Benzonatate Capsules, USP

150 mg

NDC: 69499-329-15
AWP: $1,185.00 per 15 capsule bottle
30 Day Supply = 2 - 6 Bottles

* Up to $75.00 off patient’s copay per bottle
or $150.00 to $225.00 off per Rx

CONTAINS:
Each capsule, for oral administration, contains benzonatate in the following strengths: 150 mg.

Store at 20° to 25° C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light.
Dispense in a tight, light-resistant container as defined in the USP. Keep tightly closed.

INDICATIONS AND USAGE:
Benzonatate is indicated for the symptomatic relief of cough.

Unit Detail:
- 15 capsules per bottle
- 1 case = 12 bottles of 15 capsules

USUAL DOSAGE: One capsule (150 mg) three times daily as needed for cough. Recommended for adults and children over 10 years of age.

See reverse for complete prescribing information.
DESCRIPTION:
Benzonatate is 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 603.00 (av).

Each capsule, for oral administration, contains benzonatate in the following strengths: 150 mg.

All strengths contain the following inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, microcrystalline cellulose, and silicon dioxide. Capsule shells for all strengths are composed of gelatin, titanium dioxide, FD&C Blue #1 and the following: FD&C Yellow #6, D&C Red #28. Imprinting ink is composed of black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac and strong ammonium solution.

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 treatment of acute and chronic cough resulting in discomfort or sleeplessness.

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 reported within one hour of ingestion. If accidental ingestion occurs, seek medical attention immediately.

PRECAUTIONS:
Benzonatate is chemically related to anesthetic agents of the paraaminobenzoic 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 in adults or children may include:

- Severe 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 stomach 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 shortacting 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 overdose. Do not use CNS stimulants.

DOSE AND ADMINISTRATION:
Adults and Children over 10 years of age: Usual dose is one 100 mg, 150 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.

HOW SUPPLIED:
Benzonatate Capsules, USP is supplied as:

- 150 mg: opaque white body and opaque light blue cap imprinted “BZT” on the body and “331” on the cap, in black ink, in bottles of 15 capsules, NDC 69499-329-15.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature] Protect from light.
Dispense in a tight, light-resistant container as defined in the USP. Keep tightly closed.

Manufactured for:
Solubionix, LLC, Madisonville, LA 70447
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