PHENOBARBITAL WITH BELLADONNA ALKALOIDS- phenobarbital with belladonna alkaloids 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.

PHENOBARBITAL WITH BELLADONNA ALKALOIDS ELIXIR

PHENOBARBITAL with BELLADONNA ALKALOIDS ELIXIR

Rx Only

Rev. 1/18

DESCRIPTION:

Each 5 mL (teaspoonful) of elixir 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:

Ethyl Alcohol, Purified Water, Glycerin, Methylparaben Sodium, Propylparaben Sodium, Saccharin Sodium, Xylitol, Citric Acid, Stevia Reb-A, Natural and Artificial Grape Flavor

CLINICAL PHARMACOLOGY:

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

INDICATIONS AND USAGE:

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:

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.

Phenobarbital with Belladonna Alkaloids Elixir is 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:

In the presence of a high environmental temperature, heat prostration can occur with belladonna alkaloids (fever and heatstroke due to decreased sweating). Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful.

Phenobarbital with Belladonna Alkaloids Elixir may produce drowsiness or blurred vision. The patient should be warned, should these occur, 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

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. Theoretically, with overdosage, a curare-like action may occur.

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Pregnancy Category C

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

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. Elderly patients may react with symptoms of excitement, agitation, drowsiness, and other untoward manifestations 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.

DOSAGE AND ADMINISTRATION:

The dosage of *Phenobarbital with Belladonna Alkaloids Elixir* should be adjusted to the needs of the

individual patient to assure symptomatic control with a minimum of adverse effects.

Adults:

One or two teaspoonfuls of 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

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, 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 added.

HOW SUPPLIED:

Phenobarbital with Belladonna Alkaloids Elixir is supplied as a purple colored, grape flavored liquid.

4 oz. bottles

NDC: 17856-0162-1

NDC: 17856-0162-2

NDC: 17856-0162-3

AVOID FREEZING

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.

All prescriptions using this product shall be pursuant to State statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on the therapeutic equivalence.

WARNINGS: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

20101 N.E 116th PLACE

MIAMI, FL 33179

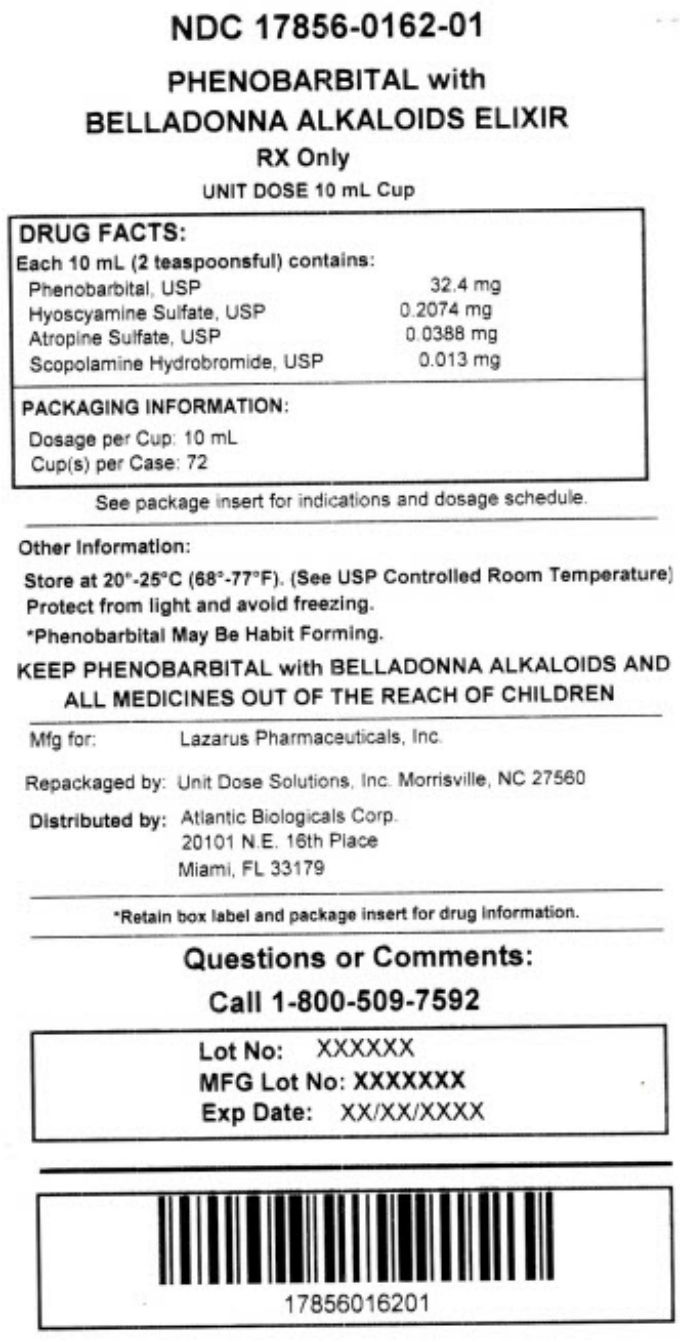
Principal Display Panel

NDC 17856-0162-1

PHENOBARBITAL WITH BELLADONNA ALKALOIDS ELIXIR

10mL/72 Cup

Rx Only



NDC 17856-0162-2

PHENOBARBITAL WITH BELLADONNA ALKALOIDS ELIXIR

5mL/72 Cup

Rx Only

NDC 17856-0162-02

PHENOBARBITAL with BELLADONNA ALKALOIDS ELIXIR

RX ONLY

UNIT DOSE 5 mL Cup

DRUG FACTS:

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

PACKAGING INFORMATION:

Dosage per Cup: 5 mL

Cup(s) per Case: 72

See package insert for indications and dosage schedule.

