**RE-PB HYOS ELIXIR- belladonna alkaloids w/ phenobarbital elixir**
**Rebel Distributors 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.*

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**Belladonna/Phenobarbital**

## DESCRIPTION

Each 5 mL (teaspoonful) of elixir contains:

Phenobarbital, USP ..... 16.2 mg
(WARNING: may be habit forming)
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:

Artificial Grape Flavor, Ethyl Alcohol, FD and C Blue #1, FD and C Red #40, Glycerin, Purified Water USP, Sodium Saccharin,
Sorbitol Solution 70%, and Sucrose.

## CLINICAL PHARMACOLOGY

This drug combination provides peripheral anticholinergic/antispasmodic action and mild sedation.

## INDICATION AND USAGE

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

RE-PB Hyos 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.

It is also contraindicated in patients with glaucoma, obstructive uropathy; paralytic ileus; myasthenia gravis;
intestinal atony; unstable cardiovascular status in acute hemorrhage; 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, especially in patients with ileostomy or colostomy.
In this instance, treatment with this drug could be harmful.

RE-PB Hyos 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 needed 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,
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 RE-PB Hyos Elixir. It is not known whether RE-PB Hyos Elixir
can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. RE-PB Hyos 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 RE-PB Hyos Elixir is administered to a nursing woman.

**ADVERSE REACTIONS**

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.

**Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.**

## 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 RE-PB Hyos 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 |

## HOW SUPPLIED

RE-PB Hyos Elixir is a purple colored, grape flavored liquid.

NDC 21695-594-16 in bottles of 16 oz.

**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.**

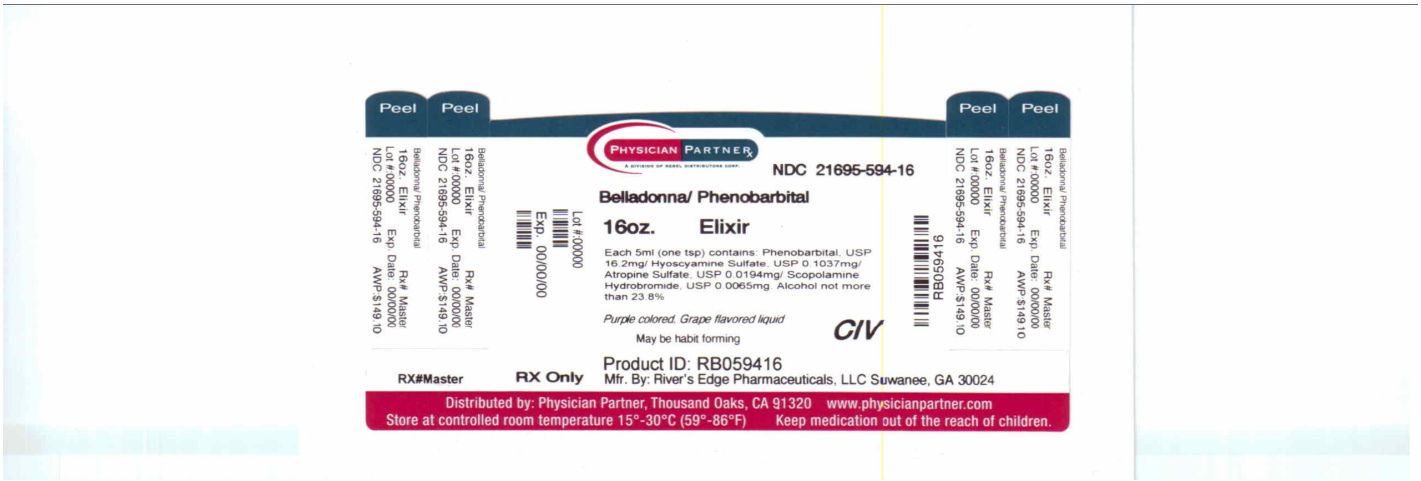
**Manufactured by:**
**Great Southern Laboratories**
**Houston, TX 77099-3405**

**Manufactured for:**
**River's Edge Pharmaceuticals, LLC**
**Suwanee, GA 30024**

**Repackaged by:**
**Rebel Distributors Corp**

**Thousand Oaks, CA 91320**

## Principal Display Panel




# RE-PB HYOS ELIXIR

belladonna alkaloids w/ phenobarbital elixir

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:21695-594(NDC:68032-395) |
| **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** |

| | |
|---|---|
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **SUCROSE** (UNII: C151H8M554) | |

## 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:21695-594-16 | 480 mL in 1 BOTTLE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| Unapproved drug other | | 10/20/2009 | |

## Labeler - Rebel Distributors Corp (118802834)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Rebel Distributors Corp | | 118802834 | RELABEL, REPACK |

Revised: 1/2011 Rebel Distributors Corp