

DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide) has been classified as “possibly” effective for use as an adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.

DONNATAL 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.

DONNATAL reduces abdominal pain, motility and may provide mild sedation.

When you help patients reduce the symptoms of IBS, you may be helping them get out of the bathroom and back to their lives.



 **Donnatal**[®]

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

CON / DON / PM / 0002

Indication and Important Safety Information
DONNATAL® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) Tablets and Elixir (grape and mint flavor)

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 for DONNATAL® 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.

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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.); severe ulcerative colitis especially if complicated by toxic megacolon; paralytic ileus, intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; hiatal hernia associated with reflux esophagitis, myasthenia gravis; and 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® can cause fetal harm when administered to a pregnant woman. 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.
- Belladonna alkaloids may produce a delay in gastric emptying (antral stasis) which would complicate the management of gastric ulcer.
- 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.
- Use with caution in patients with: autonomic neuropathy; hepatic or renal disease; hyperthyroidism; coronary heart disease; congestive heart failure; cardiac arrhythmias; tachycardia; and hypertension.
- 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.
- In patients habituated to barbiturates, abrupt withdrawal may produce delirium or convulsions.
- Since barbiturates are metabolized in the liver, they should be used with caution and initial doses should be small in patients with hepatic dysfunction.
- Do not rely on the use of the drug in the presence of complication of biliary tract disease.

- DONNATAL® Elixir – Mint contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.
- 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.
- 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.
- Elderly patients may react with symptoms of excitement, agitation, drowsiness, and other untoward manifestations to even small doses of the drug.

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.

Please see Prescribing Information

FOR MORE INFORMATION ABOUT DONNATAL® visit www.DONNATAL.com or call Concordia Pharmaceuticals Inc. at 1-877-370-1142.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

DONNATAL® is manufactured for:
Concordia Pharmaceuticals Inc.
St. Michael, Barbados BB11005

Revised: January 2016



HOW IT WORKS

DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide) Tablets and Elixir (grape and mint flavor) is a prescription drug taken by mouth as an adjunctive therapy for the treatment of irritable bowel syndrome (IBS) and acute inflammation of the small bowel (acute enterocolitis).

Donnatal reduces abdominal pain, motility, and acts on the brain to produce a calming effect.

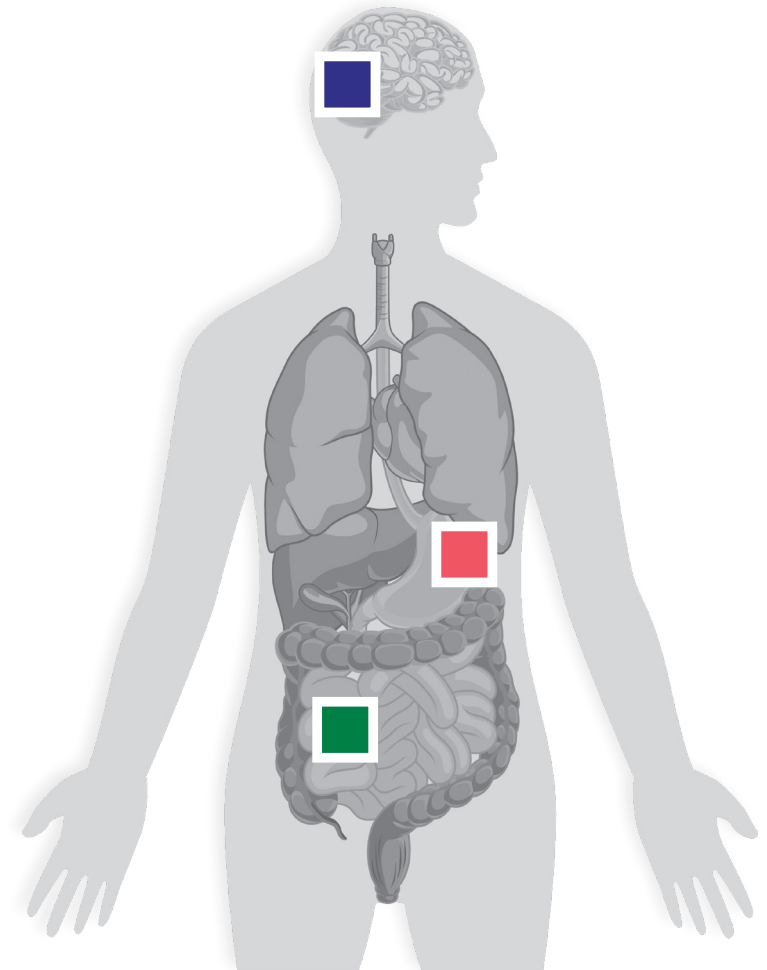
Pain

Motility

Calming Effect

The natural belladonna alkaloids in a specific, fixed ratio, combined with phenobarbital, provide peripheral anticholinergic/antispasmodic action and may provide mild sedation. Phenobarbital may produce excitement in some patients, rather than a sedative effect.

DONNATAL has been designated as “possibly” effective.



