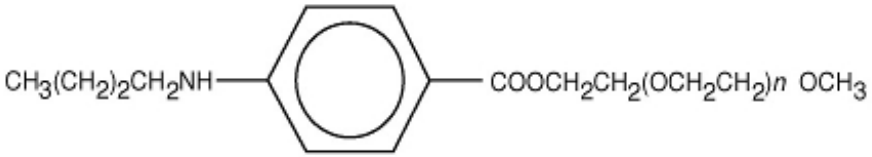
BENZONATATE- benzonatate capsule
AiPing Pharmaceutical, Inc.

Benzonatate Capsules, USP

100 mg, 150 mg and 200 mg

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.



$C_{30}H_{53}NO_{11}$

Each soft gelatin capsule, for oral administration, contains 100 mg, 150 mg or 200 mg of benzonatate USP. Benzonatate Capsules, USP also contain the following inactive ingredients: D&C Yellow #10, gelatin, glycerin, purified water, methylparaben and propylparaben. Imprinting ink is composed of isopropyl alcohol, n-butyl alcohol, propylene glycol, shellac, 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 USP 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 Efects

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 capsules 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 15-20 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 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 capsule, 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 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 should be swallowed whole.** Benzonatate capsules are not to be broken, chewed, dissolved, cut or crushed.

HOW SUPPLIED

Benzonatate Capsules USP, 100 mg: Yellow soft gelatin capsules, imprinted " Ꝑ28 "with white ink, quantity of 44,000 capsules (NDC 11788-028-00)

Benzonatate Capsules USP, 150 mg: Yellow soft gelatin capsules, imprinted " Ꝑ29 "with white ink, quantity of 32,000 capsules (NDC 11788-029-00)

Benzonatate Capsules USP, 200 mg: Yellow soft gelatin capsules, imprinted " Ꝑ27"with white ink, quantity of 24,000 capsules (NDC 11788-027-00)

Store at room temperature 15-30°C

Manufacturer:

Anishi Pharmaceutical (Zhongshan) Inc.

National Health Technology Park, Zhongshan, Guangdong. China

For:

AiPing Pharmaceutical, Inc.

Hauppauge, NY 11788 USA

PRINCIPAL DISPLAY PANEL - SHIPPING LABEL

Manufactured for:

AiPing Pharmaceutical, Inc.

Hauppauge, NY 11788, USA

Manufactured by:

Anshi Pharamceutical (Zhongshan) Inc.

National Health Technology Park

Zhongshan, Guangdong, China

WARNING:

KEEP OUT OF THE REACH OF CHILDREN. THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE REPACKAGED IMMEDIATELY AND LABELED IN STRICK CONFORMANCE WITH THE FOOD DRUG & COSMETIC ACT AND REGULATIONS THEREUNDER.

Benzonatate Capsules, USP 100 mg

Quantity: 8 Kg/Case

NDC 11788-028-00

AiPing PHARMACEUTICAL, INC.	**Benzonatate Capsules, USP 100 mg** **苯佐那酯软胶囊，USP 100 mg**
STRENGTH: 规格	Each Capsule Contains 每粒软胶囊含: Benzonatate 100 mg 苯佐那酯 100 mg
NDC:	11788-028-00
QUANTITY: 数量	**NET WT.:** 净重 8 Kg/Case 8 公斤/箱
LOT: 批号	
MFG. DATE: 生产日期	**PKG. BY DATE:** 最终包装有效期
STORAGE: 储藏	Store at room temperature 15-30°C 室温 15-30°C 下保存
MANUFACTURER: 生产企业	Anshi Pharmaceutical (Zhongshan) Inc. National Health Technology Park, Zhongshan, Guangdong, P.R. China 安士制药（中山）有限公司 中国广东省中山市国家健康科技产业基地
FOR: 委托方	AiPing Pharmaceutical, Inc. Hauppauge, NY 11788 USA

AiPing PHARMACEUTICAL, INC.	**SHIPPING LABEL**
PRODUCT NAME: 产品名称	**Benzonatate Capsules, USP 100 mg** **苯佐那酯软胶囊，USP 100 mg**
GROSS WEIGHT: 毛重	9.0 Kg/Case 9.0 公斤/箱
VOLUME: 体积	0.5 M× 0.25 M× 0.17 M= 0.021 M^3 0.5 米×0.25 米×0.17 米= 0.021 立方米
SHIP TO: 运往	AiPing Pharmaceutical, Inc. Hauppauge, NY 11788 USA
TELEPHONE: 电话	1-844-374-0016
WARNING: 敬告	**KEEP OUT OF THE REACH OF CHILDREN** 请存放在儿童不能接触的地方 **THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE REPACKAGED IMMEDIATELY AND LABELED IN STRICK CONFORMANCE WITH THE FOOD DRUG & COSMETIC ACT AND REGULATIONS THEREUNDER.** 该产品散装，应尽快进行再包装并贴有完全符合食品、药品和化妆品管理法案及其他法规要求的标示。

PRINCIPAL DISPLAY PANEL - SHIPPING LABEL

Manufactured for:

AiPing Pharmaceutical, Inc.

Hauppauge, NY 11788, USA

Manufactured by:

Anshi Pharamceutical (Zhongshan) Inc.

National Health Technology Park

Zhongshan, Guangdong, China

WARNING:

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Benzonatate Capsules, USP 150mg

Quantity: 8 Kg/Case

NDC 11788-029-00

	Benzonatate Capsules, USP 150 mg **苯佐那酯软胶囊，USP 150 mg**
STRENGTH: 规格	Each Capsule Contains 每粒软胶囊含: Benzonatate 150 mg 苯佐那酯 150 mg
NDC:	11788-029-00
QUANTITY: 数量	**NET WT.:** 净重 8 Kg/Case 8 公斤/箱
LOT: 批号	
MFG. DATE: 生产日期	**PKG. BY DATE:** 最终包装有效期
STORAGE: 储藏	Store at room temperature 15-30°C 室温 15-30°C 下保存
MANUFACTURER: 生产企业	Anshi Pharmaceutical (Zhongshan) Inc. National Health Technology Park, Zhongshan, Guangdong, P.R. China 安士制药（中山）有限公司 中国广东省中山市国家健康科技产业基地
FOR: 委托方	AiPing Pharmaceutical, Inc. Hauppauge, NY 11788 USA

	SHIPPING LABEL
PRODUCT NAME: 产品名称	**Benzonatate Capsules, USP 150 mg** **苯佐那酯软胶囊，USP 150 mg**
GROSS WEIGHT: 毛重	9.0 Kg/Case 9.0 公斤/箱
VOLUME: 体积	0.5 M× 0.25 M× 0.17 M= 0.021 M^3 0.5 米×0.25 米×0.17 米= 0.021 立方米
SHIP TO: 运往	AiPing Pharmaceutical, Inc. Hauppauge, NY 11788 USA
TELEPHONE: 电话	1-844-374-0016
WARNING: 敬告	**KEEP OUT OF THE REACH OF CHILDREN** 请存放在儿童不能接触的地方 **THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE REPACKAGED IMMEDIATELY AND LABELED IN STRICK CONFORMANCE WITH THE FOOD DRUG & COSMETIC ACT AND REGULATIONS THEREUNDER.** 该产品散装，应尽快进行再包装并贴有完全符合食品、药品和化妆品管理法案及其他法规要求的标示。

PRINCIPAL DISPLAY PANEL - SHIPPING LABEL

Manufactured for:

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Hauppauge, NY 11788, USA

Manufactured by:

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National Health Technology Park

Zhongshan, Guangdong, China

WARNING:

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Benzonatate Capsules, USP 200mg

Quantity: 8 Kg/Case

NDC 11788-027-00

Benzonatate Capsules, USP 200 mg
苯佐那酯软胶囊，USP 200 mg

STRENGTH: 规格	Each Capsule Contains 每粒软胶囊含: Benzonatate 200 mg 苯佐那酯 200 mg		
NDC:	11788-027-00		
QUANTITY: 数量		**NET WT.:** 净重	8 Kg/Case 8 公斤/箱
LOT: 批号			
MFG. DATE: 生产日期		**PKG. BY DATE:** 最终包装有效期	
STORAGE: 储藏	Store at room temperature 15-30°C 室温 15-30°C 下保存		
MANUFACTURER: 生产企业	Anshi Pharmaceutical (Zhongshan) Inc. National Health Technology Park, Zhongshan, Guangdong, P.R. China 安士制药（中山）有限公司 中国广东省中山市国家健康科技产业基地		
FOR: 委托方	AiPing Pharmaceutical, Inc. Hauppauge, NY 11788 USA		

SHIPPING LABEL

PRODUCT NAME: 产品名称	**Benzonatate Capsules, USP 200 mg** **苯佐那酯软胶囊，USP 200 mg**
GROSS WEIGHT: 毛重	9.0 Kg/Case 9.0 公斤/箱
VOLUME: 体积	0.5 M× 0.25 M× 0.17 M= 0.021 M^3 0.5 米×0.25 米×0.17 米= 0.021 立方米
SHIP TO: 运往	AiPing Pharmaceutical, Inc. Hauppauge, NY 11788 USA
TELEPHONE: 电话	1-844-374-0016

WARNING: 敬告	**KEEP OUT OF THE REACH OF CHILDREN** 请存放在儿童不能接触的地方 **THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE REPACKAGED IMMEDIATELY AND LABELED IN STRICK CONFORMANCE WITH THE FOOD DRUG & COSMETIC ACT AND REGULATIONS THEREUNDER.** 该产品散装，应尽快进行再包装并贴有完全符合食品、药品和化妆品管理法案及其他法规要求的标示。

BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11788-028

Route of Administration	ORAL

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

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	CAPSULE	**Size**	9mm
Flavor		**Imprint Code**	Logo;28
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11788-028-00	44000 in 1 CARTON; Type 0: Not a Combination Product	03/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210562	03/14/2019	

BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11788-029
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZONATATE (UNII: 5P4DHS6ENR) (BENZONATATE - UNII:5P4DHS6ENR)	BENZONATATE	150 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	CAPSULE	**Size**	10mm
Flavor		**Imprint Code**	Logo;29
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11788-029-00	32000 in 1 CARTON; Type 0: Not a Combination Product	03/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210562	03/14/2019	

BENZONATATE

benzonatate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11788-027
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**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	CAPSULE	**Size**	11mm
Flavor		**Imprint Code**	Logo;27
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11788-027-00	24000 in 1 CARTON; Type 0: Not a Combination Product	03/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210562	03/14/2019	

Labeler - AiPing Pharmaceutical, Inc. (079674526)

Establishment

Name	Address	ID/FEI	Business Operations
Anshi Pharmaceutical (Zhongshan) Inc.		528101821	manufacture(11788-028, 11788-029, 11788-027)

Revised: 6/2020 AiPing Pharmaceutical, Inc.