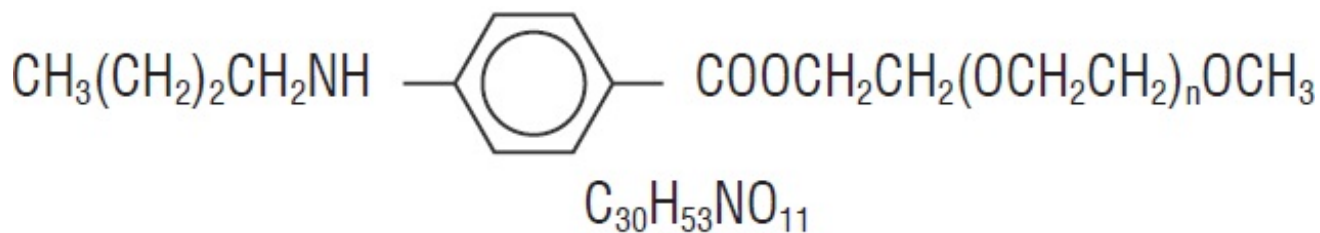


BENZONATATE- benzonatate capsule, liquid filled
Redpharm Drug

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-nonaaoxaoctacosan-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.

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:

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.

Do not use CNS stimulants.

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

East Brunswick, NJ 08816

1.866.901.DRUG (3784)



51U000000461US01

Revised: 04/2024

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 100 mg

NDC23155- 898-01

Benzonatate Capsules, USP

100 mg

100 Capsules

Rx only

The image shows a rectangular label for Benzonatate Capsules, USP. The label is divided into several sections. At the top left, it says "NDC 23155-898-01". Below this, the product name "Benzonatate Capsules, USP" is prominently displayed in a large, bold, blue font. Underneath the product name, there is a blue box containing "100 mg" in white, followed by "100 Capsules" and "Rx only" in a smaller font. The Avet Pharma logo is at the bottom left. The right side of the label contains detailed information: "Each capsule contains: Benzonatate, USP 100 mg", "Usual Dosage: See package insert for dosage information.", "Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (between 59° and 86°F) [see USP Controlled Room Temperature].", "KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.", "Dispense in a tight, light-resistant container as defined in the USP", "Distributed by: Avet Pharmaceuticals Inc., East Brunswick, NJ 08816, 1.866.901.DRUG (3784)", "51U000000457US01", "Rev. 04/2024", and a barcode with the number "N 3 23155 89801 9". A dashed line separates the main label from a "Non Varnished Area" on the right, which is labeled "1" x 1.5".

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 200 mg

NDC23155- 899-01

Benzonatate Capsules, USP

200 mg

100 Capsules

Rx only

NDC 23155-899-01

Benzonatate

Capsules, USP

200 mg

100 Capsules

Rx only

Avet Pharma®

Each capsule contains:
Benzonatate, USP200 mg

Usual Dosage: See package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (between 59° and 86°F) [see USP Controlled Room Temperature].

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Dispense in a tight, light-resistant container as defined in the USP

Distributed by:
Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816
1.866.901.DRUG (3784)
51U000000459US01

Rev. 04/2024

N 3

23155-89901

6

Non Varnished Area
1" x 1.5"

BENZONATATE			
benzonatate capsule, liquid filled			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:67296-2202(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:67296-2202-3	30 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 - Redpharm Drug (828374897)**Establishment**

Name	Address	ID/FEI	Business Operations
Redpharm Drug		828374897	repack(67296-2202)

Revised: 12/2025

Redpharm Drug