DONNATAL - phenobarbital elixir elixir
PBM Pharmaceuticals Inc.

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.

Donnatal Elixir Mint 4 oz

DESCRIPTION

Donnatal® Elixir - Mint: Each 5 mL (teaspoonful) of elixir (alcohol not more than 23.8%) 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, Glycerin, Purified Water, Saccharin Sodium, Sorbitol, Sucrose, Natural Mint Flavor, FD &C Yellow #5, FD & C Blue #1 and FD&C Red #40.

DESCRIPTION

Donnatal® Elixir - Mint: Each 5 mL (teaspoonful) of elixir (alcohol not more than 23.8%) 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, Glycerin, Purified Water, Saccharin Sodium, Sorbitol, Sucrose, Natural Mint Flavor, FD &C Yellow #5, FD & C Blue #1 and FD&C Red #40.

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

Based on a review of this drug by the National Academy of Sciences-National Research Council 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

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.

Donnatal® 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.

Donnatal® 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.

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

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with Donnatal® Elixir. It is not known whether Donnatal®

Elixir can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Donnatal® 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 Donnatal® Elixir is administered to a nursing woman.

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.

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.

DOSAGE AND ADMINISTRATION

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

Donnatal® Elixir. 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) ½ tsp ¾ tsp

75 lb. (34 kg) ¾ tsp 1 tsp

100 lb. (45.4 kg) 1 tsp 1½ tsp

STORAGE CONDITIONS

Donnatal® Elixir - Grape is a purple colored, grape flavored liquid.

4 fl oz (118 mL) bottles NDC 66213-423-04.

1 Pint (473 mL) bottles NDC 66213-423-16.

Donnatal® Elixir - Mint is a green colored, mint flavored liquid.

4 fl oz (118 mL) bottles NDC 66213-422-04.

1 Pint (473 mL) bottles NDC 66213-422-16.

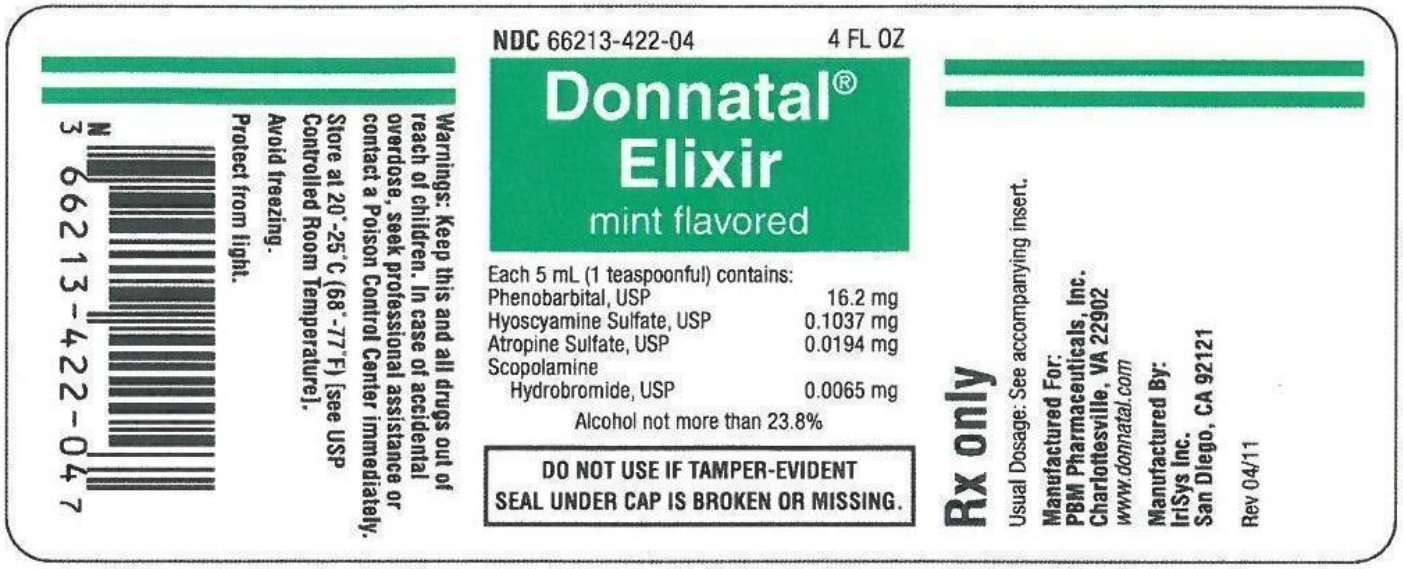
AVOID FREEZING

Store Donnatal® 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.

Example bottle label



DONNATAL

phenobarbital elixir elixir

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66213-422
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
Scopolamine hydrobromide (UNII: 451IFR0GXB) (Scopolamine - UNII:DL48G20X8X)	Scopolamine hydrobromide	0.0065 mg in 5 mL
Atropine sulfate (UNII: 03J5ZE7KA5) (Atropine - UNII:7C0697DR9I)	Atropine sulfate	0.0194 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Glycerin (UNII: PDC6A3C0OX)	2.007 g in 5 mL
alcohol (UNII: 3K9958V90M)	.4158 g in 5 mL
water (UNII: 059QF0KO0R)	2.1432 g in 5 mL

sucrose (UNII: C151H8M554)	.2925 g in 5 mL
sorbitol (UNII: 506T60A25R)	.9068 g in 5 mL
saccharin sodium (UNII: SB8ZUX40TY)	.02925 g in 5 mL
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
FD&C Red No. 3 (UNII: PN2ZH5LOQY)	
MINT (UNII: FV98Z8GITP)	.041 g in 5 mL

Product Characteristics

Color	green	**Score**	
Shape		**Size**	
Flavor	MINT (Natural mint)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66213-422-04	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2011	

Labeler - PBM Pharmaceuticals Inc. (785470050)

Registrant - IriSys, Inc. (959205568)

Establishment

Name	Address	ID/FEI	Business Operations
IriSys, Inc.		959205568	manufacture(66213-422)

Revised: 12/2013 PBM Pharmaceuticals Inc.