute risk increase was small (0.07% per year).

Usage in Pregnancy

1. Warnings.

The following adverse reactions have been reported:

Other. Nausea and vomiting, somnolence, headaches.

Drug dependence on barbiturates arises from repeated administration of small therapeutic doses of barbiturates. Dependence is characterized by tolerance, manifested by a reduced response to a given dose of the drug, and by withdrawal symptoms, which occur when the drug is stopped or the dose is reduced. The clinical picture is reminiscent of alcohol withdrawal, with the onset of symptoms occurring within 1 day, reaching a peak within 2 to 3 days, and then subsiding in 2 to 3 weeks. The withdrawal syndrome may be severe, with symptoms of unsteadiness of gait, tremor, nausea, vomiting, abdominal cramps, and diarrhea. In the more severe cases, insomnia, anxiety, agitation, and confusion may persist for several weeks. Treatment of withdrawal involves the gradual reduction of the dose of Phenobarbital. The dose of Phenobarbital must be individualized with full knowledge of its particular characteristics. Factors of consideration are the patient's age, weight, and condition.

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