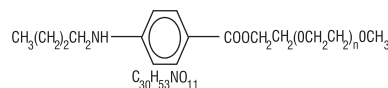


Benzonatate Capsules USP

DESCRIPTION

Benzonatate capsules USP a non-narcotic oral antitussive agent, is 2, 5, 8, 11, 14, 17, 20, 23, 26-nonaoxaocctacosan-28-yl p-(butylamino) benzoate; with a molecular weight of 603.7.



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: D&C Yellow 10, gelatin, glycerin, methylparaben and propylparaben.

Ingredients of the imprinting ink are: Propylene glycol, shellac resins, sodium lauryl sulphate, isopropyl alcohol 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

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 (see OVERDOSAGE).

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 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 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, skip that dose and take the next dose at the next scheduled time. Do not take 2 doses of benzonatate at one time.

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 have not been established. Accidental ingestion resulting in death has been reported in children below age 10. Keep out of reach of children.

ADVERSE REACTIONS

Potential Adverse Reactions to benzonatate may include:

Hypersensitivity reactions including broncho-spasm, 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.

Call your doctor for medical advice about side effects. You may report side effects to Strides Pharma Inc. at 1-877-244-9825 or go to www.stridesshasun.com

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 15-20 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.

DOSAGE AND ADMINISTRATION

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 USP should be swallowed whole.** Benzonatate capsules USP are not to be broken, chewed, dissolved, cut or crushed.

HOW SUPPLIED

Benzonatate capsules USP, 100 mg are available as yellow colored, oval shaped soft gelatin capsules, imprinted as '705' in white ink and containing clear, pale yellow viscous liquid.

NDC 64380-712-06 in bottles of 100 capsules.

NDC 64380-712-07 in bottles of 500 capsules.

Benzonatate capsules USP, 200 mg are available as yellow colored, oval shaped soft gelatin capsules, imprinted as '704' in white ink and containing clear, pale yellow viscous liquid.

NDC 64380-713-06 in bottles of 100 capsules.

NDC 64380-713-07 in bottles of 500 capsules.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15-30°C (59-86°F) [See USP controlled room temperature].

PROTECT FROM LIGHT

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

Manufactured by:

Strides Shasun Limited
Bengaluru - 560076, India.

Distributed by:

Strides Pharma Inc.
East Brunswick, NJ 08816

Rx Only

Revised: 01/2018



1036079



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Size : 180 x 200mm

Front Side

Size : 180 x 200mm

Back Side

ARTWORK DETAIL LABEL

| | | | |
|----------------------|---------------------------------|-----------------------|----------------|
| Product | BENZONATATE 100/200mg | | |
| Buyer/Country | STRIDES PHARMA INC - US | Component | PACK INSERT |
| Dimension | 180 x 200 mm - Same size | | Pack — |
| New Item Code | 1036079 | Old Item Code | 1035741 |
| Colour Shades | BLACK | No. of Colours | 1 |

| | | | |
|------------------------------------|---|------------------------|-----|
| Change Control No. | PC-ODF/2018/027 - Record Number: 170680 | Artwork Version | 8.0 |
| Design/Style | Front & Back side printing. To be supplied in the Booklet form with pasting and folding size of 29 x 29mm | | |
| Substrate | 40 / 45 GSM paper | | |
| Special Instructions | - Sequential 2D Data matrix Barcode to be printed by the vendor. | | |
| Autocartanator Requirements | NA | | |

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

RD/PD/003/F-08/R0



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