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.

**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 *Phenobarbital* with *Belladonna Alkaloids Elixir* is administered to a nursing mother.

**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.

To report SUSPECTED ADVERSE REACTIONS, contact Lazarus Pharmaceuticals, Inc. at 1-888-296-9383 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSEAGE 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:

<table>
<thead>
<tr>
<th>Body Weight q4h q6h</th>
<th>10 lb. (4.5 kg)</th>
<th>15 lb. (6.8 kg)</th>
<th>20 lb. (9.1 kg)</th>
<th>30 lb. (13.6 kg)</th>
<th>50 lb. (22.7 kg)</th>
<th>75 lb. (34 kg)</th>
<th>100 lb. (45.4 kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 mL</td>
<td>0.75 mL</td>
<td>1.0 mL</td>
<td>1.5 mL</td>
<td>2.0 mL</td>
<td>3/4 tsp</td>
<td>1 tsp</td>
<td>1 1/2 tsp</td>
</tr>
<tr>
<td>1.0 mL</td>
<td>1.5 mL</td>
<td>2.0 mL</td>
<td></td>
<td></td>
<td>1 tsp</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

NDC: 71914-162-01: 5 mL unit-dose cup
NDC: 71914-162-10: Case contains 10 unit-dose cups of 5 mL (NDC: 71914-162-01), packed in 1 tray of 10 unit-dose cups
4 oz. bottles
NDC: 71914-162-04
16 oz. (Pint) bottles
NDC: 71914-162-16

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.

Manufactured for:
Lazarus Pharmaceuticals, Inc.

Principal Display Panel
NDC 71914-162-04
PHENOBARBITAL
with
BELLADONNA
ALKALOIDS
ELIXIR
4 oz. Bottle
Rx Only

PHENOBARBITAL
with BELLADONNA ALKALOIDS ELIXIR
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

USUAL ADULT DOSAGE
See accompanying product literature for complete information.
Store at 20° – 25° C (68° - 77°F) (See USP Controlled Room Temperature). Protect from light and avoid freezing.
Keep container tightly closed.
Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

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

Manufactured for: Lazarus Pharmaceuticals, Inc.

NDC 71914-162-16
PHENOBARBITAL
with
BELLADONNA
ALKALOIDS
ELIXIR
16 oz. Bottle
Rx Only
PHENOBARBITAL WITH BELLADONNA ALKALOIDS ELIXIR

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

USUAL ADULT DOSAGE
See accompanying product literature for complete information.

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

Keep container tightly closed.

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

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

Manufactured for: Lazarus Pharmaceuticals, Inc.

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN PRESCRIPTION DRUG</th>
<th>Item Code (Source)</th>
<th>NDC: 71914-162</th>
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<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
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## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHENOBARBITAL (UNII: YQE403BP4D) (PHENOBARBITAL - UNII:YQE403BP4D)</td>
<td>PHENOBARBITAL</td>
<td>16.2 mg in 5 mL</td>
</tr>
<tr>
<td>HYOSCYAMINE SULFATE (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X)</td>
<td>HYOSCYAMINE SULFATE</td>
<td>0.1037 mg in 5 mL</td>
</tr>
<tr>
<td>ATROPINE SULFATE (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)</td>
<td>ATROPINE SULFATE</td>
<td>0.0194 mg in 5 mL</td>
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<tr>
<td>SCOPOLAMINE HYDROBROMIDE (UNII: 451IFR0GXB) (SCOPOLAMINE - UNII:DL48G20X8X)</td>
<td>SCOPOLAMINE HYDROBROMIDE</td>
<td>0.0065 mg in 5 mL</td>
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## Inactive Ingredients

<table>
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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>ALCOHOL (UNII: 3K9958V90M)</td>
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<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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</tr>
<tr>
<td>GLYCERIN (UNII: PDC6A3COOX)</td>
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<tr>
<td>METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)</td>
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<tr>
<td>PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)</td>
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<tr>
<td>SACCHARIN SODIUM (UNII: SB8ZUX40TY)</td>
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<td>XYLITOL (UNII: VCQ006KQ1E)</td>
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<tr>
<td>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)</td>
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<tr>
<td>REBAUDIOSIDE A (UNII: B3FUD0528F)</td>
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## Product Characteristics

| Color | purple |
| Shape | Size |
| Flavor | grape |

## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:71914-162-04</td>
<td>120 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
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<td>NDC:71914-162-16</td>
<td>473 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
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<tr>
<td>3</td>
<td>NDC:71914-162-01</td>
<td>5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product</td>
<td>06/11/2019</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NDC:71914-162-10</td>
<td>1 in 1 CASE</td>
<td>06/11/2019</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NDC:71914-162-01</td>
<td>10 in 1 TRAY</td>
<td></td>
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</tr>
<tr>
<td>4</td>
<td>NDC:71914-162-01</td>
<td>5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product</td>
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</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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