PHENOHYTRO- phenobarbital, hyoscyamine sulfate, atropine sulfate, and scopolamine hydrobromide elixir
ATLANTIC BIOLOGICALS CORP.

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® ELIXIR

Rx Only

DESCRIPTION

PHENOHYTRO® ELIXIR Grape Flavored

each 5 mL (teaspoonful) oral-administered dose of elixir contains:

Phenobarbital, USP (**WARNING:** may be habit forming)	16.2 mg
Hyoscyamine Sulfate, USP	0.1037 mg
Atropine Sulfate, USP	0.0194 mg
Scopolamine Hydrobromide, USP	0.0065 mg
Alcohol not more than 23.8%	

INACTIVE INGREDIENTS

Purified water, glycerin, sorbitol, ethyl alcohol, sucrose, sodium saccharin, artificial grape flavor, FD&C Red No. 3, FD&C Blue No. 1.

DESCRIPTION

PHENOHYTRO® ELIXIR Mint Flavored

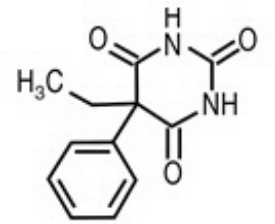
each 5 mL (teaspoonful) oral-administered dose of elixir contains:

Phenobarbital, USP (**WARNING:** may be habit forming)	16.2 mg
Hyoscyamine Sulfate, USP	0.1037 mg
Atropine Sulfate, USP	0.0194 mg
Scopolamine Hydrobromide, USP	0.0065 mg
Alcohol not more than 23.8%	

INACTIVE INGREDIENTS

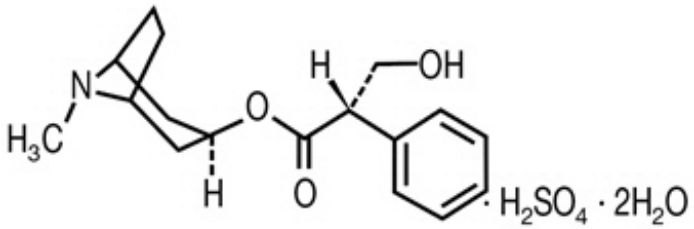
Purified water, glycerin, sorbitol, ethyl alcohol, sucrose, sodium saccharin, artificial mint flavor, FD&C Yellow No. 5, FD&C Blue No. 1.

Phenobarbital is a barbiturate with the chemical name 2,4,6(1H,3H,5H) -Pyrimidinetrione, 5-ethyl-5-phenyl-. It has the following structural formula:



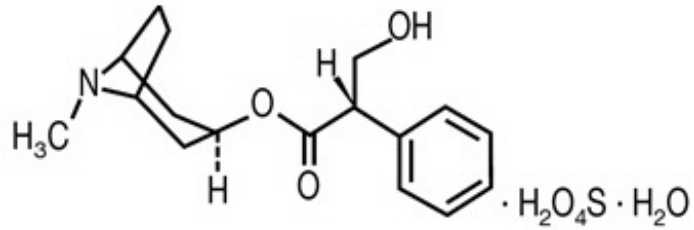
C12H12N2O3 Chemical Structure M.W. 232.2

Hyoscyamine sulfate is a belladonna alkaloid with the chemical name Benzeneacetic acid, α-(hydroxmethyl)-, 8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester, [3(S)-endo]-, sulfate (2:1), dihydrate. It has the following structural formula:



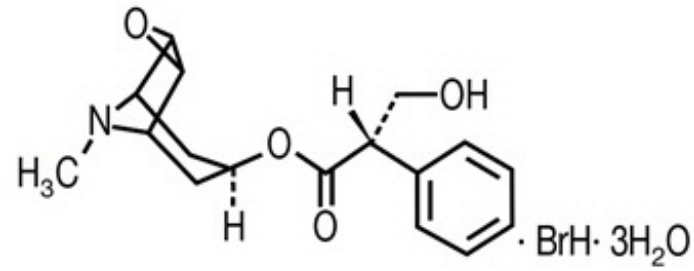
(C17H23NO3)2 • H2SO4 • 2H2O Chemical Structure M.W. 712.85

Atropine sulfate is belladonna alkaloid with the chemical name: Benzeneacetic acid, α-(Hydroxymethyl)benzeneacetic acid 8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester. It has the following structural formula:



(C34H46N2O6 • H2O4S • H2O Chemical Structure M.W. 694.83

Scopolamine hydrobromide is a belladonna alkaloid with the chemical name Benezeneacetic acid, α-(hydroxymethyl)-, 9-methyl-3-oxa-9-azatricyclo[3.31.0.2,4]non-[7-yl ester, hydrobromide, trihydrate, [7(S)-(1α,2β,4β,5α,7β)]-. It has the following structural formula:



C17H21NO4 • BrH • 3H2O Chemical Structure M.W. 438.31

CLINICAL PHARMACOLOGY

This drug combination provides phenobarbital combined with belladonna alkaloids in a specific, fixed ratio to provide anticholinergic/antispasmodic action and mild sedation.

Phenobarbital is a barbiturate, nonselective central nervous system depressant. It is primarily used as a sedative hypnotic and also as an anticonvulsant in subhypnotic doses.

Atropine Sulfate, Hyoscyamine Sulfate, and Scopolamine are belladonna alkaloids classified as anticholinergic, antimuscarinic drugs. They act to inhibit muscarinic actions of acetylcholine at postganglionic parasympathetic neuron effector sites. These drugs are also used as antispasmodics due to their anticholinergic action. They produce the effect in the body of reduced muscle spasms in the digestive or urinary tract, and reduced fluid secretions from certain glands or organs.

INDICATIONS AND USAGE

Based on the National Academy of Sciences-National Research Council's review of this drug and/or other information, FDA has classified the following indications as "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.

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® ELIXIR is contraindicated in patients with known hypersensitivity to any of the ingredients. Phenobarbital is contraindicated in patients with acute intermittent porphyria and in those patients in which phenobarbital produces restlessness and/or excitement.

PHENOHYTRO® ELIXIR is also contraindicated in patients with glaucoma, obstructive uropathy; paralytic ileus; myasthenia gravis; intestinal atony; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis especially if complicated by toxic megacolon; hiatal hernia associated with reflux esophagitis; obstructive disease of the gastrointestinal tract; or severe ulcerative colitis.

WARNINGS

Heat prostration can occur with belladonna alkaloids in high temperatures.

Diarrhea may be an early symptom of incomplete intestinal obstruction, particularly in patients with ileostomy or colostomy. In this instance, treatment with this drug could be harmful.

PHENOHYTRO® ELIXIR may produce drowsiness and blurred vision. The patient should be warned about engaging in hazardous work or activities requiring mental alertness,

such as operating a motor vehicle or other machinery.

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

Phenobarbital may be habit forming and should not be administered to patients who are susceptible to addiction or to those with a history of physical and/or psychological drug dependence.

Barbiturates should be used with caution in patients with hepatic dysfunction.

PRECAUTIONS

GENERAL

Use 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.

Do not rely on the use of the drug in the presence of complication of biliary tract disease. Theoretically, a curare-like action may occur with overdosage.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

PREGNANCY

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with PHENOHYTRO® ELIXIR. It is not known whether PHENOHYTRO® ELIXIR can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PHENOHYTRO® ELIXIR should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when administering PHENOHYTRO® ELIXIR to a nursing woman.

INFORMATION FOR PATIENTS

Practitioners should give the following information and instructions to patients:

- Do not increase the dose of this drug without consulting a physician.
- Do not share this medication with others.
- The use of this product carries with it an associated risk of psychological and/or physical dependence.
- The use of this product may impair mental and/or physical abilities required for the

performance of potentially hazardous tasks such as driving or operating machinery.
- Use of this product with alcohol may result in additional central nervous system depressant effects.
- Tell your doctor or pharmacist if you also take antihistamines, anti-seizure drugs, medicine for sleep or anxiety, muscle relaxants, narcotic pain relievers, or psychiatric medicines.
- This drug may increase the risk for heatstroke because it decreases sweating. Avoid becoming overheated in hot weather, saunas, and during exercise or other strenuous activity.

ADVERSE REACTIONS

Call your doctor for medical advice about side effects.

Adverse reactions associated with anticholinergics and/or anticonvulsants are: dry mouth; tachycardia; urinary hesitancy and retention; palpitation; blurred vision; prolonged pupil dilation; cycloplegia; increased ocular tension; loss of taste sense; headache; nervousness; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; severe allergic reaction or drug idiosyncrasies, including anaphylaxis, hives and/or other dermal manifestations; decreased sweating; impotence; suppression of lactation; constipation; bloated feeling and musculoskeletal pain. Elderly patients may react with symptoms of excitement, agitation and drowsiness to even small doses of the drug. 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 FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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. Call your doctor or local Poison Control Center if overdosage is suspected.

