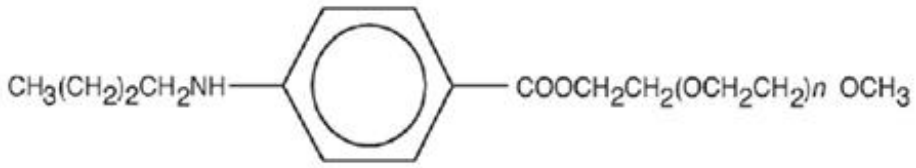
BENZONATATE- benzonatate capsule
Acella Pharmaceuticals, LLC

Benzonatate Capsules, USP

DESCRIPTION

Benzonatate, 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 603.0.



$C_{30}H_{53}NO_{11}$

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: gelatin 175 bloom bone NF, glycerin 99% USP, methyl/propyl paraben blend (4:1), yellow #10-DC and white ink (shellac glaze in SD-45, titanium dioxide, isopropyl alcohol, n-butyl alcohol, propylene glycol, ammonium hydroxide and simethicone).

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 capsules USP are indicated for the symptomatic relief of cough.

CONTRAINDICATIONS

Hypersensitivity to benzonatate or related compounds.

WARNINGS

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.

Isolated instances of bizarre behavior, including mental confusion and visual hallucinations, have also been reported in patients taking benzonatate capsules USP in combination with other prescribed drugs.

PRECAUTIONS

Benzonatate is chemically related to anesthetic agents of the para-aminobenzoic 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: Release of benzonatate from the capsule in the mouth can produce a temporary local anesthesia of the oral mucosa and choking could occur. Therefore, the capsules should be swallowed without chewing.

Usage in Pregnancy: Pregnancy Category C. Animal reproduction studies have not been conducted with benzonatate capsules USP. It is also not known whether benzonatate capsules USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzonatate capsules USP 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 USP are administered to a nursing woman.

Carcinogenesis, mutagenesis, impairment of fertility: Carcinogenicity, mutagenicity, and reproduction studies have not been conducted with benzonatate capsules USP.

Pediatric Use: Safety and effectiveness in children below the age of 10 have not been established.

ADVERSE REACTIONS

Potential Adverse Reactions to benzonatate capsules USP may include: Hypersensitivity reactions including bronchospasm, laryngospasm, and 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.

Rare instances of deliberate or accidental overdose have resulted in death.

OVERDOSAGE

Overdose may result in death.

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:

If capsules are chewed or dissolved in the mouth, oropharyngeal anesthesia will develop rapidly. CNS stimulation may cause restlessness and tremors which may proceed to clonic convulsions followed by profound CNS depression.

Treatment:

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: Usual dose is one 100 mg or 200 mg capsule t.i.d. as required. If necessary, up to 600 mg daily may be given.

HOW SUPPLIED

Benzonatate capsules USP 100 mg are available for oral administration as a clear, colorless to pale yellow oil in a clear, yellow softgel shell imprinted "A" in white ink.

They are supplied as follows:
Bottles of 100 (NDC 42192-617-01)
Bottles of 500 (NDC 42192-617-05)

Benzonatate capsules USP 200 mg are available for oral administration as a clear, colorless to pale yellow oil in a clear, yellow softgel shell imprinted "A2" in white ink.

They are supplied as follows:
Bottles of 100 (NDC 42192-618-01)
Bottles of 500 (NDC 42192-618-05)

Storage

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].

