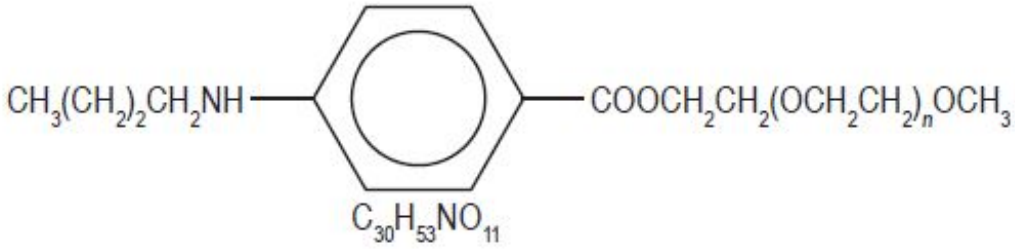
BENZONATATE- benzonatate capsule
American Health Packaging

Benzonatate Capsules, USP
8221401/0921
Rx only

DESCRIPTION

Benzonatate capsules, USP, 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.



Each benzonatate capsule for oral administration contains 100 mg or 200 mg of benzonatate. In addition, each capsule also contains the following inactive ingredients: gelatin, glycerin, noncrystallising sorbitol solution, methylparaben, propylparaben and purified water.

CLINICAL PHARMACOLOGY

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

INDICATIONS AND USAGE

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

HOW SUPPLIED

Benzonatate capsules USP, 100 mg are light yellow-colored, round-shaped soft gelatin capsules, imprinted with "Z" containing pale yellow-colored clear viscous liquid and are supplied as follows:
Unit dose packages of 100 (10 x 10) NDC 68084-214-01

Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]

FOR YOUR PROTECTION: Do not use if blister is torn or broken.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

PACKAGING INFORMATION

American Health Packaging unit dose blisters (see How Supplied section) contain drug product from Zydus Pharmaceuticals (USA) Inc. as follows:
(100 mg/100 UD) NDC 68084-214-01 packaged from NDC 68382-247

Distributed by:
American Health Packaging
Columbus, OH 43217

8221401/0921

Package/Label Display Panel – Carton – 100 mg

NDC 68084-**214**-01

Benzonatate
Capsules, USP

100 mg

100 Capsules (10 x 10) **Rx Only**

(01) 0 03 68084 214 01 1

NDC 68084-**214**-01

Benzonatate
Capsules, USP

100 mg

100 Capsules (10 x 10) **Rx Only**

Each Capsule Contains:
Benzonatate, USP.....100 mg

Usual Dosage: See package insert for full prescribing information.

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

Keep this and all drugs out of reach of children.

FOR YOUR PROTECTION: Do not use if blister is torn or broken.

The drug product contained in this package is from NDC # 68382-247, Zydus Pharmaceuticals (USA) Inc.

Distributed by:
American Health Packaging
Columbus, Ohio 43217

801054
0224101/0321

NDC 68084- **214**-01

Benzonatate
Capsules, USP

100 mg

100 Capsules (10 x 10) **Rx Only**

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Columbus, Ohio 43217

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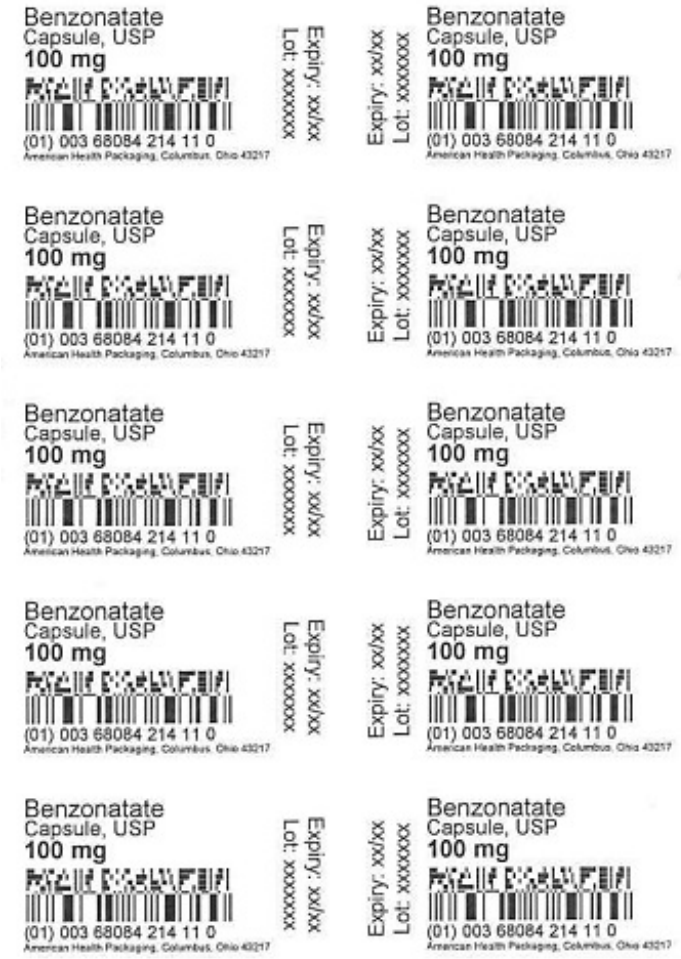
Package/Label Display Panel – Blister – 100 mg



Benzonatate
Capsule, USP

100 mg

BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68084-214(NDC:68382-247)
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, UNSPECIFIED (UNII: 2G86QN327L)	

GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	yellow (LIGHT YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	3mm
Flavor		**Imprint Code**	Z
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68084-214-01	10 in 1 CARTON	05/01/2021	
1	NDC:68084-214-11	10 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	ANDA040597	10/03/2011	

Labeler - American Health Packaging (929561009)

Establishment

Name	Address	ID/FEI	Business Operations
American Health Packaging		929561009	repack(68084-214)

Revised: 8/2022 American Health Packaging