

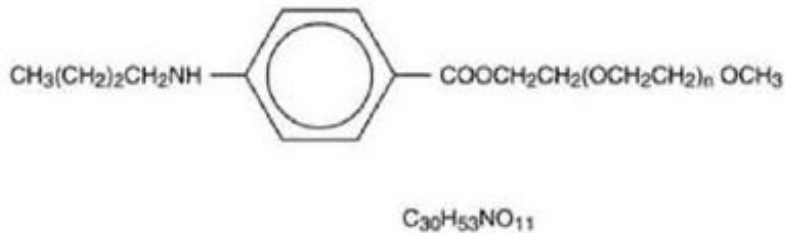
**BENZONATATE- benzonatate capsule, liquid filled  
Apotheca Inc.**

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**Benzonatate Capsules, USP**

**100 mg and 200 mg**

**DESCRIPTION**

Benzonatate, a non-narcotic antitussive agent, is 2, 5, 8, 11, 14, 17, 20, 23, 26-nonaoxaoctacosan-28-yl p-(butylamino) benzoate; with a molecular weight of 603.7.



Benzonatate Capsules, USP contain 100 mg or 200 mg of benzonatate, USP.

Benzonatate Capsules also contain: D&C Yellow No. 10, gelatin, glycerin, methylparaben sodium and propylparaben sodium.

**CLINICAL PHARMACOLOGY**

Benzonatate acts peripherally by anesthetizing the stretch receptors located in the respiratory passages, lungs, and pleura by dampening their activity and thereby reducing the cough reflex at its source. It begins to act within 15 to 20 minutes and its effect lasts for 3 to 8 hours. Benzonatate has no inhibitory effect on the respiratory center in recommended dosage.

**INDICATIONS AND USAGE**

Benzonatate is indicated for the symptomatic relief of cough.

**CONTRAINDICATIONS**

Hypersensitivity to benzonatate or related compounds.

## BOXED WARNING

### **Hypersensitivity**

Severe hypersensitivity reactions (including bronchospasm, laryngospasm and cardiovascular collapse) have been reported which are possibly related to local anesthesia from sucking or chewing the capsule instead of swallowing it. Severe reactions have required intervention with vasopressor agents and supportive measures.

### **Psychiatric Effects**

Isolated instances of bizarre behavior, including mental confusion and visual hallucinations, have also been reported in patients taking benzonatate in combination with other prescribed drugs.

### **Accidental Ingestion and Death in Children**

Keep benzonatate out of reach of children. Accidental ingestion of benzonatate resulting in death has been reported in children below age 10. Signs and symptoms of overdose have been reported within 15 to 20 minutes and death has been reported within one hour of ingestion. If accidental ingestion occurs, seek medical attention immediately (see OVERDOSAGE).

## PRECAUTIONS

Benzonatate is chemically related to anesthetic agents of the para-amino-benzoic acid class (e.g., procaine; tetracaine) and has been associated with adverse CNS effects possibly related to a prior sensitivity to related agents or interaction with concomitant medication.

### **Information for Patients :**

Swallow benzonatate capsules whole. Do not break, chew, dissolve, cut, or crush benzonatate capsules. Release of benzonatate from the capsule in the mouth can produce a temporary local anesthesia of the oral mucosa and choking could occur. If numbness or tingling of the tongue, mouth, throat, or face occurs, refrain from oral ingestion of food or liquids until the numbness has resolved. If the symptoms worsen or persist, seek medical attention.

Keep benzonatate out of reach of children. Accidental ingestion resulting in death has been reported in children. Signs and symptoms of overdose have been reported within 15 to 20 minutes and death has been reported within one hour of ingestion. Signs and symptoms may include restlessness, tremors, convulsions, coma and cardiac arrest. If accidental ingestion occurs, seek medical attention immediately.

Overdosage resulting in death may occur in adults.

Do not exceed a single dose of 200 mg and a total daily dose of 600 mg. If you miss a dose of benzonatate, skip that dose and take the next dose at the next scheduled time. Do not take 2 doses of benzonatate at one time.

### **Usage in Pregnancy:**

Pregnancy Category C.

Animal reproduction studies have not been conducted with benzonatate. It is also not known whether benzonatate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzonatate 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 benzonatate is administered to a nursing woman.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility:**

Carcinogenicity, mutagenicity, and reproduction studies have not been conducted with benzonatate.

### **Pediatric Use:**

Safety and effectiveness in children below the age of 10 has not been established. Accidental ingestion resulting in death has been reported in children below age 10. Keep out of reach of children.

### **ADVERSE REACTIONS**

Potential Adverse Reactions to benzonatate may include:

**Hypersensitivity reactions** including bronchospasm, laryngospasm, cardiovascular collapse possibly related to local anesthesia from chewing or sucking the capsule.

**CNS:** sedation; headache; dizziness; mental confusion; visual hallucinations.

**GI:** constipation, nausea, GI upset.

**Dermatologic:** pruritus; skin eruptions.

**Other:** nasal congestion; sensation of burning in the eyes; vague “chilly” sensation; numbness of the chest; hypersensitivity.

