

**BENZONATATE- benzonatate capsule**  
**Sportpharm LLC**

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**BENZONATATE CAPSULES**

**100 mg Capsules**

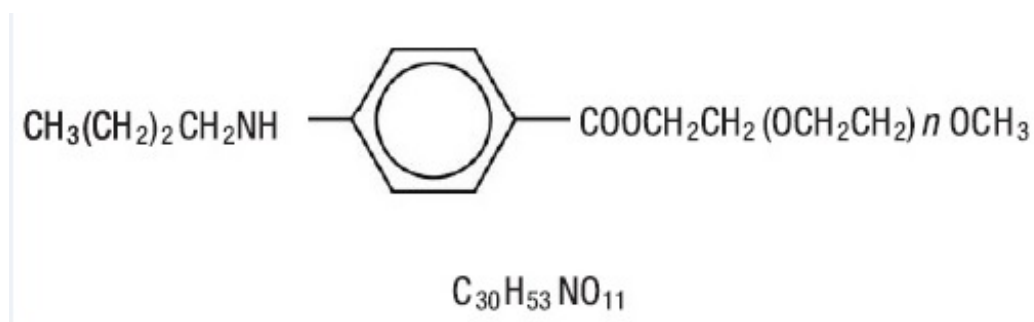
**150 mg Capsules**

**200 mg Capsules**

**(benzonatate, USP)**

**DESCRIPTION**

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



Each benzonatate capsule USP contains:

Benzonatate, USP 100 mg

Each benzonatate capsule USP contains:

Benzonatate, USP 150 mg

Each benzonatate capsule USP contains:

Benzonatate, USP 200 mg

Benzonatate capsules USP also contain: bloom gelatin, glycerin, purified water, medium chain triglycerides, lecithin, isopropyl alcohol, nitrogen.

100 mg and 200 mg capsules also contain D&C Yellow No. 10.

150 mg capsules also contain FD&C Yellow No. 6 powder.

Each capsule also contains black iron oxide, propylene glycol, hypromellose as imprinting ink.

**CLINICAL PHARMACOLOGY**

Benzonatate capsules 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 capsules has no inhibitory effect on the respiratory center in recommended dosage.

## **INDICATIONS AND USAGE**

Benzonatate capsules is 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 capsules in combination with other prescribed drugs.

### **Accidental Ingestion and Death in Children**

Keep benzonatate capsules out of reach of children. Accidental ingestion of benzonatate capsules resulting in death has been reported in children below age 10. Signs and symptoms of overdose have been reported within 15-20 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-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**

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 capsules out of reach of children. Accidental ingestion resulting in death has been reported in children. Signs and symptoms of overdose have been reported within 15-20 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 capsules, skip that dose and take the next dose at the next scheduled time. Do not take 2 doses of benzonatate capsules at one time.

### **Usage in Pregnancy**

Pregnancy Category C

Animal reproduction studies have not been conducted with benzonatate capsules. It is also not known whether benzonatate capsules can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzonatate capsules 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 is administered to a nursing woman.

### **Carcinogenesis, mutagenesis, impairment of fertility**

Carcinogenicity, mutagenicity, and reproduction studies have not been conducted with benzonatate capsules.

### **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 capsules 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.

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 15-20 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, 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 are available in 100 mg, 150 mg and 200 mg dosage strengths.

The 100 mg capsules are yellow round capsules containing clear to light yellow liquid, printed with '1' sign in black ink.

NDC 85766-066-15 (repackaged from NDC 31722-956-XX) bottles of 15 capsules

NDC 85766-066-20 (repackaged from NDC 31722-956-XX) bottles of 20 capsules

NDC 85766-066-21 (repackaged from NDC 31722-956-XX) bottles of 21 capsules

NDC 85766-066-30 (repackaged from NDC 31722-956-30) bottles of 30 capsules

NDC 85766-066-60 (repackaged from NDC 31722-956-XX) bottles of 60 capsules

NDC 85766-066-90 (repackaged from NDC 31722-956-XX) bottles of 90 capsules

NDC 85766-066-01 (repackaged from NDC 31722-956-01) bottles of 100 capsules

NDC 85766-066-05 (repackaged from NDC 31722-956-05) bottles of 500 capsules

The 150 mg capsules are orange round capsules containing clear, light yellow to orange liquid, printed with '2' sign in black ink.

NDC 85766-067-15 (repackaged from NDC 31722-957-XX) bottles of 15 capsules

NDC 85766-067-20 (repackaged from NDC 31722-957-XX) bottles of 20 capsules

NDC 85766-067-21 (repackaged from NDC 31722-957-XX) bottles of 21 capsules

NDC 85766-067-30 (relabeled from NDC 31722-957-30) bottles of 30 capsules

NDC 85766-067-60 (repackaged from NDC 31722-957-XX) bottles of 60 capsules

NDC 85766-067-90 (repackaged from NDC 31722-957-XX) bottles of 90 capsules

NDC 85766-067-01 (relabeled from NDC 31722-957-01) bottles of 100 capsules

NDC 85766-067-05 (relabeled from NDC 31722-957-05) bottles of 500 capsules

The 200 mg capsules are yellow round capsules containing clear to light yellow liquid, printed with '3' sign in black ink.

NDC 85766-068-15 (repackaged from NDC 31722-958-XX) bottles of 15 capsules

NDC 85766-068-20 (repackaged from NDC 31722-958-XX) bottles of 20 capsules

NDC 85766-068-21 (repackaged from NDC 31722-958-XX) bottles of 21 capsules

NDC 85766-068-30 (relabeled from NDC 31722-958-30) bottles of 30 capsules

NDC 85766-068-60 (repackaged from NDC 31722-958-XX) bottles of 60 capsules

NDC 85766-068-90 (repackaged from NDC 31722-958-XX) bottles of 90 capsules

NDC 85766-068-01 (relabeled from NDC 31722-958-01) bottles of 100 capsules

NDC 85766-068-05 (relabeled from NDC 31722-958-05) bottles of 500 capsules

**Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].**

Protect from light. Dispense in tight, light-resistant container as defined in the USP with a child-resistant closure.

**Distributed by:**

Sportpharm LLC

379 Van Ness Ave 1401,

Torrance, CA 90501

**Relabeled and Repackaged by:**

Enovachem PHARMACEUTICALS

Torrance, CA 9050

**PRINCIPAL DISPLAY PANEL-100mg**

Repackaged For:

**SPORTPHARM**

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-15  
 Qty: 15

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-956-XX  
 Description: yellow round capsules/1  
 Lot #: 00000000 Exp: (10) 00000000  
 Batch #: 00000000  
 Drug Status: RX

0110 0385766 06615 7  
 (17)  
 (10) 00000000  
 (21)

Packaged By: EnovaChem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-15  
 S/N:  
 Qty: 15

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-15  
 S/N:  
 Qty: 15

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-15  
 S/N:  
 Qty: 15

Relabeled For:

**SPORTPHARM**

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-30  
 Qty: 30

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-956-30  
 Description: yellow round capsules/1  
 Lot #: 00000000 Exp: (10) 00000000  
 Batch #: 00000000  
 Drug Status: RX

0110 0385766 06630 0  
 (17)  
 (10) 00000000  
 (21)

Packaged By: EnovaChem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-30  
 S/N:  
 Qty: 30

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-30  
 S/N:  
 Qty: 30

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-30  
 S/N:  
 Qty: 30

Repackaged For:

**SPORTPHARM**

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-20  
 Qty: 20

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-956-XX  
 Description: yellow round capsules/1  
 Lot #: 00000000 Exp: (10) 00000000  
 Batch #: 00000000  
 Drug Status: RX

0110 0385766 06620 1  
 (17)  
 (10) 00000000  
 (21)

Packaged By: EnovaChem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-20  
 S/N:  
 Qty: 20

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-20  
 S/N:  
 Qty: 20

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-20  
 S/N:  
 Qty: 20

Relabeled For:

**SPORTPHARM**

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-01  
 Qty: 100

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-956-01  
 Description: yellow round capsules/1  
 Lot #: 00000000 Exp: (10) 00000000  
 Batch #: 00000000  
 Drug Status: RX

0110 0385766 06601 0  
 (17)  
 (10) 00000000  
 (21)

Packaged By: EnovaChem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-01  
 S/N:  
 Qty: 100

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-01  
 S/N:  
 Qty: 100

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-01  
 S/N:  
 Qty: 100

Repackaged For:

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Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-21  
 Qty: 21

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-956-XX  
 Description: yellow round capsules/1  
 Lot #: 00000000 Exp: (10) 00000000  
 Batch #: 00000000  
 Drug Status: RX

0110 0385766 06621 8  
 (17)  
 (10) 00000000  
 (21)

Packaged By: EnovaChem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-21  
 S/N:  
 Qty: 21

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-21  
 S/N:  
 Qty: 21

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-21  
 S/N:  
 Qty: 21

Relabeled For:

**SPORTPHARM**

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-05  
 Qty: 500

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-956-05  
 Description: yellow round capsules/1  
 Lot #: 00000000 Exp: (10) 00000000  
 Batch #: 00000000  
 Drug Status: RX

0110 0385766 06605 8  
 (17)  
 (10) 00000000  
 (21)

Packaged By: EnovaChem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-05  
 S/N:  
 Qty: 500

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-05  
 S/N:  
 Qty: 500

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-05  
 S/N:  
 Qty: 500

Repackaged For:

**SPORTPHARM**

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-60  
 Qty: 60

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-956-XX  
 Description: yellow round capsules/1  
 Lot #: 00000000 Exp: (10) 00000000  
 Batch #: 00000000  
 Drug Status: RX

0110 0385766 06660 7  
 (17)  
 (10) 00000000  
 (21)

Packaged By: EnovaChem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-60  
 S/N:  
 Qty: 60

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-60  
 S/N:  
 Qty: 60

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-60  
 S/N:  
 Qty: 60

Repackaged For:

**SPORTPHARM**

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-90  
 Qty: 90

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-956-XX  
 Description: yellow round capsules/1  
 Lot #: 00000000 Exp: (10) 00000000  
 Batch #: 00000000  
 Drug Status: RX

0110 0385766 06690 4  
 (17)  
 (10) 00000000  
 (21)

Packaged By: EnovaChem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-90  
 S/N:  
 Qty: 90

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-90  
 S/N:  
 Qty: 90

Benzonatate Capsules, USP 100 mg  
 NDC: 85766-066-90  
 S/N:  
 Qty: 90

# PRINCIPAL DISPLAY PANEL-150mg

Repackaged For:

**SPORTPHARM**

**Benzonatate Capsules, USP 150 mg**  
 NDC: 85766-067-15  
 Qty: 15

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-957-XX  
 Description: orange round capsules/2  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX

Package By: Enovachem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0385766 06715 4  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-15  
 S/N:  
 Qty: 15

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-15  
 S/N:  
 Qty: 15

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-15  
 S/N:  
 Qty: 15

Relabeled For:

**SPORTPHARM**

**Benzonatate Capsules, USP 150 mg**  
 NDC: 85766-067-30  
 Qty: 30

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-957-30  
 Description: orange round capsules/2  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX

Package By: Enovachem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0385766 06730 7  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-30  
 S/N:  
 Qty: 30

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-30  
 S/N:  
 Qty: 30

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-30  
 S/N:  
 Qty: 30


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**SPORTPHARM**

**Benzonatate Capsules, USP 150 mg**  
 NDC: 85766-067-20  
 Qty: 20

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-957-XX  
 Description: orange round capsules/2  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX

Package By: Enovachem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0385766 06720 8  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-20  
 S/N:  
 Qty: 20

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-20  
 S/N:  
 Qty: 20

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-20  
 S/N:  
 Qty: 20


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**Benzonatate Capsules, USP 150 mg**  
 NDC: 85766-067-01  
 Qty: 100

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-957-01  
 Description: orange round capsules/2  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX

Package By: Enovachem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0385766 06701 7  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-01  
 S/N:  
 Qty: 100

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-01  
 S/N:  
 Qty: 100

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-01  
 S/N:  
 Qty: 100


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**SPORTPHARM**

**Benzonatate Capsules, USP 150 mg**  
 NDC: 85766-067-21  
 Qty: 21

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-957-XX  
 Description: orange round capsules/2  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX

Package By: Enovachem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0385766 06721 5  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-21  
 S/N:  
 Qty: 21

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-21  
 S/N:  
 Qty: 21

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-21  
 S/N:  
 Qty: 21


Relabeled For:

**SPORTPHARM**

**Benzonatate Capsules, USP 150 mg**  
 NDC: 85766-067-05  
 Qty: 500

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-957-05  
 Description: orange round capsules/2  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX

Package By: Enovachem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0385766 06705 5  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-05  
 S/N:  
 Qty: 500

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-05  
 S/N:  
 Qty: 500

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-05  
 S/N:  
 Qty: 500


Repackaged For:

**SPORTPHARM**

**Benzonatate Capsules, USP 150 mg**  
 NDC: 85766-067-60  
 Qty: 60

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-957-XX  
 Description: orange round capsules/2  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX

Package By: Enovachem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0385766 06760 4  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-60  
 S/N:  
 Qty: 60

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-60  
 S/N:  
 Qty: 60

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-60  
 S/N:  
 Qty: 60


Repackaged For:

**SPORTPHARM**

**Benzonatate Capsules, USP 150 mg**  
 NDC: 85766-067-90  
 Qty: 90

Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-957-XX  
 Description: orange round capsules/2  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX

Package By: Enovachem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0385766 06790 1  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-90  
 S/N:  
 Qty: 90

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-90  
 S/N:  
 Qty: 90

Benzonatate Capsules, USP 150 mg  
 NDC: 85766-067-90  
 S/N:  
 Qty: 90

# PRINCIPAL DISPLAY PANEL-200mg

Repackaged For:  
**SPORTPHARM**  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-15  
 Qty: 15  
 Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-958-XX  
 Description: yellow round capsules/3  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX  
 Packaged By: Enochem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0365766 06815 1  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-15  
 S/N:  
 Qty: 15  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-15  
 S/N:  
 Qty: 15  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-15  
 S/N:  
 Qty: 15

Repackaged For:  
**SPORTPHARM**  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-20  
 Qty: 20  
 Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-958-XX  
 Description: yellow round capsules/3  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX  
 Packaged By: Enochem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0365766 06820 5  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-20  
 S/N:  
 Qty: 20  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-20  
 S/N:  
 Qty: 20  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-20  
 S/N:  
 Qty: 20

Repackaged For:  
**SPORTPHARM**  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-21  
 Qty: 21  
 Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-958-XX  
 Description: yellow round capsules/3  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX  
 Packaged By: Enochem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0365766 06821 2  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-21  
 S/N:  
 Qty: 21  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-21  
 S/N:  
 Qty: 21  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-21  
 S/N:  
 Qty: 21

Repackaged For:  
**SPORTPHARM**  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-60  
 Qty: 60  
 Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-958-XX  
 Description: yellow round capsules/3  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX  
 Packaged By: Enochem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0365766 06860 1  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-60  
 S/N:  
 Qty: 60  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-60  
 S/N:  
 Qty: 60  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-60  
 S/N:  
 Qty: 60

Repackaged For:  
**SPORTPHARM**  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-90  
 Qty: 90  
 Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-958-XX  
 Description: yellow round capsules/3  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX  
 Packaged By: Enochem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0365766 06890 8  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-90  
 S/N:  
 Qty: 90  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-90  
 S/N:  
 Qty: 90  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-90  
 S/N:  
 Qty: 90

Relabeled For:  
**SPORTPHARM**  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-30  
 Qty: 30  
 Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-958-30  
 Description: yellow round capsules/3  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX  
 Packaged By: Enochem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0365766 06830 4  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-30  
 S/N:  
 Qty: 30  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-30  
 S/N:  
 Qty: 30  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-30  
 S/N:  
 Qty: 30

Relabeled For:  
**SPORTPHARM**  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-01  
 Qty: 100  
 Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-958-01  
 Description: yellow round capsules/3  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX  
 Packaged By: Enochem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0365766 06801 4  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-01  
 S/N:  
 Qty: 100  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-01  
 S/N:  
 Qty: 100  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-01  
 S/N:  
 Qty: 100

Relabeled For:  
**SPORTPHARM**  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-05  
 Qty: 500  
 Manufactured For: Camber Pharmaceuticals, Inc.  
 Source NDC: 31722-958-05  
 Description: yellow round capsules/3  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: RX  
 Packaged By: Enochem Pharmaceuticals Torrance, CA 90501  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) (SEE USP CONTROLLED ROOM TEMP).



(01) 0 0365766 06805 2  
 (17)  
 (10) 00000000  
 (21)

Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-05  
 S/N:  
 Qty: 500  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-05  
 S/N:  
 Qty: 500  
 Benzonatate Capsules, USP 200 mg  
 NDC: 85766-068-05  
 S/N:  
 Qty: 500

# BENZONATATE

benzonatate capsule

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:85766-066(NDC:31722-956)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZONATATE</b> (UNII: 5P4DHS6ENR) (BENZONATATE - UNII:5P4DHS6ENR)	BENZONATATE	100 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>NITROGEN</b> (UNII: N762921K75)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	1
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85766-066-15	15 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
2	NDC:85766-066-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
3	NDC:85766-066-21	21 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
4	NDC:85766-066-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
5	NDC:85766-066-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
6	NDC:85766-066-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
7	NDC:85766-066-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
8	NDC:85766-066-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211518	02/22/2019	

## BENZONATATE

benzonatate capsule

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:85766-067(NDC:31722-957)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZONATATE</b> (UNII: 5P4DHS6ENR) (BENZONATATE - UNII:5P4DHS6ENR)	BENZONATATE	150 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>NITROGEN</b> (UNII: N762921K75)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	

**Product Characteristics**

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	2
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:85766-067-15	15 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
2	NDC:85766-067-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
3	NDC:85766-067-21	21 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
4	NDC:85766-067-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
5	NDC:85766-067-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
6	NDC:85766-067-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
7	NDC:85766-067-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	

8	NDC:85766-067-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025
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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211518	02/22/2019	

### BENZONATATE

benzonatate capsule

#### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:85766-068(NDC:31722-958)
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)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
NITROGEN (UNII: N762921K75)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

#### Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	3
Contains			

#### Packaging

Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85766-068-15	15 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
2	NDC:85766-068-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
3	NDC:85766-068-21	21 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
4	NDC:85766-068-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
5	NDC:85766-068-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
6	NDC:85766-068-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
7	NDC:85766-068-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	
8	NDC:85766-068-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211518	02/22/2019	

**Labeler** - Sportpharm LLC (125298538)

Revised: 4/2026

Sportpharm LLC