DONNATAL EXTENTABS - phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide tablet, film coated, extended release
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 Extentabs

Patient Insert

DONNATAL EXTENTABS®

Rx Only

Rev. 06/07

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 ingredi¬ents 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 and C Yellow #10 Aluminum Lake, FD and C Blue #1 Aluminum Lake, Hydroxypropyl Methylcellulose, Polydextrose, Polyethylene Glycol, Titanium Dioxide, and Triacetin. The printing ink contains Titanium Dioxide.

ACTIONS:

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

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® 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® 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:

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:

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®. It is not known whether Donnatal Extentabs® can cause fetal harm when administered to a pregnant woman or can affect

reproduction capacity. Donnatal Extentabs® 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® 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 barbituates 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.

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
Bottles of 500 tablets

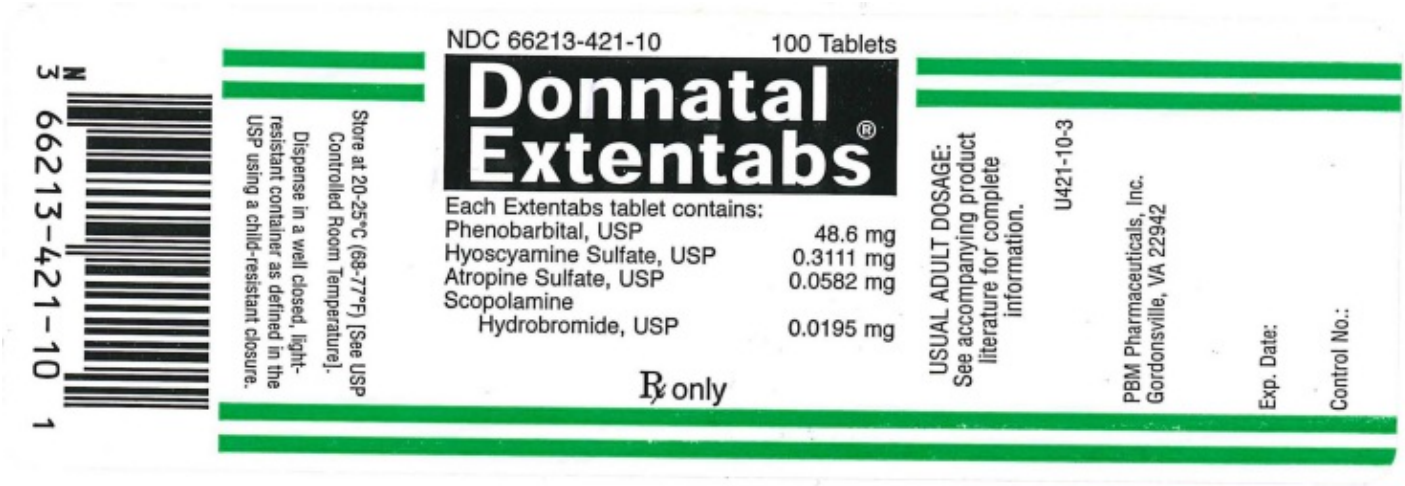
Store at 20-25°C (68-77°F) [See USP Controlled Room Temperature]. Protect from light and moisture.

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

Manufactured By:
West-ward Pharmaceutical Corp.
Eatontown, NJ 07724 Revised June 2007