Deliberate or accidental overdose has resulted in death, particularly in children.

### **OVERDOSAGE**

Intentional and unintentional overdose may result in death, particularly in children.

The drug is chemically related to tetracaine and other topical anesthetics and shares various aspects of their pharmacology and toxicology. Drugs of this type are generally well absorbed after ingestion.

#### **Signs and Symptoms:**

The signs and symptoms of overdose of benzonatate have been reported within 15 to 20 minutes. If capsules are chewed or dissolved in the mouth, oropharyngeal anesthesia will develop rapidly, which may cause choking and airway compromise.

CNS stimulation may cause restlessness and tremors, which may proceed to clonic convulsions followed by profound CNS depression. Convulsions, coma, cerebral edema and cardiac arrest leading to death have been reported within 1 hour of ingestion.

#### **Treatment:**

In case of overdose, seek medical attention immediately. Evacuate gastric contents and administer copious amounts of activated charcoal slurry. Even in the conscious patient, cough and gag reflexes may be so depressed as to necessitate special attention to protection against aspiration of gastric contents and orally administered materials. Convulsions should be treated with a short-acting barbiturate given intravenously and carefully titrated for the smallest effective dosage. Intensive support of respiration and cardiovascular-renal function is an essential feature of the treatment of severe intoxication from overdosage.

Do not use CNS stimulants.

### **DOSAGE AND ADMINISTRATION**

Adults and Children over 10 years of age:

Usual dose is one 100 mg or 200 mg capsule three times a day as needed for cough. If necessary to control cough, up to 600 mg daily in three divided doses may be given. **Benzonatate should be swallowed whole.** Benzonatate Capsules are not to be broken, chewed, dissolved, cut or crushed.

## HOW SUPPLIED

Benzonatate Capsules, USP are available as:

**100 mg** (oval, yellow) soft gelatin capsules with imprint “A1”.

Bottles of 100: NDC 65162-536-10

Bottles of 500: NDC 65162-536-50

**200 mg** (oblong, yellow) soft gelatin capsules with imprint “A2”.

Bottles of 100: NDC 65162-537-10

Bottles of 500: NDC 65162-537-50

**Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].** Dispense in tight, light-resistant container as defined in the USP.

Manufactured by:

**Amneal Pharmaceuticals of NY**

Hauppauge, NY 11788

Distributed by:

**Amneal Pharmaceuticals**

Glasgow, KY 42141

Rev. 01-2011

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 100mg

See insert for full prescribing information.

**Benzonatate 100mg**  
NDC: 12634-826-80 20 Capsules  
LOT:                      EXP:

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NDC: 12634-826-80 20 Capsules  
LOT:                      EXP:

**Benzonatate 100mg**  
NDC: 12634-826-80 20 Capsules  
LOT:                      EXP:

Repackaged & Distributed by:  
Apotheca, Inc Phoenix, AZ 85006

93522082680\*

**Benzonatate 100mg**  
**20 Capsules**  
**NDC: 12634-826-80**

LOT:                      EXP:

COMPARE TO:    TESSALON PERLE<sup>®</sup>  
Rx Only  
Dispensed In A Tight, Light Resistant  
Container, As Defined in The  
USP, Using A Child Resistant Closure.

**APOTHECA, INC.**  
SPECIALTY IN GENERAL PHARMACEUTICALS  
Manufactured - Distributed - Repackaged  
REV. DATE: 12/2015

**BULK SOURCE DATA**  
Manufactured By:  
Amneal Pharmaceutical of NY  
Hauppauge, NY 11788  
Call your doctor for Medical Advice about Side Effects.  
You may Report Side Effects to FDA at: 1-800-FDA-1088

**PRODUCT ID:**  
Imprinted "A1"  
Bulk NDC: 65162-536-10

Swallow do not chew.  
Keep this and all Medication Out of the Reach of Children.  
Do not use with alcohol or nonprescribed drugs without  
consulting the prescribing practitioner. Take with Food.

**Directions:**  
Take \_\_\_\_\_ capsule(s) by mouth \_\_\_\_\_  
times a day, as directed by physician.  
Store at 20-25 C (68-77 F) [See USP Controlled  
Room Temperature]. Protect from light and moisture.

## BENZONATATE

benzonatate capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:12634-826(NDC:65162-536)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
BENZONATATE (UNII: 5P4DHS6ENR) (BENZONATATE - UNII:5P4DHS6ENR)	BENZONATATE	100 mg

### Product Characteristics

Color	yellow	Score	no score
Shape	OVAL (Soft Gelatin Capsules)	Size	9mm
Flavor		Imprint Code	A1
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12634-826-01	100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:12634-826-54	14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:12634-826-61	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:12634-826-71	30 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:12634-826-80	20 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:12634-826-82	12 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:12634-826-85	15 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:12634-826-88	18 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:12634-826-91	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040682	06/04/2010	

**Labeler** - Apotheca Inc. (051457844)

### Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Inc.		051457844	repack(12634-826) , relabel(12634-826)

Revised: 12/2015

Apotheca Inc.