

**PHENOHYTRO- phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide tablet**  
**Winder Laboratories, LLC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**Phenohtro™ (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) Tablets**

**Rx Only**

**DESCRIPTION**

Each Phenohtro™ Tablet contains:

Phenobarbital, USP..... 16.2 mg  
Hyoscyamine Sulfate, USP..... 0.1037 mg  
Atropine Sulfate, USP .....0.0194 mg  
Scopolamine Hydrobromide, USP .....0.0065 mg

Inactive Ingredients: Anhydrous Lactose, Calcium Stearate, Colloidal Silicon Dioxide, Corn Starch, and Microcrystalline Cellulose.

**CLINICAL PHARMACOLOGY**

Phenohtro™ Tablets combine natural belladonna alkaloids in a specific, fixed ratio with phenobarbital to provide peripheral anticholinergic/antispasmodic action and mild sedation.

**INDICATIONS AND USAGE**

Based on a review of this drug by the National Academy of Sciences–National Research Council and/or other information, FDA has classified the indications as follows: “Possibly” effective: For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.  
May also be useful as adjunctive therapy in the treatment of duodenal ulcer.  
Final classification of the less-than-effective indications requires further investigation.  
IT HAS NOT BEEN SHOWN CONCLUSIVELY WHETHER ANTICHOLINERGIC/ANTISPASMODIC DRUGS AID IN THE HEALING OF A DUODENAL ULCER, DECREASE THE RATE OF RECURRENCES OR PREVENT COMPLICATIONS.

## **CONTRAINDICATIONS**

Phenohydro™ Tablets are contraindicated in patients with glaucoma; obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.); paralytic ileus, intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis especially if complicated by toxic megacolon; myasthenia gravis; hiatal hernia associated with reflux esophagitis.

Phenohydro™ Tablets are contraindicated in patients with known hypersensitivity to any of the ingredients. Phenobarbital is contraindicated in acute intermittent porphyria and in those patients in whom phenobarbital produces restlessness and/or excitement.

## **WARNINGS**

Phenohydro™ Tablets can cause fetal harm when administered to a pregnant woman. Animal reproduction studies have not been conducted with Phenohydro™. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

In the presence of a high environmental temperature, heat prostration (fever and heatstroke due to decreased sweating) can occur with belladonna alkaloids.

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. Administration of Phenohydro™ Tablets to a patient exhibiting diarrhea would be inappropriate and possibly harmful.

Phenohydro™ Tablets may produce drowsiness or blurred vision. Should these occur, the patient should be warned not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery, and not to perform hazardous work.

Phenobarbital may decrease the effect of anticoagulants, and necessitate larger doses of the anticoagulant for optimal effect. When the phenobarbital is discontinued, the dose of the anticoagulant may have to be decreased.

Phenobarbital may be habit forming and should not be administered to individuals known to be addiction prone or to those with a history of physical and/or psychological dependence upon drugs.

Since barbiturates are metabolized in the liver, they should be used with caution and initial doses should be small in patients with hepatic dysfunction.

## **PRECAUTIONS**

### **GENERAL**

Phenohydro™ Tablets should be used with caution in patients with: autonomic neuropathy, hepatic or renal disease, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia, and hypertension.

Belladonna alkaloids may produce a delay in gastric emptying (antral stasis) which would complicate the management of gastric ulcer.

Phenohydro™ Tablets should not be used in the presence of complication of biliary tract disease.

In the event of overdosage of Phenohydro™ Tablets, a curare-like action may occur.

## **CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY**

Long-term studies in animals have not been performed to evaluate carcinogenic potential of Phenohydro™ Tablets.

## **USE IN SPECIAL PATIENT POPULATIONS**

### **PREGNANCY**

#### **PREGNANCY CATEGORY D**

Animal reproduction studies have not been conducted with Phenohydro™. There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks (see WARNINGS).

### **NURSING MOTHERS**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Phenohydro™ Tablets are administered to a nursing woman.

### **GERIATRIC USE**

Elderly patients may react with symptoms of excitement, agitation, drowsiness, and other untoward manifestations to even small doses of the drug.

## **ADVERSE REACTIONS**

Adverse reactions may include xerostomia; urinary hesitancy and retention; blurred vision; tachycardia; palpitation; mydriasis; cycloplegia; increased ocular tension; loss of taste sense; headache; nervousness; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; impotence; suppression of lactation; constipation; bloated feeling; musculoskeletal pain; severe allergic reaction or drug idiosyncrasies, including anaphylaxis, urticaria and other dermal manifestations; and decreased sweating.