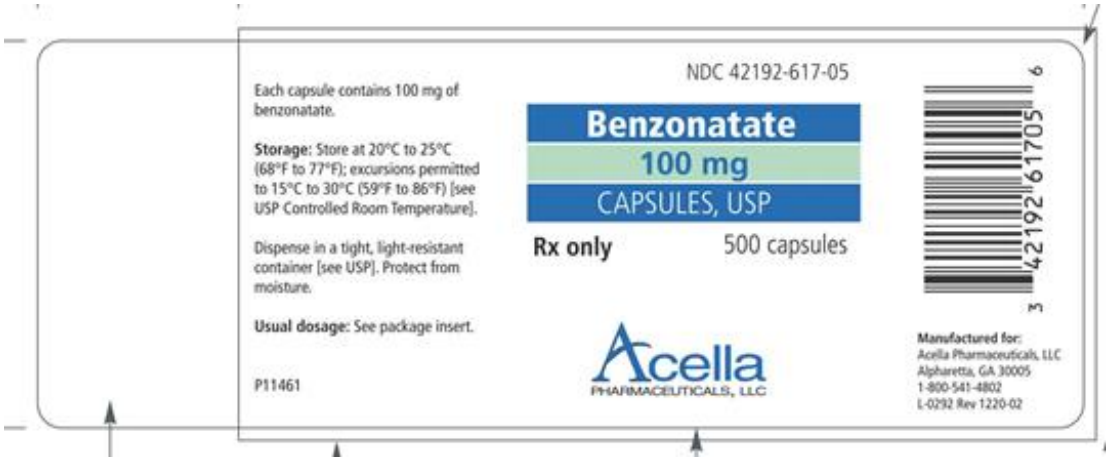
Dispense in a tight, light-resistant container [see USP].

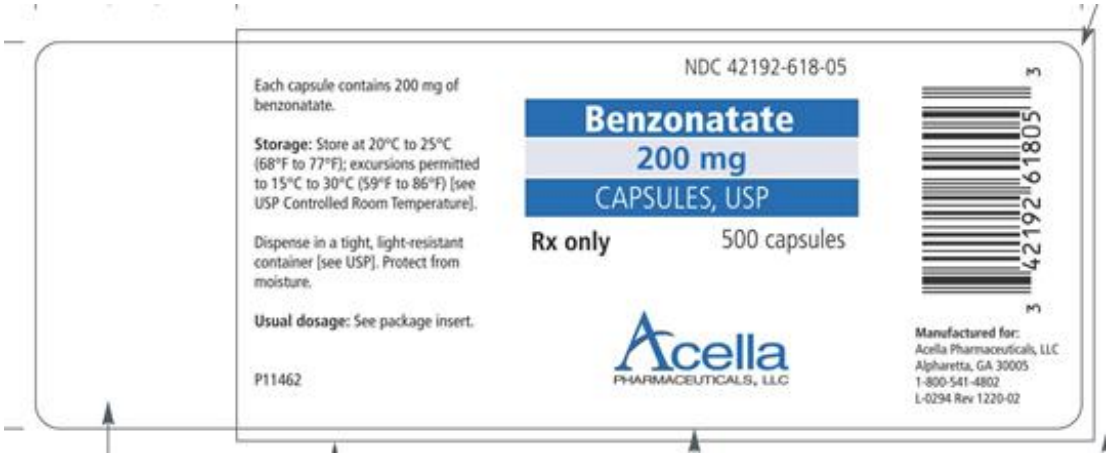
Protect from moisture.

Manufactured by:
Catalent Pharma Solutions
Windsor, ON
Canada N9C 3R5

Manufactured for:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30005
L-0273 Rev 1020-01

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-617
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 (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMMONIA (UNII: 5138Q19F1X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	YELLOW (clear; yellow)	**Score**	no score
Shape	CAPSULE	**Size**	6mm
Flavor		**Imprint Code**	A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-617-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/02/2021	
2	NDC:42192-617-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/02/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091310	08/02/2021	

BENZONATATE

benzonatate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-618
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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMMONIA (UNII: 5138Q19F1X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	YELLOW (clear; yellow)	**Score**	no score
Shape	CAPSULE	**Size**	11mm
Flavor		**Imprint Code**	A2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-618-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/02/2021	
2	NDC:42192-618-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/02/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091310	08/02/2021	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Registrant - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Catalent Ontario Limited		248441727	MANUFACTURE(42192-617, 42192-618) , ANALYSIS(42192-617, 42192-618)

Establishment

Name	Address	ID/FEI	Business Operations
Catalent Ontario Limited		243944050	LABEL(42192-617, 42192-618) , PACK(42192-617, 42192-618)

Revised: 7/2021 Acella Pharmaceuticals, LLC