

BENZONATATE- benzonatate capsule DIRECT RX

BENZONATATE

Benzonatate capsules, USP, a non-narcotic oral antitussive agent, is 2, 5, 8, 11, 14, 17, 20, 23, 26- onaoxaoctacosan-28-ylp-(butylamino) benzoate; with a molecular weight of 603.7. [structure formula] Each benzonatate capsules, USP for oral administration contains 100 mg or 200 mg benzonatate, USP. In addition, each capsule contains the following inactive ingredients: D&C Yellow #10, gelatin, glycerin, lecithin, light mineral oil, propylene glycol, purified water, shellac glaze, titanium dioxide, and white edible ink.

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.

Benzonatate capsules, USP are indicated for the symptomatic relief of cough.

Hypersensitivity to benzonatate or related compounds.

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 15-20 minutes and death has been reported within one hour of ingestion. If accidental ingestion occurs, seek medical attention immediately (see OVERDOSAGE).

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 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.

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.

Hypersensitivity reactions

including bronchospasm, laryngospasm, cardiovascular collapse possibly related to local anesthesia from chewing or sucking the capsule.

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 capsules 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 overdosage.

Do not use CNS stimulants.

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.

Benzonatate Capsules USP, 100 mg are clear yellow, oval-shaped softgel capsules imprinted with "PC14" and are supplied as follows:

Benzonatate Capsules USP, 200 mg are clear yellow, oval-shaped softgel capsules imprinted with "PC15" and are supplied as follows:

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

PROTECT FROM LIGHT

Dispense in tight (USP), child-resistant containers.

Rx Only

Manufactured by:

Humanwell PuraCap Pharmaceutical

Wuhan, Hubei 430206, China

Distributed by:

Epic Pharma, LLC

Laurelton, NY 11413

Rev. 10-2018-00

PI-EBEN-00

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed. Dosage: See package insert. Store between 68-77 degrees F. For RX ONLY. Keep out of reach of children.

NDC 72189-194-30

BENZONATATE

100mg **30 Caps**

Generic For: **TESSALON PERLES**
Each Softgel (soft gelatin capsule) Contains:
Benzonate, USP...100 mg

Lot# 26MA2108
Prod# 4125-100-30

Discard After: 4/30/22
72189-194-30
26MA2108
4/30/22
BAV4L

Dawsonville, GA 30534

Dist. By Epic Pharma, LLC
Laurelton, NY 11413
NDC 42806-714-05

Mfg Lot: 1006307
BW 3/26/2021 1318907

BENZONATATE 100mg
NDC 72189-194-30 30 Caps
Lot 26MA2108 Exp 4/30/22
Mfg NDC 42806-714-05

BENZONATATE 100mg
NDC 72189-194-30 30 Caps
Lot 26MA2108 Exp 4/30/22
Mfg NDC 42806-714-05

BENZONATATE 100mg
NDC 72189-194-30 30 Caps
Lot 26MA2108 Exp 4/30/22
Mfg NDC 42806-714-05

BENZONATATE 100mg
NDC 72189-194-30 30 Caps
Lot 26MA2108 Exp 4/30/22
Mfg NDC 42806-714-05

Packaged and Distributed By: **DIRECT R**

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed. Dosage: See package insert. Store between 68-77 degrees F. For RX ONLY. Keep out of reach of children.

NDC 72189-192-20

BENZONATATE

200mg **20 Caps**

Generic For: **TESSALON PERLES**
Each Softgel (soft gelatin capsule) contains:
Benzonate, USP...200 mg

Lot# 20AP2122
Prod# 4125-200-20

Discard After: 7/31/22
72189-192-20
20AP2122
7/31/22
888K3

Dawsonville, GA 30534

Dist. By Epic Pharma, LLC
Laurelton, NY 11413
NDC 42806-715-05

Mfg Lot: 1008905
TR 4/20/2021 6820485

BENZONATATE 200mg
NDC 72189-192-20 20 Caps
Lot 20AP2122 Exp 7/31/22
Mfg NDC 42806-715-05

BENZONATATE 200mg
NDC 72189-192-20 20 Caps
Lot 20AP2122 Exp 7/31/22
Mfg NDC 42806-715-05

BENZONATATE 200mg
NDC 72189-192-20 20 Caps
Lot 20AP2122 Exp 7/31/22
Mfg NDC 42806-715-05

BENZONATATE 200mg
NDC 72189-192-20 20 Caps
Lot 20AP2122 Exp 7/31/22
Mfg NDC 42806-715-05

Packaged and Distributed By: **DIRECT R**

NDC 72189-192-20

BENZONATATE

200mg **20 Caps**

Generic For: **TESSALON PERLES**
 Each Softgel (soft gelatin capsule) contains:
 Benzonatate, USP...200 mg

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed. Dosage: See package insert. Store between 68-77 degrees F. For RX ONLY. Keep out of reach of children.

