**DONNATAL - phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide tablet**
**Concordia 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® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) Tablets**
**Rx Only**
**Revised: 02/20**

## DESCRIPTION

### Donnatal® Tablets

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

Dibasic Calcium Phosphate Dihydrate, Compressible Sugar, Microcrystalline Cellulose, Sodium Starch Glycolate, Stearic Acid, Silicon Dioxide Colloidal, Magnesium Stearate.

## 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® Tablets can cause fetal harm when administered to a pregnant woman. Animal reproduction studies have not been conducted with Donnatal® Tablets. 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® Tablets 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.

### Information for Patients

Donnatal® Tablets 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

Animal reproduction studies have not been conducted with Donnatal® Tablets. 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® Tablets are 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 at 1-877-370-1142 or FDA at 1-800-FDA-1088 or 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.

## DOSAGE AND ADMINISTRATION

The dosage of Donnatal® Tablets should be adjusted to the needs of the individual 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.

## HOW SUPPLIED

Donnatal® Tablets are supplied as: white, D-shaped, flat faced beveled edge tablets embossed "D" on one side and debossed "Donnatal" on the other side.

- Bottles of 100 tablets - NDC 59212-425-10.
- Bottles of 4 tablets - NDC 59212-425-04.

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.

DEA EXEMPT PRODUCT

**Mfd. for:**
Concordia Pharmaceuticals

**Distributed by:**
Amdipharm Limited
17 Northwood House
Dublin 9, Ireland

**Revised: 02/20**

## PRINCIPAL DISPLAY PANEL

NDC 59212-425-10 100 Tablets

Donnatal®
(Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide)

Each tablet contains:

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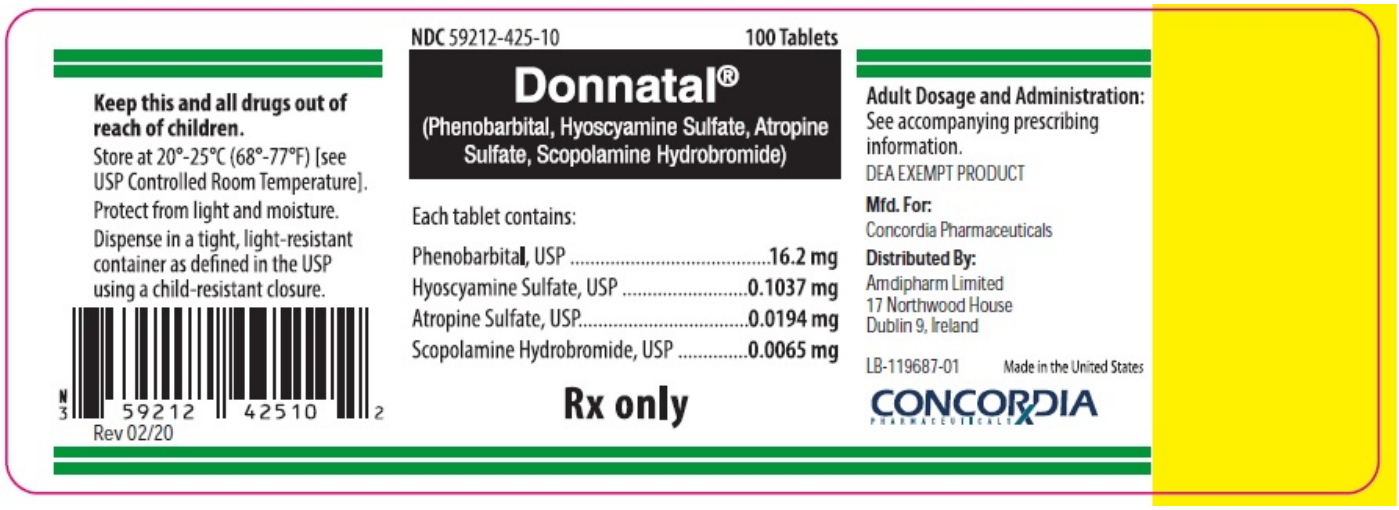
Hyoscyamine Sulfate, USP..... 0.1037 mg
Atropine Sulfate, USP .....0.0194 mg
Scopolamine Hydrobromide, USP .....0.0065 mg

Rx only




# DONNATAL

phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:59212-425 |
| **Route of Administration** | ORAL | **DEA Schedule** | CIV |

| 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** |
| **DIBASIC CALCIUM PHOSPHATE DIHYDRATE** (UNII: O7TSZ97GEP) | |
| **SUCROSE** (UNII: C151H8M554) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |

| 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:59212-425-10 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/30/1980 | |
| 2 | NDC:59212-425-11 | 1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/30/1980 | 07/22/2019 |
| 3 | NDC:59212-425-04 | 04 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/30/1980 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| UNAPPROVED DRUG OTHER | | 12/30/1980 | |

## Labeler - Concordia Pharmaceuticals Inc. (815240092)

Revised: 1/2023 Concordia Pharmaceuticals Inc.