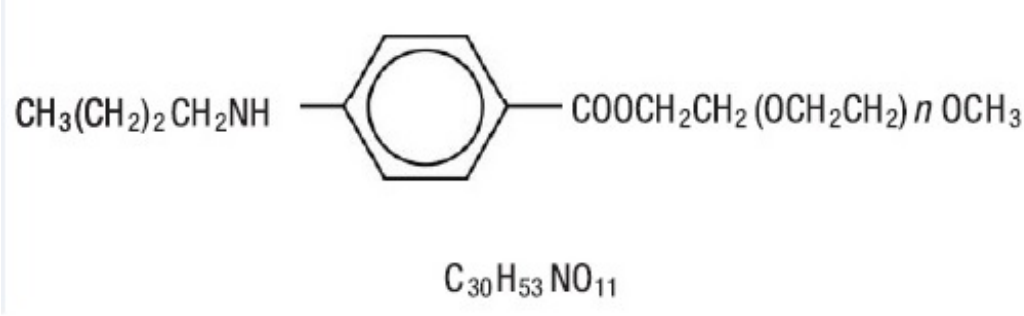
BENZONATATE- benzonatate capsule
Camber Pharmaceuticals, Inc.

BENZONATATE CAPSULES
100 mg Capsules
150 mg Capsules
200 mg Capsules
(benzonatate, USP)

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 benzonatate capsule USP contains:

Benzonatate, USP 100 mg

Each benzonatate capsule USP contains:

Benzonatate, USP 150 mg

Each benzonatate capsule USP contains:

Benzonatate, USP 200 mg

Benzonatate capsules USP also contain: bloom gelatin, glycerin, purified water, medium chain triglycerides, lecithin, isopropyl alcohol, nitrogen.

100 mg and 200 mg capsules also contain D&C Yellow No. 10.

150 mg capsules also contain FD&C Yellow No. 6 powder.

Each capsule also contains black iron oxide, propylene glycol, hypromellose as imprinting ink.

CLINICAL PHARMACOLOGY

Benzonatate capsules 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 capsules has no inhibitory effect on the respiratory center in recommended dosage.

INDICATIONS AND USAGE

Benzonatate capsules 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 capsules in combination with other prescribed drugs.

Accidental Ingestion and Death in Children

Keep benzonatate capsules out of reach of children. Accidental ingestion of benzonatate capsules 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 capsules 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 capsules, skip that dose and take the next dose at the next scheduled time. Do not take 2 doses of benzonatate capsules at one time.

Usage in Pregnancy

Pregnancy Category C

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

Carcinogenesis, mutagenesis, impairment of fertility

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

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 capsules 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 capsules should be swallowed whole.** Benzonatate capsules are not to be broken, chewed, dissolved, cut or crushed.

HOW SUPPLIED

Benzonatate Capsules, USP are available in 100 mg, 150 mg and 200 mg dosage strengths.

The 100 mg capsules are yellow round capsules containing clear to light yellow liquid, printed with ‘1’ sign in black ink.

NDC 31722-956-30 bottles of 30 capsules

NDC 31722-956-01 bottles of 100 capsules

NDC 31722-956-05 bottles of 500 capsules

The 150 mg capsules are orange round capsules containing clear, light yellow to orange liquid, printed with ‘2’ sign in black ink.

NDC 31722-957-30 bottles of 30 capsules

NDC 31722-957-01 bottles of 100 capsules

NDC 31722-957-05 bottles of 500 capsules

The 200 mg capsules are yellow round capsules containing clear to light yellow liquid, printed with ‘3’ sign in black ink.

NDC 31722-958-30 bottles of 30 capsules

NDC 31722-958-01 bottles of 100 capsules

NDC 31722-958-05 bottles of 500 capsules

Store at 20°C to 25°C (68°F to77°F) [see USP Controlled Room Temperature].

Protect from light. Dispense in tight, light-resistant container as defined in the USP with a child-resistant closure.

Manufactured by:

Ascent Pharmaceuticals, Inc.

Central Islip, NY 11722

Manufactured for:

Camber Pharmaceuticals, Inc.

Piscataway, NJ 08854

Rev: 07/21

Benzonatate Capsules 100 mg-500 ct

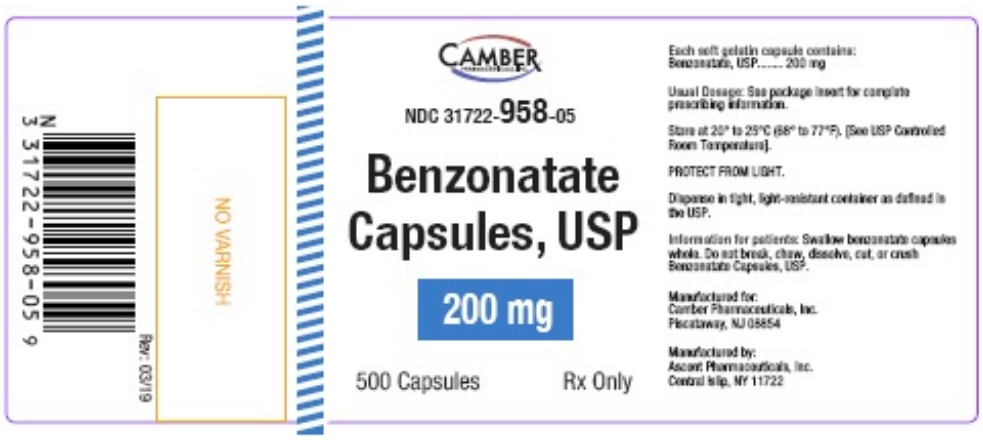
NDC:31722-956-05

Benzonatate Capsules 150 mg-500 ct

NDC:31722-957-05

Benzonatate Capsules 200 mg-500 ct

NDC:31722-958-05



BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:31722-956
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**
GELATIN (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

ISOPROPYL ALCOHOL (UNII: ND2M416302)	
NITROGEN (UNII: N762921K75)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:31722-956-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2019	
2	NDC:31722-956-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2019	
3	NDC:31722-956-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211518	02/22/2019	

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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:31722-957
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
GELATIN (UNII: 2G86QN327L)	

WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
NITROGEN (UNII: N762921K75)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:31722-957-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2019	
2	NDC:31722-957-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2019	
3	NDC:31722-957-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211518	02/22/2019	

BENZONATATE

benzonatate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:31722-958
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
GELATIN (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
NITROGEN (UNII: N762921K75)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:31722-958-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2019	
2	NDC:31722-958-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2019	
3	NDC:31722-958-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211518	02/22/2019	

Labeler - Camber Pharmaceuticals, Inc. (826774775)

Registrant - Ascent Pharmaceuticals, Inc. (080938961)

Establishment

Name	Address	ID/FEI	Business Operations
Ascent Pharmaceuticals, Inc.		080938961	analysis(31722-956, 31722-957, 31722-958) , manufacture(31722-956, 31722-957, 31722-958) , pack(31722-956, 31722-957, 31722-958)