Lot# 20AP2122
 Prod# 4125-200-20
 Packaged and Distributed By: **DIRECT R**

Discard After: 7/31/22
 72189-192-20
 20AP2122 Dawsonville, GA 30534
 7/31/22
 888K3

Mfg Lot: 1006905
 TR 4/20/2021 6920486
 BENZONATATE 200mg
 NDC 72189-192-20 20 Caps
 Lot 20AP2122 Exp 7/31/22
 Mfg NDC 42806-715-05

Mfg Lot: 1006905
 TR 4/20/2021 6920486
 BENZONATATE 200mg
 NDC 72189-192-20 20 Caps
 Lot 20AP2122 Exp 7/31/22
 Mfg NDC 42806-715-05

Mfg Lot: 1006905
 TR 4/20/2021 6920486
 BENZONATATE 200mg
 NDC 72189-192-20 20 Caps
 Lot 20AP2122 Exp 7/31/22
 Mfg NDC 42806-715-05

Mfg Lot: 1006905
 TR 4/20/2021 6920486
 BENZONATATE 200mg
 NDC 72189-192-20 20 Caps
 Lot 20AP2122 Exp 7/31/22
 Mfg NDC 42806-715-05

Dist. By Epic Pharm, LLC
 Laurelton, NY 11413
 NDC 42806-715-05

NDC 72189-192-30

BENZONATATE

200mg **30 Caps**

Generic For: **TESSALON PERLES**
 Each Softgel (soft gelatin capsule) contains:
 Benzonatate, USP...200 mg

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed. Dosage: See package insert. Store between 68-77 degrees F. For RX ONLY. Keep out of reach of children.

Lot# 18MA2117
 Prod# 4125-200-30
 Packaged and Distributed By: **DIRECT R**

Discard After: 7/31/22
 72189-192-30
 18MA2117 Dawsonville, GA 30534
 7/31/22
 8A0H0

Mfg Lot: 1006905
 SW 3/19/2021 1316460
 BENZONATATE 200mg
 NDC 72189-192-30 30 Caps
 Lot 18MA2117 Exp 7/31/22
 Mfg NDC 42806-715-01

Mfg Lot: 1006905
 SW 3/19/2021 1316460
 BENZONATATE 200mg
 NDC 72189-192-30 30 Caps
 Lot 18MA2117 Exp 7/31/22
 Mfg NDC 42806-715-01

Mfg Lot: 1006905
 SW 3/19/2021 1316460
 BENZONATATE 200mg
 NDC 72189-192-30 30 Caps
 Lot 18MA2117 Exp 7/31/22
 Mfg NDC 42806-715-01

Mfg Lot: 1006905
 SW 3/19/2021 1316460
 BENZONATATE 200mg
 NDC 72189-192-30 30 Caps
 Lot 18MA2117 Exp 7/31/22
 Mfg NDC 42806-715-01

Dist. By Epic Pharm, LLC
 Laurelton, NY 11413
 NDC 42806-715-01

BENZONATATE

benzonatate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72189-194(NDC:42806-714)
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
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
SHELLAC (UNII: 46N107B71O)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	yellow	Score	no score
Shape	OVAL	Size	7mm
Flavor		Imprint Code	PC14
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-194-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2021	
2	NDC:72189-194-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206948	03/30/2021	

BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72189-192(NDC:42806-715)
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
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	

LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
WATER (UNII: 059QF0KO0R)
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)
LIGHT MINERAL OIL (UNII: N6K5787QVP)
SHELLAC (UNII: 46N107B71O)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	9mm
Flavor		Imprint Code	PC15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-192-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2021	
2	NDC:72189-192-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206948	06/03/2021	

Labeler - DIRECT RX (079254320)

Registrant - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(72189-194, 72189-192)

Revised: 1/2025

DIRECT RX