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

DOSAGE AND ADMINISTRATION

Adults

One or two teaspoonfuls of PHENOHYTRO® ELIXIR three or four times a day according to conditions and severity of symptoms.

Pediatric patients

may be dosed every 4 to 6 hours.

Starting Dosage

Body Weight	q4h	q6h
10 lb. (4.5 kg)	0.5 mL	0.75 mL
20 lb. (9.1 kg)	1.0 mL	1.5 mL
30 lb. (13.6 kg)	1.5 mL	2.0 mL
50 lb. (22.7 kg)	1/2 tsp	3/4 tsp
75 lb. (34 kg)	3/4 tsp	1 tsp
100 lb. (45.4kg)	1 tsp	1 1/2 tsp

HOW SUPPLIED

PHENOHYTRO® ELIXIR Grape Flavored is a purple colored, grape flavored liquid.

NDC 17856-0125-01 Grape Flavored in 10mL 72 CUP

NDC 17856-0125-02 Grape Flavored in 5mL 72 CUP

STORAGE CONDITIONS

AVOID FREEZING

Store PHENOHYTRO® ELIXIR 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.

WARNINGS: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

IN THE CASE OF OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

Contains color additives, including FD&C Yellow No. 5 (tartrazine).

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

20101 N.E 16TH PLACE

MIAMI, FL 33179

PRINCIPAL DISPLAY PANEL - 16 fl. oz. Bottle Label - Grape

NDC 17856-0125-02

Phenohytro®

Elixir 5mL CUP

Grape Flavored

Each 5 mL (1 teaspoonful) contains:

Phenobarbital, USP
16.2 mg

Hyoscyamine Sulfate, USP
0.1037 mg

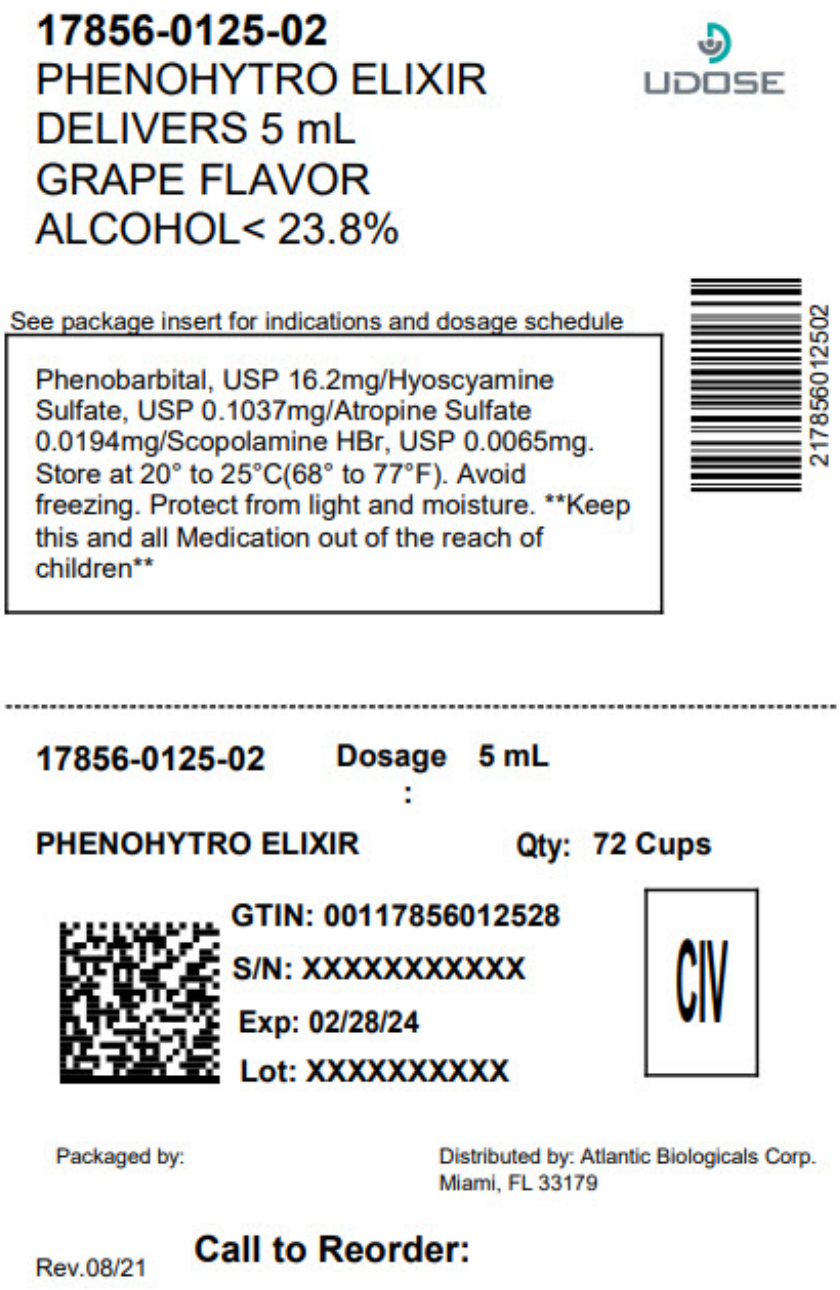
Atropine Sulfate, USP
0.0194 mg

Scopolamine Hydrobromide, USP
0.0065 mg

Alcohol not more than 23.8%

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

Rx Only
16 fl. oz.



PRINCIPAL DISPLAY PANEL - 16 fl. oz. Bottle Label - Grape

NDC 17856-0125-01

Phenohytro®

Elixir 10mL CUP

Grape Flavored

Each 5 mL (1 teaspoonful) contains:

Phenobarbital, USP
16.2 mg

Hyoscyamine Sulfate, USP
0.1037 mg

Atropine Sulfate, USP
0.0194 mg

Scopolamine Hydrobromide, USP
0.0065 mg

Alcohol not more than 23.8%

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

Rx Only
16 fl. oz.

17856-0125-01
PHENOHYTRO ELIXIR
DELIVERS 10 mL
GRAPE FLAVOR
ALCOHOL< 23.8%

UDOSE

See package insert for indications and dosage schedule

Phenobarbital, USP 32.4mg/Hyoscyamine Sulfate, USP 0.2074mg/Atropine Sulfate 0.0388mg/Scopolamine HBr, USP 0.013mg. Store at 20° to 25°C(68° to 77°F). Avoid freezing. Protect from light and moisture. **Keep this and all Medication out of the reach of children**

21856012501

17856-0125-01 **Dosage :** **10mL**

PHENOHYTRO ELIXIR **Qty: 72 Cups**

GTIN: 00117856012511
S/N: XXXXXXXXXXX
Exp: 02/28/24
Lot: XXXXXXXXXX

CIV

Packaged by:

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21 **Call to Reorder:**

PHENOHYTRO
phenobarbital, hyoscyamine sulfate, atropine sulfate, and scopolamine hydrobromide elixir

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17856-0125(NDC:75826-127)
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 in 5 mL
Hyoscyamine Sulfate (UNII: F2R8V82B84) (Hyoscyamine - UNII:PX44XO846X)	Hyoscyamine Sulfate	0.1037 mg in 5 mL
Atropine sulfate (UNII: 03J5ZE7KA5) (Atropine - UNII:7C0697DR9I)	Atropine sulfate	0.0194 mg in 5 mL
Scopolamine Hydrobromide (UNII: 451IFR0GXB) (Scopolamine - UNII:DL48G20X8X)	Scopolamine Hydrobromide	0.0065 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	1981 mg in 5 mL
ALCOHOL (UNII: 3K9958V90M)	407 mg in 5 mL
WATER (UNII: 059QF0KO0R)	2119 mg in 5 mL
Sucrose (UNII: C151H8M554)	289 mg in 5 mL
Sorbitol (UNII: 506T60A25R)	895 mg in 5 mL
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	28.9 mg in 5 mL
FD&C Red No. 3 (UNII: PN2ZH5LOQY)	0.075 mg in 5 mL
FD&C Blue No. 1 (UNII: H3R47K3TBD)	0.005 mg in 5 mL
Grape (UNII: 6X543N684K)	2 mg in 5 mL

Product Characteristics

Color	PURPLE	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0125-1	72 in 1 BOX	04/08/2024	
1	NDC:17856-0125-3	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-0125-2	72 in 1 BOX	04/08/2024	
2	NDC:17856-0125-4	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		08/30/2018	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-0125)

Revised: 4/2024 ATLANTIC BIOLOGICALS CORP.