Acquired hypersensitivity to barbiturates consists chiefly in allergic reactions that occur especially in persons who tend to have asthma, urticaria, angioedema and similar conditions. Hypersensitivity reactions in this category include localized swelling, particularly of the eyelids, cheeks, or lips, and erythematous dermatitis. Rarely, exfoliative dermatitis (e.g. Stevens-Johnson syndrome and toxic epidermal necrolysis) may be caused by phenobarbital and can prove fatal. The skin eruption may be associated with fever, delirium, and marked degenerative changes in the liver and other parenchymatous organs. In a few cases, megaloblastic anemia has been associated with the chronic use of phenobarbital.

Phenobarbital may produce excitement in some patients, rather than a sedative effect. In patients habituated to barbiturates, abrupt withdrawal may produce delirium or convulsions.

**To report SUSPECTED ADVERSE REACTIONS, contact Winder Laboratories, LLC at 1-770-307-0702 or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## **DOSAGE AND ADMINISTRATION**

The dosage of Phenohydro™ should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse effects.

*Phenohydro™ Tablets* - Adults: One or two Phenohydro™ Tablets three or four times a day according to condition and severity of symptoms.

## **OVERDOSAGE**

The signs and symptoms of overdose are headache, nausea, vomiting, blurred vision, dilated pupils, hot and dry skin, dizziness, dryness of the mouth, difficulty in swallowing, and CNS stimulation. Treatment should consist of gastric lavage, emetics, and activated charcoal. If indicated, parenteral cholinergic agents such as physostigmine or bethanechol chloride should be used.

## **HOW SUPPLIED / STORAGE AND HANDLING**

Phenohydro™ Tablets are supplied as: white, round tablets debossed "112" on one side and plain on the other side.

Bottles of 100 tablets, NDC 75826-118-10

Bottles of 1000 tablets, NDC 75826-118-00

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Protect from light and moisture.

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Use safety closures when dispensing this product unless otherwise directed by a physician or requested by purchaser.

### **Manufactured by:**

Winder Laboratories, LLC

Winder, GA 30680

**[www.phenohydro.com](http://www.phenohydro.com)**

Rev. 03/16

**Phenohydro™ - 100 Tablets**

**Adult Dosage and Administration:**  
See accompanying prescribing information.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Protect from light and moisture.

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

**KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.**

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**Manufactured by:**  
Winder Laboratories, LLC.  
Winder, GA 30680

NDC 75826-118-10

**winder**  
LABS



Each tablet contains:  
Phenobarbital, USP..... 16.2 mg  
Hyoscyamine Sulfate, USP..... 0.1037 mg  
Atropine Sulfate, USP..... 0.0194 mg  
Scopolamine Hydrobromide, USP..... 0.0065 mg

**DO NOT USE IF TAMPER-EVIDENT SEAL UNDER CAP IS BROKEN OR MISSING.**

**Rx Only**

**100 Tablets**

RLS.118.10 rev. 07/19

51403-01



## PHENOHTRO

phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:75826-118
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	CIV

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENOBARBITAL</b> (UNII: YQE403BP4D) (PHENOBARBITAL - UNII:YQE403BP4D)	PHENOBARBITAL	16.2 mg
<b>HYOSCYAMINE SULFATE</b> (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X)	HYOSCYAMINE SULFATE	0.1037 mg
<b>ATROPINE SULFATE</b> (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	ATROPINE SULFATE	0.0194 mg
<b>SCOPOLAMINE HYDROBROMIDE</b> (UNII: 451IFR0GXB) (SCOPOLAMINE - UNII:DL48G20X8X)	SCOPOLAMINE HYDROBROMIDE	0.0065 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS LACTOSE</b> (UNII: 3S5Y5LH9PMK)	
<b>CALCIUM STEARATE</b> (UNII: 776XM7047L)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	112
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75826-118-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/29/2016	
2	NDC:75826-118-00	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/29/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/29/2016	

**Labeler** - Winder Laboratories, LLC (965195170)

## Establishment

Name	Address	ID/FEI	Business Operations
Winder Laboratories, LLC		965195170	manufacture(75826-118)

Revised: 12/2019

Winder Laboratories, LLC