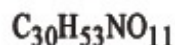
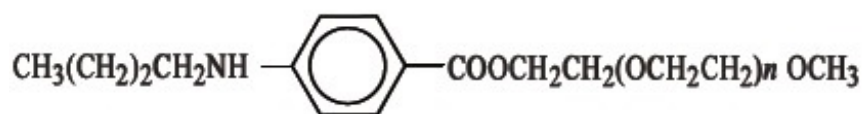


BENZONATATE- benzonatate capsule
Rising Pharma Holdings, Inc.

Benzonatate Capsules
USP, 100 mg and 200 mg

DESCRIPTION

Benzonatate, a non-narcotic oral antitussive agent, is 2, 5, 8, 11, 14, 17, 20, 23, 26-nonaoxaocacosan-28-yl p-(butylamino) benzoate; with a molecular weight of 603.7.



Each benzonatate capsule USP,100 mg contains:
Benzonatate, USP 100 mg.

Each benzonatate capsule USP,200 mg contains:
Benzonatate, USP 200 mg.

Benzonatate Capsules USP also contain: D&C Yellow 10, gelatin, glycerin, methylparaben, propylparaben, shellac and titanium dioxide.

CLINICAL PHARMACOLOGY

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

INDICATIONS AND USAGE

Benzonatate Capsule 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 Capsule 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 Capsule 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 overdose.

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 available as yellow, oval soft gelatin capsules with '1' imprinted in white ink.

Bottles of 100
NDC 64980-634-01

Bottles of 500
NDC 64980-634-50

Benzonatate Capsules USP, 200 mg are available as yellow, oval soft gelatin capsules with '2' imprinted in white ink.

Bottles of 100
NDC 64980-635-01

Bottles of 500
NDC 64980-635-50

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].

PROTECT FROM LIGHT

Manufactured by:

CSPC Ouyi Pharmaceutical Co., Ltd.
Shijiazhuang, Hebei, China, 052160

J120150136

Distributed By:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Issued: 03/2024

PRINCIPAL DISPLAY PANEL - 100 mg Capsule Bottle Label

NDC 64980-634-01

Benzonatate Capsules USP

100 mg

Rx only

100 CAPSULES

Rising Pharma Holdings, Inc.

Rising[®]
PHARMACEUTICALS NDC 64980-634-01

**Benzonatate
Capsules USP**

100 mg

100 Capsules **Rx only**

Each soft gelatin capsule contains:
Benzonatate, USP.....100 mg

PROTECT FROM LIGHT
KEEP TIGHTLY CLOSED

USUAL DOSAGE:
See package insert for dosage and 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]. Dispense in a tight, light-resistant container as defined in the USP.

Information for Patients:
Swallow benzonatate capsules USP whole. Do not break, chew, dissolve, cut, or crush benzonatate capsules USP.

Manufactured By:
CSPC-NBP PHARMACEUTICAL CO.,LTD
Shijiazhuang, Hebei, Province,
052160, China
J120150136

Distributed By:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Issued: 03/2024

3 64980163401 4

PRINCIPAL DISPLAY PANEL - 200 mg Capsule Bottle Label

NDC 64980-635-01

Benzonatate Capsules USP

200 mg

Rx only

100 CAPSULES

Rising Pharma Holdings, Inc.

 **Rising**[®]
PHARMACEUTICALS NDC 64980-635-01

Benzonatate Capsules USP

200 mg

100 Capsules

Rx only

Each soft gelatin capsule
contains:
Benzonatate, USP.....200 mg

PROTECT FROM LIGHT
KEEP TIGHTLY CLOSED

USUAL DOSAGE:
See package insert for dosage and
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].
Dispense in a tight, light-resistant container
as defined in the USP.

**Information for
Patients:**
Swallow benzonatate
capsules USP whole.
Do not break, chew,
dissolve, cut, or crush
benzonatate capsules USP.

Manufactured By:
CSPC-NBP PHARMACEUTICAL CO.,LTD
Shijiazhuang, Hebei, Province,
052160, China
J120150136

Distributed By:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Issued: 04/2024



BENZONATATE

benzonatate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64980-634
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, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	OVAL	Size	8mm
Flavor		Imprint Code	1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64980-634-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2024	
2	NDC:64980-634-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202765	07/26/2024	

BENZONATATE

benzonatate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64980-635
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, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64980-635-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2024	
2	NDC:64980-635-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202765	07/26/2024	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Registrant - CSPC Ouyi Pharmaceutical Co., Ltd. (421303775)

Establishment

Name	Address	ID/FEI	Business Operations
CSPC Ouyi Pharmaceutical Co., Ltd.		421303775	manufacture(64980-634, 64980-635) , analysis(64980-634, 64980-635)

Revised: 6/2024

Rising Pharma Holdings, Inc.