BENZONATATE- benzonatate capsule
ETHEX Corporation

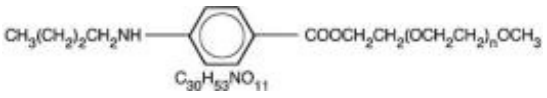
Benzonatate Capsules, USP
100 mg and 200 mg

Rx Only

P5519-1 01/08

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 603.7.



Each benzonatate capsule contains benzonatate, USP, 100 mg or 200 mg.

Benzonatate capsules, USP also contain gelatin, glycerin, methyl/propyl paraben blend, purified water, and titanium dioxide.

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-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

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, 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 round, white soft gelatin capsules, imprinted in black ink “E,” packaged as follows:

NDC 58177-091-04 bottle of 100 capsules

NDC 58177-091-08 bottle of 500 capsules

NDC 58177-091-11 unit dose package of 100 capsules (10 capsules per blister card)

Benzonatate capsules, USP 200 mg are oval, white soft gelatin capsules, imprinted in black ink “E2,” packaged as follows:

NDC 58177-092-04 bottle of 100 capsules

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature.] Protect from light.

Dispense in a tight, light resistant container as defined in the USP.

Manufactured by
AccuCaps
Windsor, Ontario, Canada
for
ETHEX Corporation
St. Louis, MO 63044 USA

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BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58177-091
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzonatate (UNII: 5P4DHS6ENR) (Benzonatate - UNII:5P4DHS6ENR)		100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
gelatin (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
methyl/propyl paraben blend ()	
water (UNII: 059QF0KO0R)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white (WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	E
Contains			
Coating	false	**Symbol**	false

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58177-091-04	100 in 1 BOTTLE		
2	NDC:58177-091-08	500 in 1 BOTTLE		
3	NDC:58177-091-11	100 in 1 BLISTER PACK		

BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58177-092
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzonatate (UNII: 5P4DHS6ENR) (Benzonatate - UNII:5P4DHS6ENR)		200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
gelatin (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
methyl/propyl paraben blend ()	
water (UNII: 059QF0KO0R)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white (WHITE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	E2
Contains			
Coating	false	**Symbol**	false

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58177-092-04	100 in 1 BOTTLE		

Labeler - ETHEX Corporation

Revised: 12/2008 ETHEX Corporation