BENZONATATE- benzonatate capsule
Chartwell RX, LLC

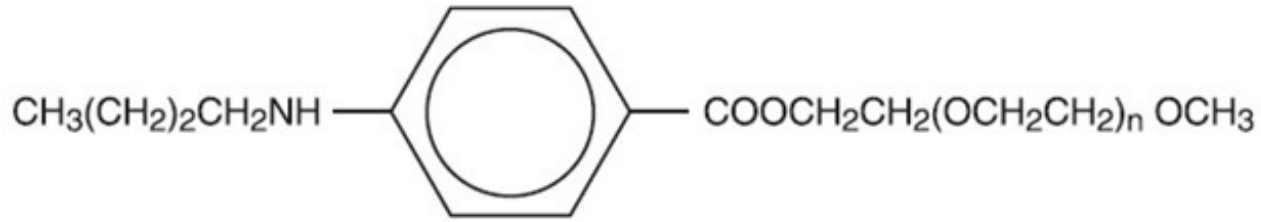
Benzonatate Capsules, USP

100 mg and 200 mg

Rx Only

DESCRIPTION

Benzonatate, a non-narcotic 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.

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 reportedwithin 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 dose 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 has 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.

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 refluxes 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, yellow) soft gelatin capsules with imprint “A5”.

NDC 62135-440-90 Bottles of 90

NDC 62135-440-01 Bottles of 100

NDC 62135-440-31 Bottles of 300

200 mg (oblong, yellow) soft gelatin capsules with imprint “A6”.

NDC 62135-441-60 Bottles of 60

NDC 62135-441-31 Bottles of 300

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.

To report SUSPECTED ADVERSE REACTIONS, contact Chartwell RX, LLC at 1-845-232-1683 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Manufactured by:

Swiss Caps AG

Kirchberg, Switzerland

Manufactured for:

Chartwell RX, LLC

77 Brenner Drive

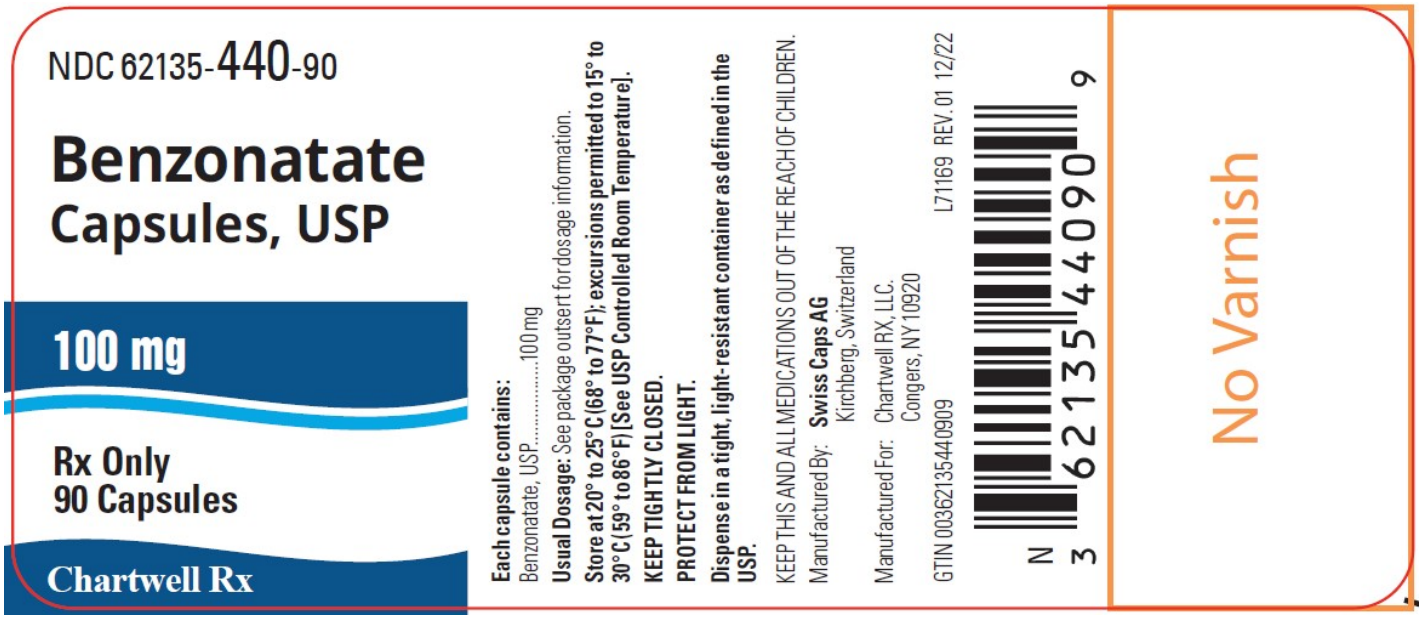
Congers, NY 10920

Revised: 03/2023

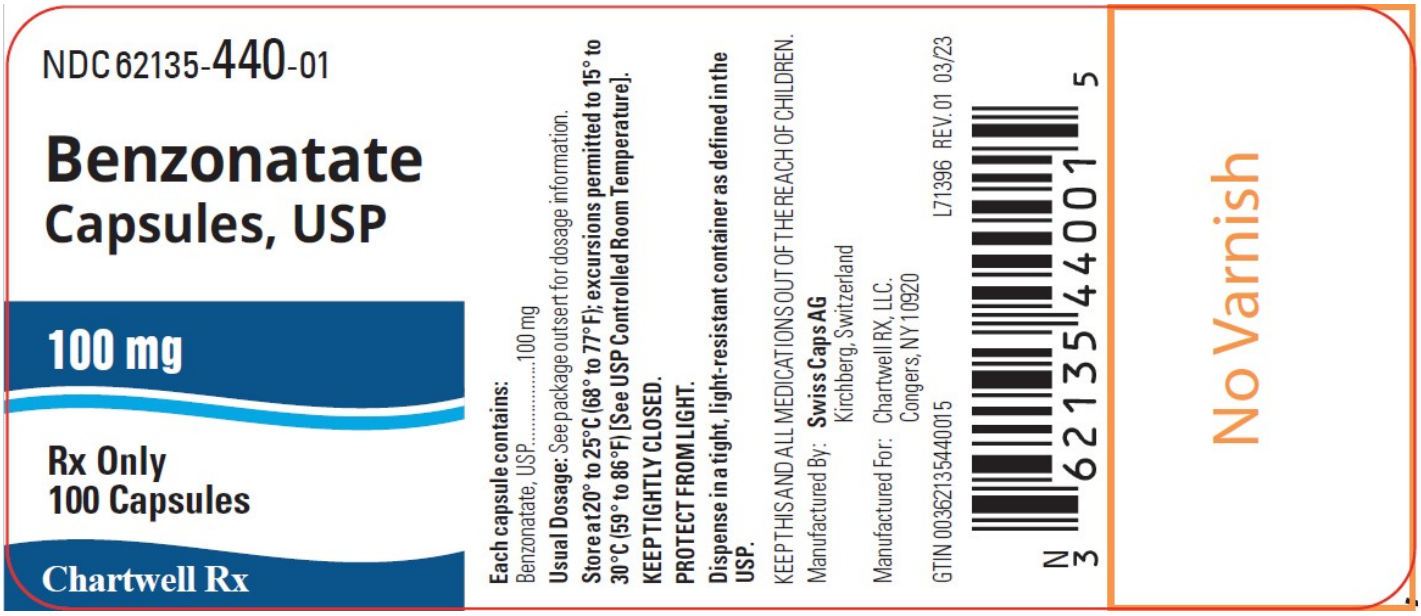
L71173

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

Benzonatate Capsules, USP 100 mg NDC 62135-440-90 - 90s Bottle Label



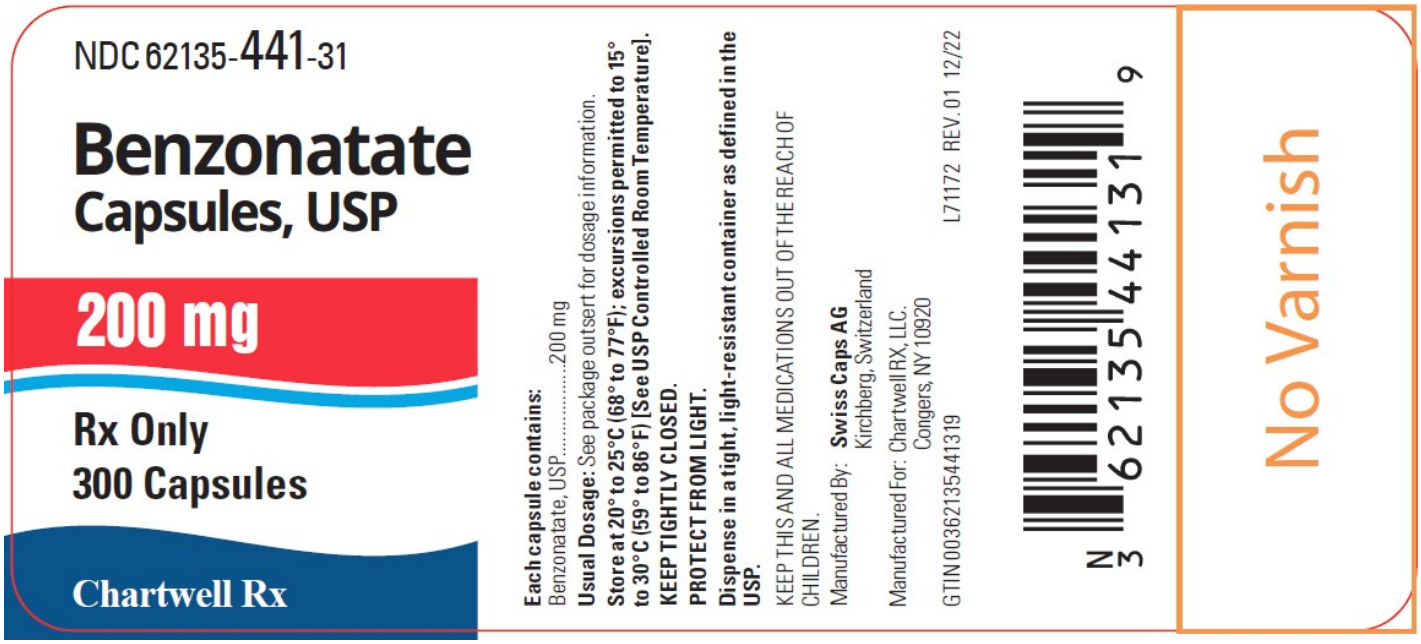
Benzonatate Capsules, USP 100 mg NDC 62135-440-01 - 100s Bottle Label



Benzonatate Capsules, USP 100 mg NDC 62135-440-31 - 300s Bottle Label

Benzonatate Capsules, USP 200 mg NDC 62135-441-60 - 60s Bottle Label

Benzonatate Capsules, USP 200 mg NDC 62135-441-31 - 300s Bottle Label



BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62135-440
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 SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	OVAL	**Size**	9mm
Flavor		**Imprint Code**	A5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62135-440-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2023	
2	NDC:62135-440-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2023	
3	NDC:62135-440-31	300 in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040682	05/01/2018	

BENZONATATE

benzonatate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62135-441
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 SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	A6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:62135-441-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2023	
2	NDC:62135-441-31	300 in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040682	05/01/2018	

Labeler - Chartwell RX, LLC (079394054)

Revised: 4/2023 Chartwell RX, LLC