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 **Donnatal**[®]
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Atropine Sulfate, Scopolamine Hydrobromide)

DOSING

DONNATAL

Each tablet or 5 mL (1 teaspoon) contains:

Phenobarbital, USP.....	16.2 mg
Hyoscyamine Sulfate, USP	0.1037 mg
Atropine Sulfate, USP.....	0.0194 mg
Scopolamine Hydrobromide, USP.	0.0065 mg



The dosage of DONNATAL should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse effects.

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DONNATAL Elixir – Grape

- 4 fl oz (118 mL) bottles
- 1 Pint (473 mL) bottles

DONNATAL Elixir – Mint

- 4 fl oz (118 mL) bottles
- 1 Pint (473 mL) bottles

DONNATAL tablets are available in packaged quantities of 100s and 1000s

Adults: 1 or 2 teaspoons of elixir 3 or 4 times a day, or 1 or 2 tablets 3 or 4 times a day, according to conditions and severity of symptoms.

Pediatric patients: May be dosed using elixir every 4 to 6 hours. See dosing card for pediatric dosage administration.

START THE CONVERSATION

IBS affects the patient's health related quality of life as well their personal and work lives. Starting the conversation may help those who feel uncomfortable with the topic get the treatment they need.

- It's been estimated that only 30% of patients with IBS symptoms seek medical care.
- Symptoms consistent with IBS are 1.5 to 3 times more prevalent among women than men.
- 50% of IBS patients report having their first symptoms before the age of 35.

Canavan C, West J, Card T. The epidemiology of irritable bowel syndrome. *Clinical Epidemiology*. 2014;6:71-80. doi:10.2147/CLEP.S40245.

Help patients determine if they have IBS:

- If patients have had abdominal pain or discomfort at least 3 days each month for the last 3 months

—AND—

- At least two of the following are true about their pain
 - ✓ It is improved by having a bowel movement.
 - ✓ Coincides with a change in how often they have a bowel movement.
 - ✓ Coincides with change in appearance or consistency of their stool.

—THEN—

They might have IBS.

Rome Foundation. (n.d.). Rome III diagnostic criteria for functional gastrointestinal disorders. Retrieved from http://www.romecriteria.org/assets/pdf/19_RomeIII_apA_885-898.pdf

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START THE
CONVERSATION

IMPACT OF IBS*

IBS symptoms are often bothersome:

- A high number of IBS patients rate their symptoms as severe or extremely severe.

IBS symptoms come and go in patients, making it unpredictable:

- Symptom flares, with severe symptoms lasting more than a few days, are common.

IBS symptoms have a substantially negative impact on quality of life:

- IBS may affect day-to-day activities, including sleep, diet, ability to travel and sexual activity.
- Surveys have found that IBS symptoms cause patients to lose time from work (absenteeism) and to be less productive while at work (presenteeism).

IBS has a significant economic impact:

- The annual cost of IBS treatment in the US has been estimated between \$1.7 billion and \$10 billion in direct medical costs (excluding prescription and over-the-counter drug costs) and \$20 billion for indirect costs.

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* Hulisz D, The Burden of Illness of Irritable Bowel Syndrome: Current Challenges and Hope for the Future. J Manag Care Pharm.2004;10(4):299-309.

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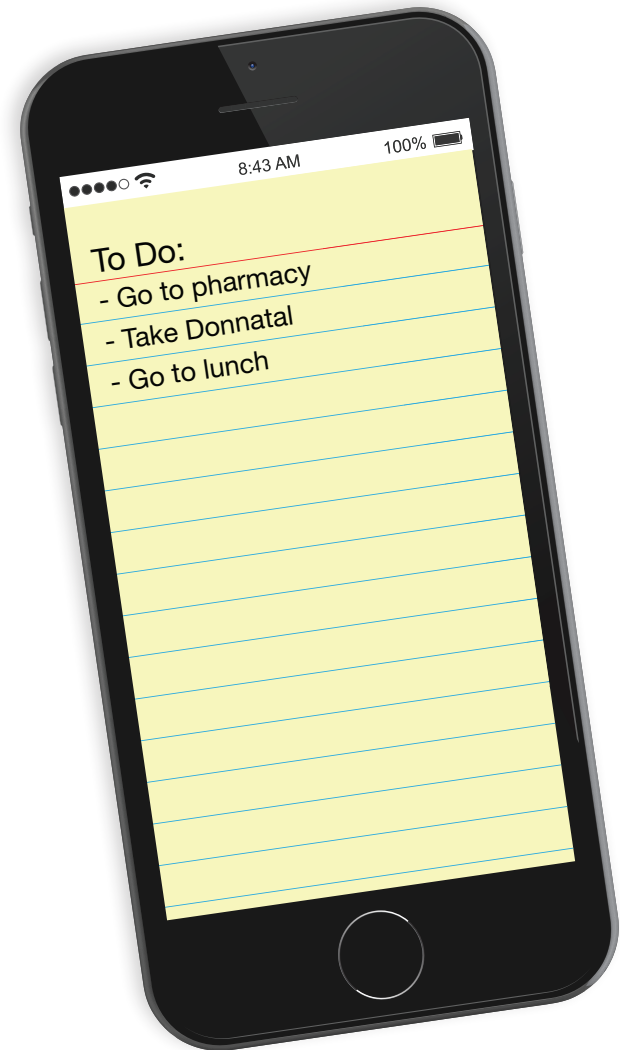
TAKING DONNATAL

