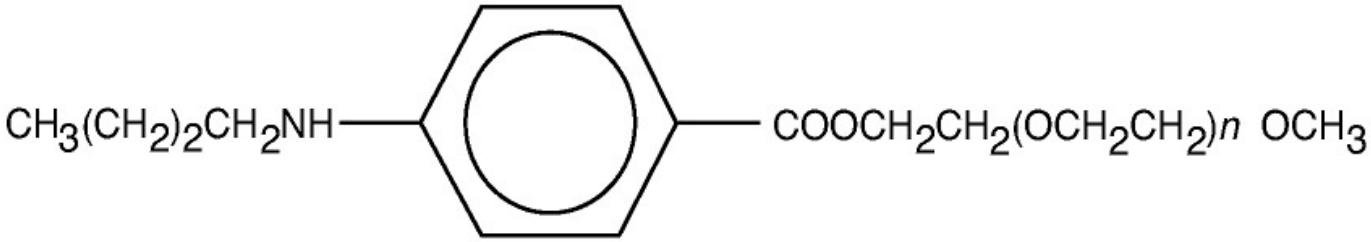
BENZONATATE- benzonatate capsule
Ascend Laboratories LLC

Benzonatate Capsules, USP
100 mg, 150 mg and 200 mg

DESCRIPTION

Benzonatate, a non-narcotic oral 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.



$C_{30}H_{53}NO_{11}$

Each soft gelatin capsule, for oral administration, contains 100 mg, 150 mg or 200 mg of benzonatate USP. Benzonatate Capsules, USP also contain the following inactive ingredients: D&C Yellow #10, gelatin, glycerin, purified water, methylparaben, propylparaben and titanium dioxide

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 USP is indicated for the symptomatic relief of cough.

CONTRAINDICATIONS

Hypersensitivity to benzonatate or related compounds.

WARNINGS

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 capsules 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 15-20 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 15-20 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 dosage of 600 mg. If you miss a dose of benzonatate capsule, 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 have 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 15-20 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, 150 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, 100 mg: Yellow soft gelatin capsules, imprinted “105”, available in bottles of 100’s (NDC 67877-573-01), and 500’s (NDC 67877-573-05).

Benzonatate Capsules USP, 150 mg: Yellow soft gelatin capsules, imprinted “128”, available in bottles of 100 (NDC 67877-574-01).

Benzonatate Capsules USP, 200 mg: Yellow soft gelatin capsules, imprinted “106”, available in bottles of 100’s (NDC 67877-575-01) and 500’s (NDC 67877-575-05).

Store at 20° to 25° C (68° to 77°F). [See USP Controlled Room Temperature]. **PROTECT FROM LIGHT.**

