DONNATAL- phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide tablet
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.

Donnatal Tablets

DONNATAL® TABLETS

Rx Only

Rev. 06/07

DESCRIPTION:

Each Donnatal® Tablet 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:

Anhydrous Lactose, Calcium Stearate, Colloidal Silicon Dioxide, Corn Starch, and Microcrystalline Cellulose.

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 mega-colon; myasthenia gravis; hiatal hernia associated with reflux esophagitis.

Donnatal® 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® 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®. It is not known whether Donnatal® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Donnatal® 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® 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. Acquired hypersensitivity to barbituates consists chiefly in allergic reactions that occur especially in persons who tend to have asthma, urticaria, angiodema 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® should be adjusted to the needs of the dividual patient to assure symptomatic control with a minimum of adverse effects.

Donnatal® Tablets. Adults: One or two Donnatal® tablets three or four times a day according to condition and severity of symptoms.

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.

Donnatal® Tablets are supplied as: White, D-shaped tablets debossed “D” on one side and “Donnatal” on the other side.

Bottles of 20 tablets.

AVOID FREEZING

Store 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.
Also available: Donnatal Extentabs® Tablets, the only extended release formulation, in bottles of 100 and 500 tablets.

Donnatal® Elixir, a purple colored, grape flavored liquid, in 4 fl oz (118 mL) and 1 pint (473 mL)

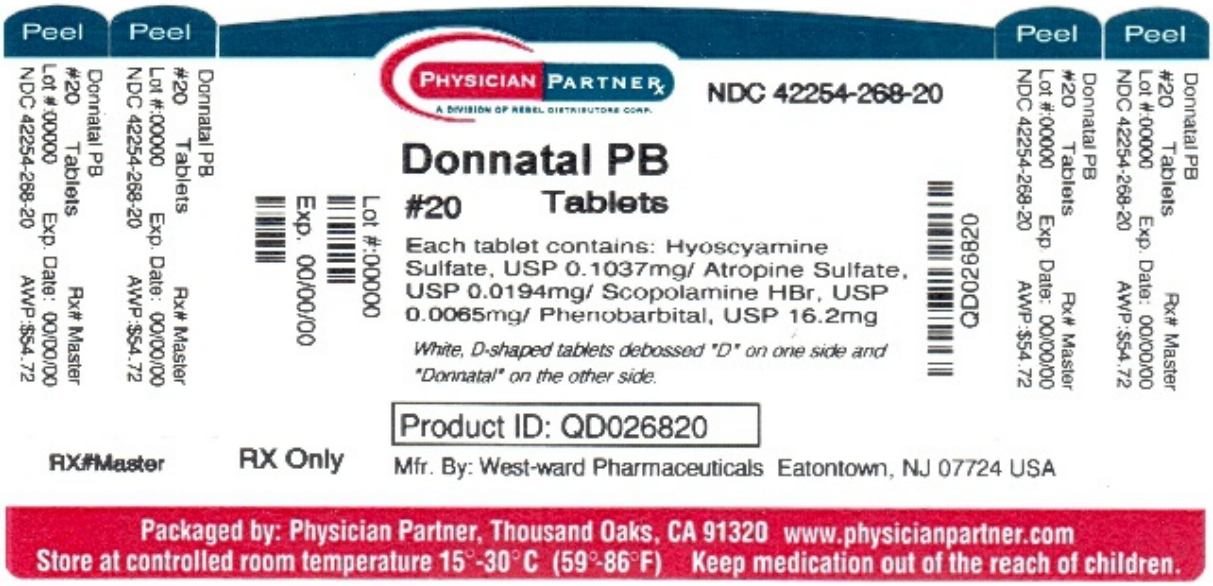
bottles.

Manufactured For:
PBM Pharmaceuticals, Inc.
Gordonsville, VA 22942

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

Repackaged by:
Rebel Distributors Corp.
Thousand Oaks, CA 91320

Principal Display Panel



DONNATAL

phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42254-268(NDC:66213-425)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Phenobarbital (UNII: YQE403BP4D) (Phenobarbital - UNII:YQE403BP4D)	Phenobarbital	16.2 mg
HYOSCYAMINE SULFATE (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X)	HYOSCYAMINE SULFATE	0.1037 mg
ATROPINE SULFATE (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	ATROPINE SULFATE	0.0194 mg
SCOPOLAMINE HYDROBROMIDE (UNII: 451IFR0GXB) (SCOPOLAMINE - UNII:DL48G20X8X)	SCOPOLAMINE HYDROBROMIDE	0.0065 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CALCIUM STEARATE (UNII: 776XM7047L)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	**Score**	no score
Shape	SEMI-CIRCLE (D-shaped tablet)	**Size**	8mm
Flavor		**Imprint Code**	D;Donnatal
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-268-20	20 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 - Rebel Distributors Corp (118802834)

Registrant - PSS World Medical, Inc. (101822862)

Establishment

Name	Address	ID/FEI	Business Operations
PSS World Medical, Inc.		791528623	REPACK(42254-268)

Establishment

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	REPACK(42254-268)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	RELABEL(42254-268) , REPACK(42254-268)

Establishment

Name	Address	ID/FEI	Business Operations
SCRIPT PAK		964420108	RELABEL(42254-268) , REPACK(42254-268)

Establishment

Name	Address	ID/FEI	Business Operations
Keltman Pharmaceuticals, Inc.		362861077	REPACK(42254-268)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distirbutors Corp.		118802834	RELABEL(42254-268) , REPACK(42254-268)

Revised: 7/2012

Rebel Distributors Corp