Other Information:

Store at 20°-25°C (68°-77°F). [See USP Controlled Room Temperature].
Protect from light and avoid freezing.

*Phenobarbital May Be Habit Forming.

KEEP PHENOBARBITAL with BELLADONNA ALKALOIDS AND ALL MEDICINES OUT OF REACH OF CHILDREN

Mfg for: Lazarus Pharmaceuticals, Inc.

Repackaged by: Unit Dose Solutions, Inc. Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.
20101 N.E. 16th Place
Miami, FL 33179

***Retain box label and package insert for drug information.**

Questions or Comments:
Call 1-800-509-7592

Lot No: XXXXXX
MFG Lot No: XXXXXXXX
Exp Date: XX/XX/XXXX

17856016202

NDC 17856-0162-3

PHENOBARBITAL WITH BELLADONNA ALKALOIDS ELIXIR

5mL/10 Cup

Rx Only

NDC 17856-0162-03

PHENOBARBITAL with BELLADONNA ALKALOIDS ELIXIR

RX ONLY

UNIT DOSE 5 mL Cup

DRUG FACTS:

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

PACKAGING INFORMATION:

Dosage per Cup: 5 mL

Cup(s) per Case: 10

See package insert for indications and dosage schedule.

Other Information:

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

Protect from light and avoid freezing.

* Phenobarbital May Be Habit Forming.

KEEP PHENOBARBITAL with BELLADONNA ALKALOIDS AND ALL MEDICINES OUT OF REACH OF CHILDREN

Mfg for: Lazarus Pharmaceuticals, Inc.

Repackaged by: Unit Dose Solutions, Inc. Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.
20101 N.E. 16th Place
Miami, FL 33179

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Questions or Comments:
Call 1-800-509-7592

Lot No: XXXXXX
MFG Lot No: XXXXXXX
Exp Date: XX/XX/XXXX

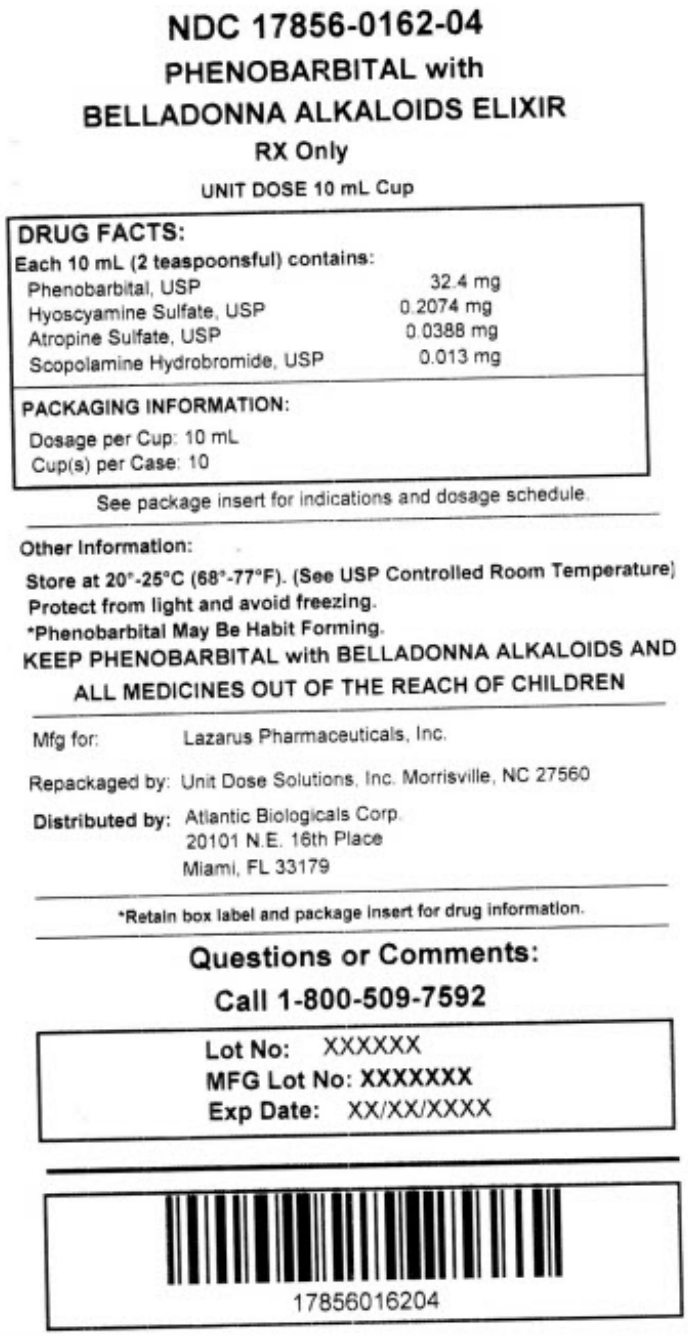
17856016203

NDC 17856-0162-4

PHENOBARBITAL WITH BELLADONNA ALKALOIDS ELIXIR

10mL/10 Cup

Rx Only



PHENOBARBITAL WITH BELLADONNA ALKALOIDS

phenobarbital with belladonna alkaloids elixir

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17856-0162(NDC:71914-162)
Route of Administration	ORAL		

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	.0065 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XYLITOL (UNII: VCQ006KQ1E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
REBAUDIOSIDE A (UNII: B3FUD0528F)	

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:17856-0162-1	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	06/15/2018	
2	NDC:17856-0162-2	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	06/15/2018	
3	NDC:17856-0162-3	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	06/15/2018	
4	NDC:17856-0162-4	10 in 1 BOX	06/15/2018	
4		10 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		05/21/2018	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations

ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-0162) , relabel(17856-0162)