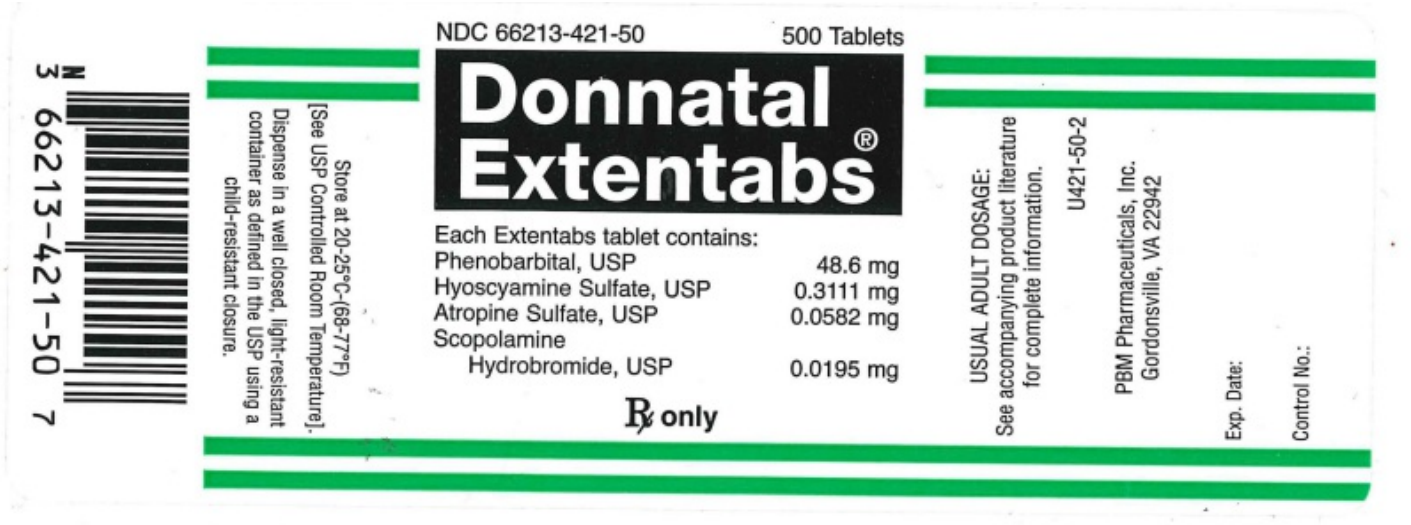
NDC 66213-421-10 100 Tablets

Donnatal Extentabs®
Each Extentabs tablet contains:
Phenbarbital, USP . . . . 48.6 mg
Hyoscyamine Sulfate, USP . . . . . 0.3111 mg
Atropine Sulfate, USP . . . . . 0.0582 mg
Scopolamine Hydrobromide, USP . . . . . 0.0195 mg
RX only

Usual Adult Usage:
See accompanying product literature for complete information.
U421-10-3

PBM Pharmaceuticals, Inc.
Charlottesville, VA 22902
Exp. Date:
Control No:

Store at 20-25°C (68-77°F) [See USP Controlled Room Temperature].
Dispense in a well closed, light resistant container as defined in the USP using a child-resistant closure.



NDC 66213-421-50 500 Tablets
Donnatal Extentabs®
Each Extentabs tablet contains:
Phenbarbital, USP . . . . 48.6 mg
Hyoscyamine Sulfate, USP . . . . . 0.3111 mg
Atropine Sulfate, USP . . . . . 0.0582 mg
Scopolamine Hydrobromide, USP . . . . . 0.0195 mg
RX only

Usual Adult Usage:
See accompanying product literature for complete information.

U425-50-2
PBM Pharmaceuticals, Inc.
Charlottesville, VA 22902
Exp. Date:
Control No:

Store at 20-25°C (68-77°F) [See USP Controlled Room Temperature].
Dispense in a well closed, light resistant container as defined in the USP using a child-resistant closure.

DONNATAL EXTENTABS

phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide tablet, film coated, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66213-421
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

Phenobarbital (UNII: YQE403BP4D) (Phenobarbital - UNII:YQE403BP4D)	Phenobarbital	48.6 mg
HYOSCYAMINE SULFATE (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X)	HYOSCYAMINE SULFATE	0.3111 mg
ATROPINE SULFATE (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	ATROPINE SULFATE	0.0582 mg
SCOPOLAMINE HYDROBROMIDE (UNII: 451IFR0GXB) (SCOPOLAMINE - UNII:DL48G20X8X)	SCOPOLAMINE HYDROBROMIDE	0.0195 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CALCIUM SULFATE, UNSPECIFIED (UNII: WAT0DDB505)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE 2208 (4000 MPA.S) (UNII: 39J80LT57T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	green (film coated)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	421
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66213-421-10	100 in 1 BOTTLE, PLASTIC		
2	NDC:66213-421-50	500 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/07/2008	

Labeler - PBM Pharmaceuticals, Inc (785470050)

Establishment

Name	Address	ID/FEI	Business Operations
West-ward Pharmaceutical Corp.		001230762	manufacture, analysis, label, recovery, relabel, repack