

**DONNATAL® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) Elixir**

Rx Only

Revised: 4/2015

**DESCRIPTION**

**Donnatal® Elixir - Grape**

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**

Purified Water, Glycerin, Sorbitol, Ethyl Alcohol, Sucrose, Saccharin Sodium, Artificial and Natural Grape Flavor, FD&C Red #3, and FD&C Blue #1.

**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**

Purified Water, Glycerin, Sorbitol, Ethyl Alcohol, Sucrose, Saccharin Sodium, Natural Mint Flavor, FD&C Yellow #5, and FD&C Blue #1.

**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 indications as follows: “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.

Final classification of the less-than-effective indications requires further investigation.

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;
- 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**

Donnatal® Elixir can cause fetal harm when administered to a pregnant woman. Animal reproduction studies have not been conducted with Donnatal® Elixir. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

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
- 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.

Donnatal® Elixir – Mint contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

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### Information for Patients

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.

### Drug Interactions

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.

### Carcinogenesis, Mutagenesis, Impairment of Fertility

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

### Pregnancy

#### Pregnancy Category D

Animal reproduction studies have not been conducted with Donnatal® Elixir. There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks (*see WARNINGS*).

### 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.

### Geriatric Use

Elderly patients may react with symptoms of excitement, agitation, drowsiness, and other untoward manifestations to even small doses of the drug.

### 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.

Acquired hypersensitivity to barbiturates consists chiefly in allergic reactions that occur especially in persons who tend to have asthma, urticaria, angioedema, and similar conditions. Hypersensitivity reactions in this category include localized swelling, particularly of the eyelids, cheeks, or lips, and erythematous dermatitis. Rarely, exfoliative dermatitis (e.g. Stevens-Johnson syndrome and toxic epidermal necrolysis) may be caused by phenobarbital and can prove fatal. The skin eruption may be associated with fever, delirium, and marked degenerative changes in the liver and other parenchymatous organs. In a few cases, megaloblastic anemia has been associated with the chronic use of phenobarbital.

Phenobarbital may produce excitement in some patients, rather than a sedative effect.

To report SUSPECTED ADVERSE REACTIONS, contact Concordia Pharmaceuticals Inc. at 1-877-370-1142 or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### DRUG ABUSE AND DEPENDENCE

#### Abuse

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 (*see WARNINGS*).

### Dependence

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.

### DOSSAGE 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. Use a pediatric dosing device or oral syringe to measure the dose.

Body weight	Starting Dosage	
	Every 4 hours	Every 6 hours
10 lb. (4.5 kg)	0.5 mL	0.75 mL
20 lb. (9.1 kg)	1 mL	1.5 mL
30 lb. (13.6 kg)	1.5 mL	2 mL
50 lb. (22.7 kg)	2.5 mL	3.75 mL
75 lb. (34 kg)	3.75 mL	5 mL
100 lb. (45.4 kg)	5 mL	7.5 mL

### HOW SUPPLIED

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

- 4 fl oz (118 mL) bottles- NDC 59212-423-04.
- 1 Pint (473 mL) bottles- NDC 59212-423-16.
- 10 mL bottles- NDC 59212-423-11 - single bottle.
- Twelve 10 mL bottles- NDC 59212-423-12 - single bottles (59212-423-11) packaged in a box of 12.

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

- 4 fl oz (118 mL) bottles- NDC 59212-422-04.
- 1 Pint (473 mL) bottles- NDC 59212-422-16.
- 10 mL bottles- NDC 59212-422-11 - single bottle.
- Twelve 10 mL bottles- NDC 59212-422-12 - single bottles (59212-422-11) packaged in a box of 12.

### 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.

### Manufactured For:

Concordia Pharmaceuticals Inc.  
St. Michael, Barbados BB11005  
[www.donnatal.com](http://www.donnatal.com)

### Manufactured By:

IriSys, LLC  
San Diego, CA 92121

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