

**Summary of Information About
DONNATAL®
(Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide)
Tablets and Elixir (grape and mint flavor), for Oral Use**

Talk to your doctor if you have any questions about your medical condition or treatment. Talk to your doctor if you have any questions about DONNATAL (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide).

WHAT IS DONNATAL?

DONNATAL is a prescription drug used with other drugs for the treatment of irritable bowel syndrome (IBS) and inflammation of the small bowel (acute enterocolitis). It is not known if DONNATAL is effective for use*. DONNATAL slows the natural movements of the gut by relaxing the muscles in the stomach and intestines and acts on the brain to produce a calming effect.

INDICATIONS AND USAGE*¹

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.

WHO SHOULD NOT TAKE DONNATAL?

Do not take DONNATAL and tell your doctor if you have:

- the eye condition called glaucoma
- blockage of the urinary tract
- blockage of the bowel
- lack of normal tone or strength of the small bowel if you are elderly or ill
- a problem with your heart, arteries, or veins if you are bleeding
- been diagnosed with severe ulcerative colitis
- muscle weakness and fatigue
- problems with your stomach that gives heartburn
- sensitivity or allergic reaction to DONNATAL or any of the ingredients in DONNATAL, or similar drugs (DONNATAL Elixir – mint flavor can cause allergic type reaction in people with aspirin sensitivity)
- plans to become pregnant or are pregnant DONNATAL can cause harm to your baby.
- plans to breastfeed or are breastfeeding. DONNATAL may cause harm to your baby.
- problems with your liver
- been dependent on drugs (phenobarbital, one of the ingredients in DONNATAL, can be habit forming).
- a disorder of metabolism called acute intermittent porphyria (that manifests with severe abdominal pain)
- taken phenobarbital, an ingredient in DONNATAL, and experienced restlessness and/or excitement instead of feeling calm.

WHAT SHOULD I TELL MY DOCTOR BEFORE RECEIVING DONNATAL?

Before you receive DONNATAL, tell your doctor if you:

- are exposed to high temperatures as DONNATAL can cause overheating

¹ This drug has been evaluated as possibly effective for this indication. See Brief Summary.

- have diarrhea as it may be an early symptom of other medical problems
- take blood thinners
- have a nerve disorder that affects the involuntary body functions
- suffer from kidney or liver disease
- have an overactive thyroid
- have heart disease, or have hypertension
- are pregnant or plan to become pregnant. DONNATAL can cause harm to your baby.
- are breastfeeding or plan to breastfeed. DONNATAL may cause harm to your baby.
- have an aspirin sensitivity
- have experienced a reaction to DONNATAL, its ingredients, or any drug
- have asthma or experience allergic rashes (hives), with redness and swelling and similar conditions
- take any prescription, over-the-counter, and/or herbal medications
- have been or are addicted to any medication
- have a stomach ulcer

WHAT ARE THE POSSIBLE SIDE EFFECTS OF DONNATAL?

DONNATAL is not for everyone. DONNATAL may cause serious, even life threatening, allergic reactions. Stop taking DONNATAL and call your doctor right away if you have any signs of a serious allergic reaction or if you have any of the following side effects:

dryness of the mouth; difficulty eliminating urine; blurred vision; an increase in heart rate; feeling of heart beating quickly and strongly; widening of the pupil in the eye; difficulty focusing your eye; increased eye tension; loss of taste; headache; nervousness; drowsiness; weakness; dizziness; insomnia (inability to fall asleep or to remain asleep); nausea; vomiting; inability in a man to have sexual intercourse; reduced breast milk production; constipation; feeling bloated; muscle and bone pain; severe allergic reaction, including anaphylaxis, and skin reactions; decreased sweating.

Allergic type reactions may include:

- swelling, particularly of the eyelids, cheeks, or lips, and skin.
- inflammation of the skin with redness

Rarely, phenobarbital, an ingredient in DONNATAL, can cause a flaking type of skin reaction that can prove fatal. This may be associated with fever, changes in behavior, and changes in liver and other organs.

In a few cases, anemia has resulted from long time use of phenobarbital.

Seizures and confusion can occur if DONNATAL is stopped suddenly in patients with a dependence on sedatives such as phenobarbital.

Phenobarbital may produce excitement.

Elderly persons may react with feelings of excitement, agitation, drowsiness, and other ill effects.

DONNATAL may cause drowsiness or blurred vision. Do not engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery, and do not perform hazardous work.

WHAT SHOULD I KNOW ABOUT TAKING DONNATAL WITH OTHER DRUGS?

Phenobarbital, an ingredient in DONNATAL, may decrease the effect of drugs that thin the blood. Tell your doctor if you take blood thinners or any other medications.

WHAT HAPPENS IF I HAVE TAKEN TOO MUCH DONNATAL?

Contact your doctor for emergency medical attention. 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 muscle and nerve excitement.

WHO IS DONNATAL FOR?

DONNATAL Tablets and DONNATAL Elixir are for use in adults.

*This drug has been evaluated as possibly effective for this indication. See Brief Summary.

DONNATAL Elixir (grape and mint flavor) may be given to children.

HOW SHOULD DONNATAL BE TAKEN?

Your doctor will determine the individual dose that is right for you depending on your needs based upon your condition, severity of symptoms, and medical history. DONNATAL is taken orally.

Adults: For tablets, the usual dosage is 1 or 2 tablets, 3 or 4 times a day.

For elixir, the usual dosage is 1 or 2 teaspoonfuls, 3 or 4 times a day.

Children: The dosage of the elixir is determined by body weight; it can be given every 4 to 6 hours. Follow your doctor's instructions carefully when giving this medication to a child. Use a pediatric dosing device or oral syringe to measure the dose.

The information presented herein is not comprehensive. This is a Brief Summary (see full prescribing information for DONNATAL).

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT DONNATAL?

- Talk to your doctor or pharmacist
- Go to www.DONNATAL.com to obtain the product labeling
- 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: February 2015



*This drug has been evaluated as possibly effective for this indication. See Brief Summary.