

*Donnatal is back...  
self-confidence follows*



## *Irritable Bowel Syndrome*

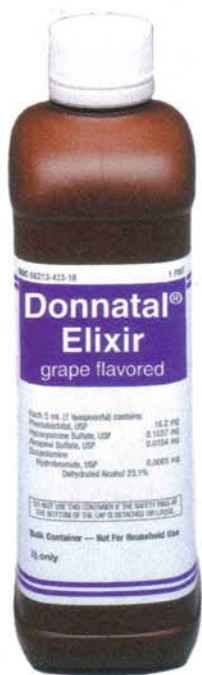
- Second most frequently encountered diagnosis in clinical practice<sup>1</sup>
- Accounts for more physician visits than any symptom except for respiratory tract infections<sup>1</sup>
- Most frequent diagnosis made in typical gastroenterologist's practice<sup>1</sup>

# Donnatal<sup>®</sup> Elixir for Quick Action

Donnatal<sup>®</sup> Elixir is grape flavored, an immediate release, adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis that is available only by prescription.

## Trusted By Doctors For Over 30 Years

- Donnatal<sup>®</sup> has an extensive documented long-term patient safety record.
- Donnatal<sup>®</sup> Elixir is only available from PBM Pharmaceuticals.



## How Donnatal<sup>®</sup> Elixir is Supplied

Donnatal<sup>®</sup> Elixir is a purple colored, grape flavored liquid.

4 fl oz (118 mL) bottles

NDC 66213-0423-04

1 Pint (473 mL) bottles

NDC 66213-0423-16

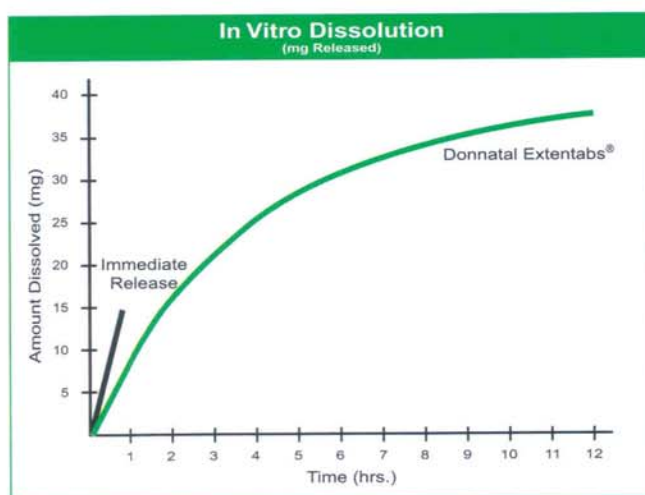


# Extentabs

for 12 hour sustained relief

## Extended Release Donnatal

Only Donnatal Extentabs® provide gradual dissolution over 12 hours, dramatically different from immediate release tablets.<sup>2</sup>



## Extended Convenience

- Only Donnatal Extentabs® provide *All Day, All Night* convenient BID dosing.
- There is no generic or multisource version of Donnatal Extentabs.®
- Only Donnatal Extentabs® afford patient convenience and lower cost.
- Donnatal Extentabs® are available on most managed care plans.

## How Donnatal® Extentabs are Supplied

Donnatal Extentabs® Tablets are film coated green, round, compressed tablets printed "P421" in black ink.

100 ct bottles

NDC 66213-0421-10

500 ct bottles

NDC 66213-0421-50

For Samples Call  
800-858-4006

### References:

1. Engstrom, PF, Gossenberg, EB. Diagnosis and Management of Bowel Diseases, First Edition, 1999; 2: 64.
2. Data on file, PBM Pharmaceuticals, Inc.

**DONNATAL EXTENTABS®**

Rev. 06/07

Rx Only

**Description:** Each Donnatal Extentabs® tablet contains:

Phenobarbital, USP (3/4 gr.)	48.6 mg
Hyoscyamine Sulfate, USP	0.3111 mg
Atropine Sulfate, USP	0.0582 mg
Scopolamine Hydrobromide, USP	0.0195 mg

Each Donnatal Extentabs® tablet contains the equivalent of three Donnatal® tablets. Extentabs are designed to release the ingredients gradually to provide effects for up to twelve (12) hours.

In addition, each tablet contains the following inactive ingredients: Anhydrous Lactose, Calcium Sulfate Granular, Colloidal Silicon Dioxide, Dibasic Calcium Phosphate, Lactose Monohydrate, Magnesium Stearate, and Stearic Acid. Film Coating and Polishing Solution contains: D&C Yellow #10 Aluminum Lake, FD&C Blue #1 Aluminum Lake, Hydroxypropyl Methylcellulose, Polydextrose, Polyethylene Glycol, Titanium Dioxide, and Triacetin. The printing ink contains Titanium Dioxide.

**DOSAGE AND ADMINISTRATION:** The dosage of Donnatal Extentabs® should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse reactions. The usual dose is one tablet every twelve (12) hours. If indicated, one tablet every eight (8) hours may be given.

**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 added.

**HOW SUPPLIED:** Donnatal Extentabs® Tablets are supplied as: film coated green, round, compressed tablets printed "P421" in black ink.

Bottles of 100 tablets	NDC 66213-0421-10
Bottles of 500 tablets	NDC 66213-0421-50

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

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

Also available: Donnatal® Tablets in bottles of 100 and 1000 tablets and Donnatal® Elixir in 4 fl oz bottles and 1 pint bottles.

Manufactured For:

PBM Pharmaceuticals, Inc. Gordonsville, VA 22942

www.Donnatal.com

**DONNATAL® ELIXIR**

Rx only

**DESCRIPTION:** Each Donnatal® 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, Artificial Grape Flavor, FD & C Red #3, and FD & C Blue #1.

**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)	tsp	tsp
75 lb. (34 kg)	tsp	1 tsp
100 lb. (45.4 kg)	1 tsp	1 tsp

**HOW SUPPLIED:**

Donnatal® Elixir 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.

**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.

Manufactured For:

PBM Pharmaceuticals, Inc. Gordonsville, VA 22942

www.DonnatalElixir.com

Rev 09/09

**ACTIONS/ 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 Extentabs®/ 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 Extentabs®/ 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 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 overdose, a curare-like action may occur.

**Carcinogenesis, mutagenesis:** Long-term studies in animals have not been performed to evaluate carcinogenic potential.

**Pregnancy Category C:** Animal reproduction studies have not been conducted with Donnatal Extentabs®/ Elixir. It is not known whether Donnatal Extentabs®/ Elixir can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Donnatal Extentabs®/ 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 Extentabs®/ 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. 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. 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.