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.

Phenohytro™ (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) Tablets

Rx Only

DESCRIPTION

Each Phenohytro™ 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

Phenohytro™ 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

Phenohytro™ 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.

Phenohytro™ 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

Phenohytro™ Tablets can cause fetal harm when administered to a pregnant woman. Animal reproduction studies have not been conducted with Phenohytro™. 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 Phenohytro™ Tablets to a patient exhibiting diarrhea would be inappropriate and possibly harmful.

Phenohytro™ 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

Phenohytro™ 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.

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

In the event of overdosage of Phenohytro™ 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 Phenohytro™ Tablets.

USE IN SPECIAL PATIENT POPULATIONS

PREGNANCY

PREGNANCY CATEGORY D

Animal reproduction studies have not been conducted with Phenohytro™. 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 Phenohytro™ 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.

DOSAGE AND ADMINISTRATION

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

Phenohytro™ Tablets - Adults: One or two Phenohytro™ 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

Phenohytro™ 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.

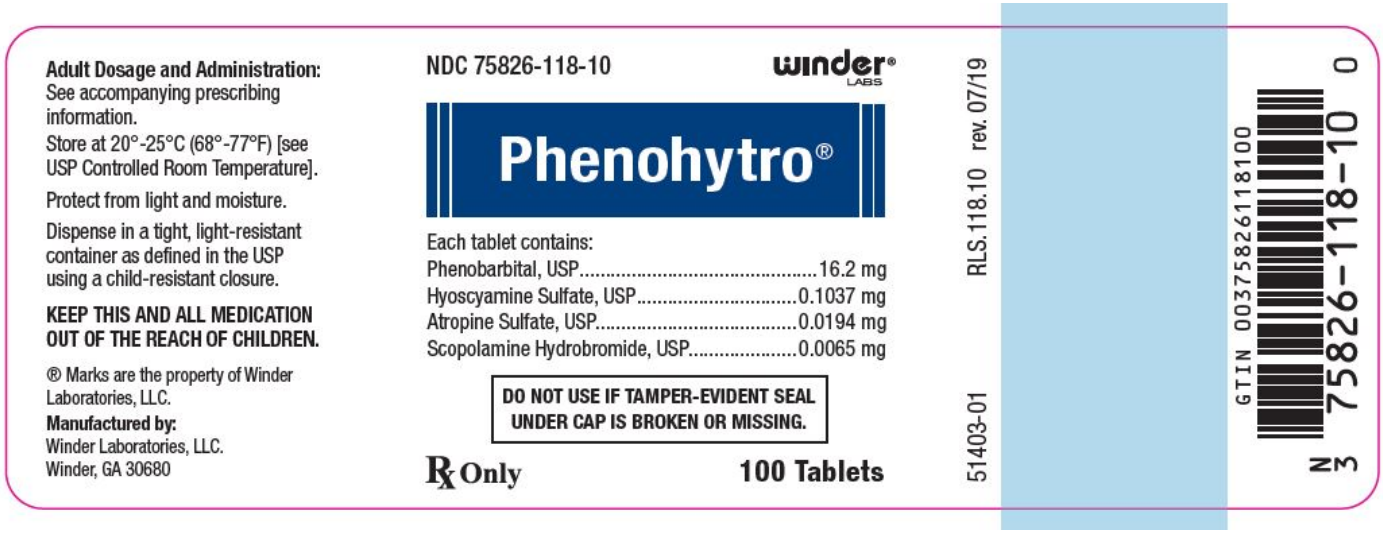
Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Use safety closures when dispensing this product unless otherwise directed by a physician or requested by purchaser.

Manufactured by:
Winder Laboratories, LLC
Winder, GA 30680

www.phenohytro.com

Rev. 03/16

Phenohytro™ - 100 Tablets



PHENOHYTRO

phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:75826-118
Route of Administration	ORAL	**DEA Schedule**	CIV

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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CALCIUM STEARATE (UNII: 776XM7047L)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	112
Contains			

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