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

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**Donnatal Tablets**

## 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.

## 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**

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.

### How Supplied

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

side.

Bottles of 100 tablets.

Bottles of 1000 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

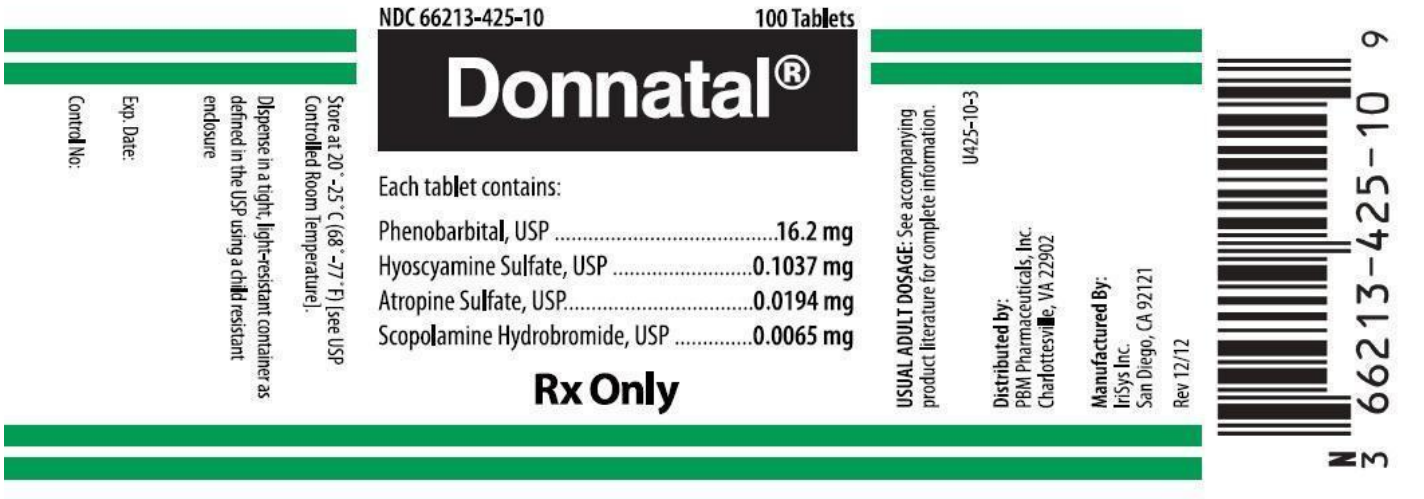
when dispensing this product unless otherwise directed by a physician or requested by purchaser.

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

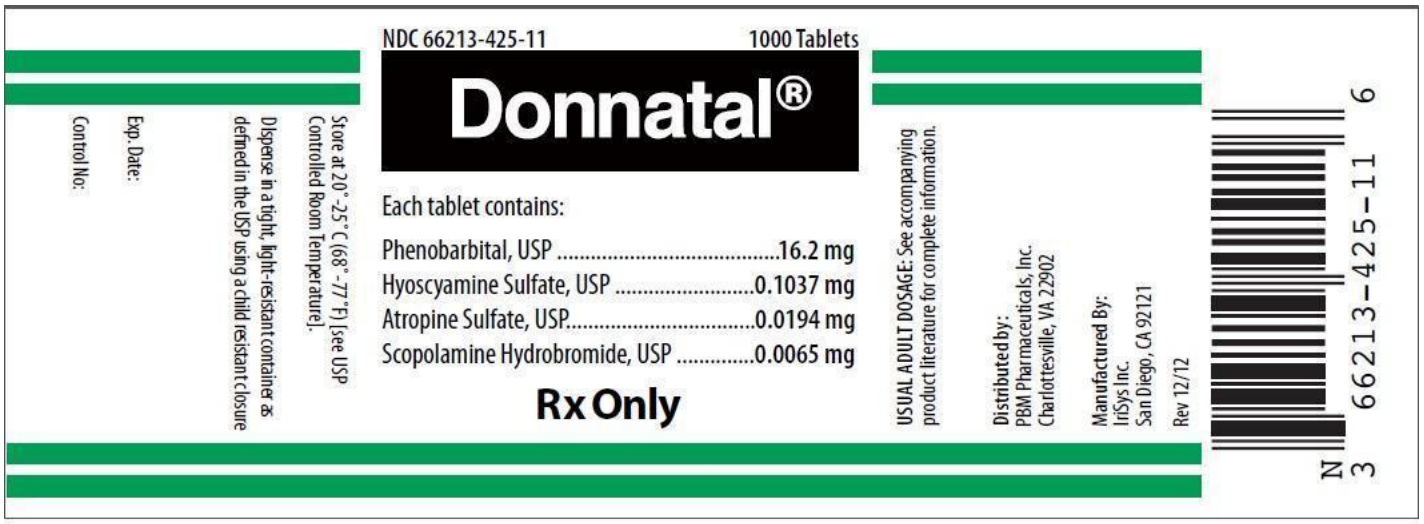
Donnatal® Elixir, a purple colored, grape flavored liquid, in 4 fl oz (118 mL) and 1 pint (473 mL) bottles.

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Donnatal label_100 tablets




Donnatal label_1000 tablets




## DONNATAL

phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | 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 | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | D;Donnatal |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:66213-425-10 | 100 in 1 BOTTLE, PLASTIC | | |
| **2** | NDC:66213-425-11 | 1000 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)

## Registrant - IriSys, Inc. (959205568)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| IriSys, Inc. | | 959205568 | manufacture(66213-425) |

Revised: 12/2013 PBM Pharmaceuticals Inc.