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

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PATIENT CONSIDERATIONS

WARNINGS & ADVERSE REACTIONS

- DONNATAL[®] (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide) may produce drowsiness or blurred vision. Patients should see how DONNATAL[®] affects them before performing activities requiring mental alertness, such as operating a car or other machinery. Should they experience drowsiness or blurred vision, they should avoid those activities.
- Phenobarbital, an ingredient of DONNATAL[®], may produce excitement in some patients, rather than a sedative effect. Elderly patients may react with symptoms of excitement, agitation, drowsiness and other untoward manifestations to even small doses of the drug.
- If patients spend time in high-temperature environments, heat prostration can occur (fever and heatstroke due to decreased sweating) when taking belladonna alkaloids, an ingredient of DONNATAL[®].
- Ask your patients if they have a history of physical and/or psychological dependence upon drugs. Phenobarbital may be habit-forming and should not be given to patients prone to addiction. In patients habituated to barbiturates, abrupt withdrawal may produce delirium or convulsions.
- Phenobarbital, an ingredient of DONNATAL[®], 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.
- 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. Patients should understand the risk if they are pregnant and should contact you if they become pregnant while taking DONNATAL[®]. It is not known whether this drug is excreted in human milk, so caution should be exercised when DONNATAL[®] is administered to a nursing woman.

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PATIENT
CONSIDERATIONS


AVAILABLE

DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide) is available in most retail pharmacies or can be filled by an online specialty pharmacy.

The online specialty pharmacy manages claims and delivers prescriptions directly to patients by mail, often within 24-48 hours.

- Simply fax the prescription to Willow Pharmacy with the completed patient information forms.
- Alert your patient they will receive a confirmation call from a representative before the prescription can be mailed.
- The online specialty pharmacy will manage commercial insurance, Medicare and Medicaid claims for you and your patient.

PLEASE PROVIDE THIS FORM TO THE PATIENT



YOU HAVE BEEN PRESCRIBED A MEDICATION BY
YOUR HEALTHCARE PROVIDER THROUGH WILLOW PHARMACY.

Please allow 3-5 business days to receive your prescription. If you have not received it by then, please call.
877.558.7943

WHO IS WILLOW PHARMACY?
Willow Pharmacy is a specialty prescription provider licensed and serving patients and physicians nationwide. Willow is committed to providing customer service and care that enhances the clinical advantages of pharmaceutical therapies impacting patient's lives. Patient care and service is our purpose and we strive to provide the best experience and treatment for patients.

WHAT ARE THE BENEFITS OF USING WILLOW PHARMACY?
Willow Pharmacy ensures your medications are exactly as your physician prescribed. We guarantee your product is directly from the manufacturer and meets all FDA requirements. We will work with you to resolve any insurance coverage issues and ensure your prescription is dispensed and sent in a timely manner.

HOW WILL I RECEIVE MY PRESCRIPTION?
Your prescription is shipped directly to the address provided by your provider via UPS, FedEx, or USPS Priority Mail. **Most of our shipments require a signature upon delivery.** If this is a problem, please call the pharmacy immediately and inform us of your needs. Prescriptions addressed to a P.O. Box will be shipped via USPS only. For expedited service, please call the pharmacy.

DOES INSURANCE COVER MY MEDICATION?
Medications are commonly covered by most commercial insurance plans. Our goal is to make sure you get the medication you need.

WHAT NUMBER CAN I CALL IF I HAVE ADDITIONAL QUESTIONS?
Call 877.558.7943 and our pharmacy staff will be more than happy to answer all of your questions.

Phone: 877.558.7943 Fax: 855.848.3661

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AVAILABLE

AFFORDABLE

DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide) is a trusted brand available at the price of a generic.

Commercial patients may pay as low as \$15/Month for a 30-day supply of DONNATAL.

Have patients who cannot afford DONNATAL? The Concordia Patient Assistance Program can help.

Visit www.RxOutreach.org or call **1-800-769-3880** for more information or to apply for the Patient Assistance Program for your patients.

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Patients may pay as low as \$15*

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INDICATIONS AND USAGE
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Claims Processor **RESTAT** Person Code: **01**
BIN # **600471** Group # **X8020** Rx PCN# **7777**
Cardholder ID # **600100101**

Attention Patient:
*Present this certificate to the pharmacist for an instant rebate of up to program maximum which is subject to change. If your total out-of-pocket pharmacy bill exceeds the program maximum, you will be responsible for the additional balance. This offer requires a minimum purchase of 60 tablets or 230ml. Not valid with any other offer.

Remember to restore patient profile to Primary PBM after claim submission.
This offer may be revoked or withdrawn without notice. Void where prohibited.
Donnatal is a registered trademark of Concordia Pharmaceuticals Inc.

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AFFORDABLE