Manufactured by
Intergel Division of IVC Industries, Inc.
Irvington, NJ 07111

Manufactured for
Ascend Laboratories, LLC
Parsippany, NJ 07054

Rev 03/18

210082

———PRINCIPAL DISPLAY PANEL 100mg———

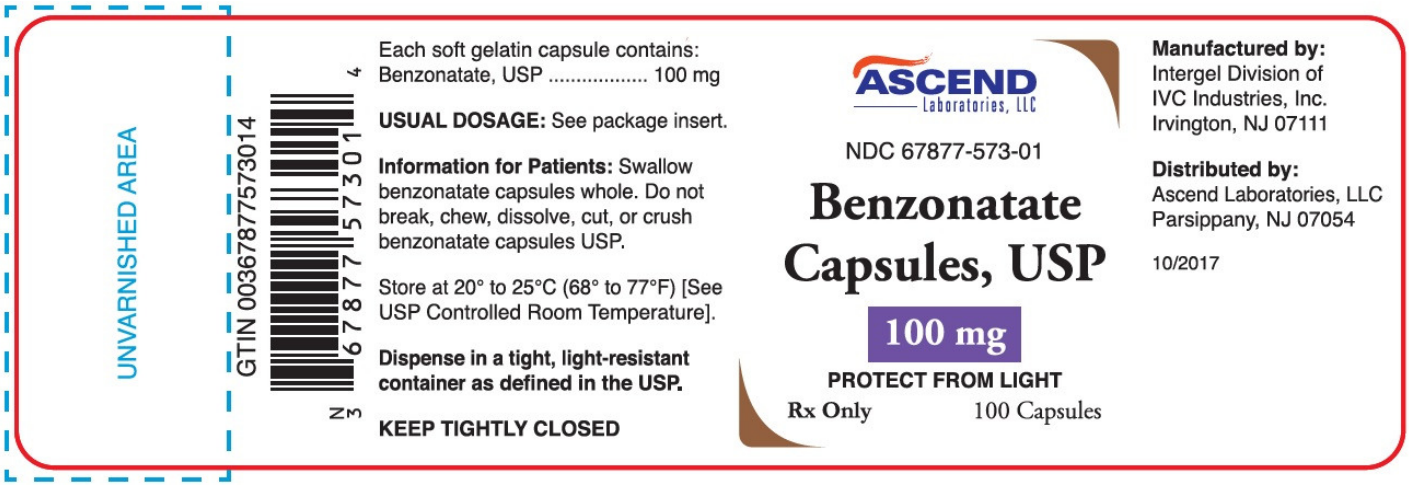
ASCEND
Laboratories, LLC

NDC 67877-573-01

Benzonatate
Capsules, USP

100 mg
PROTECT FROM LIGHT

Rx only 100 Capsules



———PRINCIPAL DISPLAY PANEL 150mg———

ASCEND
Laboratories, LLC

NDC 67877-574-01

Benzonatate
Capsules, USP

150 mg
PROTECT FROM LIGHT

Rx only 100 Capsules

———PRINCIPAL DISPLAY PANEL 200mg———

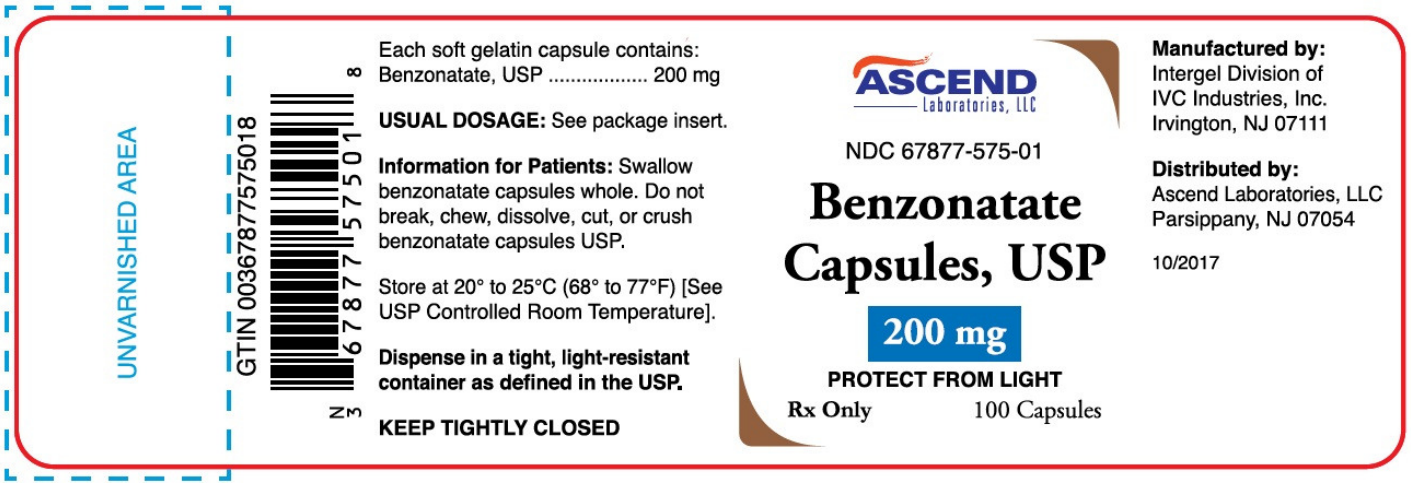
ASCEND
Laboratories, LLC

NDC 67877-575-01

Benzonatate
Capsules, USP

200 mg

Rx only 100 Capsules



BENZONATATE
benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:67877-573

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
benzonatate (UNII: 5P4DHS6ENR) (benzonatate - UNII:5P4DHS6ENR)	benzonatate	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
gelatin (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
water (UNII: 059QF0KO0R)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	105
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67877-573-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2017	
2	NDC:67877-573-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040627	03/22/2017	

BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:67877-574
Route of Administration	ORAL		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
benzonatate (UNII: 5P4DHS6ENR) (benzonatate - UNII:5P4DHS6ENR)	benzonatate	150 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
gelatin (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
water (UNII: 059QF0KO0R)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	128
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67877-574-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201209	03/22/2017	

BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:67877-575
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
benzonatate (UNII: 5P4DHS6ENR) (benzonatate - UNII:5P4DHS6ENR)	benzonatate	200 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
gelatin (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
water (UNII: 059QF0KO0R)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	106
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67877-575-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2017	
2	NDC:67877-575-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040749	03/22/2017	

Labeler - Ascend Laboratories LLC (141250469)

Establishment

Name	Address	ID/FEI	Business Operations
Intergel Pharmaceuticals Inc		964464114	manufacture(67877-573, 67877-574, 67877-575)

Revised: 12/2018 Ascend Laboratories LLC