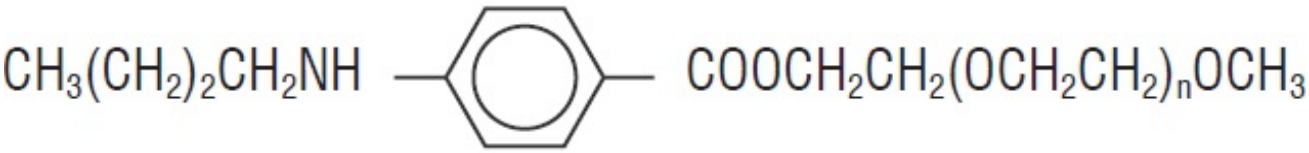
BENZONATATE- benzonatate capsule, liquid filled
Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc.

Benzonatate Capsules, USP
100 mg and 200 mg
Rx Only

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.



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

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.

The white imprinting ink contains the following inactive ingredients: ammonium hydroxide, isopropyl alcohol, n-butyl alcohol, propylene glycol, shellac glaze, simethicone and titanium dioxide.

FDA approved dissolution test specifications differ from USP.

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.

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 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 dosage 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 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.

To report SUSPECTED ADVERSE REACTIONS, contact Avet Pharmaceuticals Inc. at 1-866-901-DRUG (3784) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 Shape, imprint “100” with white ink, transparent yellow soft gelatin capsule

NDC 23155-898-01	Bottles of 100
NDC 23155-898-05	Bottles of 500

200 mg Oblong Shape, imprint “200” with white ink, transparent yellow soft gelatin capsules

NDC 23155-899-01	Bottles of 100
NDC 23155-899-05	Bottles of 500

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.

Distributed by:

Avet Pharmaceuticals Inc.

East Brunswick, NJ 08816

1.866.901.DRUG (3784)

51U000000461US01

Revised: 04/2024

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 100 mg

NDC 23155-**898**-01

Benzonatate Capsules, USP

100 mg

100 Capsules

Rx only

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 200 mg

NDC 23155-**899**-01

Benzonatate Capsules, USP

200 mg

100 Capsules

Rx only

BENZONATATE

benzonatate capsule, liquid filled

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:23155-898
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**
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
AMMONIA (UNII: 5138Q19F1X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	100
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23155-898-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/29/2024	
2	NDC:23155-898-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/29/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040682	09/29/2024	

BENZONATATE

benzonatate capsule, liquid filled

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:23155-899
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
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
AMMONIA (UNII: 5138Q19F1X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow	**Score**	no score

Shape	OVAL (Oblong Shape)	**Size**	14mm
Flavor		**Imprint Code**	200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23155-899-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/29/2024	
2	NDC:23155-899-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/29/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040682	09/29/2024	

Labeler - Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc. (780779901)

Establishment

Name	Address	ID/FEI	Business Operations
Heritage Pharma Labs Inc. d/b/a Avet Pharmaceuticals Labs Inc.		189630168	manufacture(23155-898, 23155-899) , pack(23155-898, 23155-899) , label(23155-898, 23155-899) , analysis(23155-898, 23155-899)

Revised: 9/2024 Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc.