**BENZONATATE - benzonatate capsule**
**Stat Rx USA**

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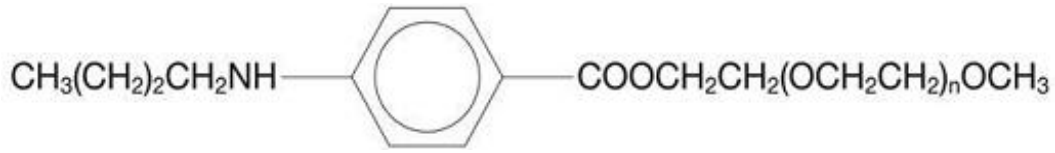
**BENZONATATE capsule, liquid filled**

**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.



Benzonatate Capsules, USP contain 100 mg or 200 mg of benzonatate, USP.

Benzonatate Capsules also contain: D and 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

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## 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.

## 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 the Patient

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. 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.

## 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.

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 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 barbiturates 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 capsules t.i.d. as required. If necessary, up to 600 mg daily may

be given.

**HOW SUPPLIED**

Benzonatate Capsules, USP are available as:

Soft gelatin capsules, 100 mg (oval, yellow); bottle of 100

Imprint: A1.

NDC# 65162-536-10

Soft gelatin capsules, 100 mg (oval, yellow); bottle of 500

Imprint: A1.

NDC# 65162-536-50

Soft gelatin capsules, 200 mg (oblong, yellow); bottle of 100

Imprint: A2.

NDC# 65162-537-10

Store at 25°-25°C (68°-77°F) [See USP Controlled Room Temperature]. Dispense in tight, light-resistant container as defined in the USP.

Manufactured by:
**Swiss Caps AG**

**Hausenstrasse 35**

**CH-9533, Kirchberg, Switzerland**

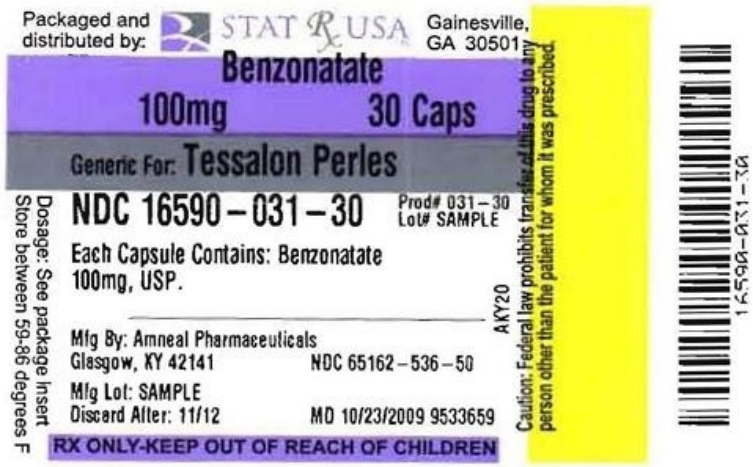
Distributed by:

**Amneal Pharmaceuticals**

**Glasgow, KY 42141**

**Rev. 09-2008**

Benzonatate 100mg Label




# BENZONATATE

benzonatate capsule

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:16590-031(NDC:65162-536) |
| **Route of Administration** | ORAL | | |

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

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | yellow | **Score** | no score |
| **Shape** | OVAL | **Size** | 9mm |
| **Flavor** | | **Imprint Code** | A1 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |

| | | | | |
|---|---|---|---|---|
| **1** | NDC:16590-031-30 | 30 in 1 BOTTLE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA040682 | 07/30/2007 | |

## Labeler - Stat Rx USA (786036330)

Revised: 10/2009 Stat Rx USA