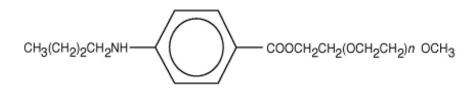
BENZONATATE- benzonatate capsule AiPing Pharmaceutical, Inc.

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, 26nonaoxaoctacosan-28-yl p-(butylamino) benzoate; with a molecular weight of 603.7.



C 30H 53NO 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

<u>Hypersensitivity</u>

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 " ²²⁸ "with white ink, available in bottles of 100's (NDC 11788-028-01), and 500's (NDC 11788-028-05).

Benzonatate Capsules USP, 150 mg: Yellow soft gelatin capsules, imprinted " ^(*)²⁹ "with white ink, available in bottles of 100's (NDC 11788-029-01), and 500's (NDC 11788-029-05).

Benzonatate Capsules USP, 200 mg: Yellow soft gelatin capsules, imprinted " 27" with white ink, available in bottles of 100's (NDC 11788-027-01) and 500's (NDC 11788-027-05).

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.

Manufactured for AiPing Pharmaceutical, Inc.

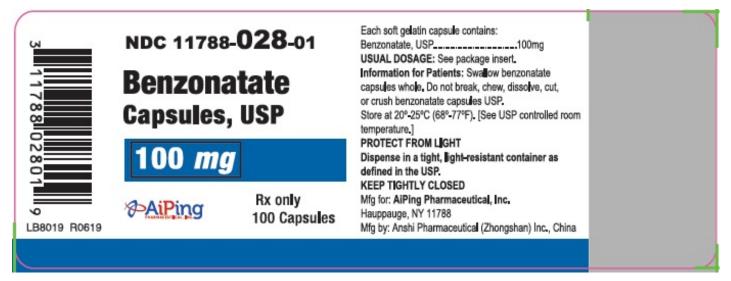
Hauppauge, NY 11788 USA

Manufactured by Anshi Pharmaceutical (Zhongshan) Inc., P.R. China

Rev 03/18

Principal Display Panel

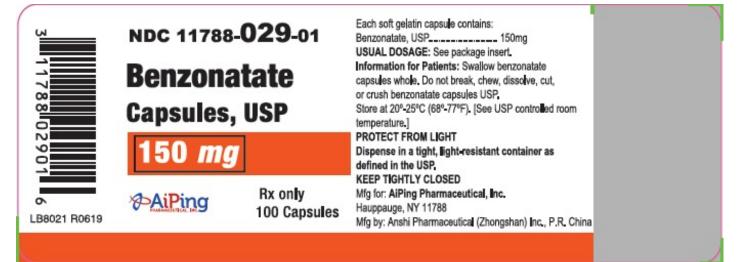
Benzonatate Capsules, USP 100 mg



Benzonatate Capsules, USP 150mg

Rx only 100 Capsules

NDC 11788-029-01



Benzonatate Capsules, USP 200mg

NDC 11788-027-01

Rx only 100 Capsules

3	NDC 11788	- 027 -01	Each soft gelatin capsule contains: Benzonatate, USP	
3 11788 02701	Benzona Capsules,			
02701	200 <i>mg</i>		PROTECT FROM LIGHT Dispense in a tight, light-resistant container as defined in the USP	
N LB8023 R0619	AiPing 100 Capsules		KEEP TIGHTLY CLOSED Mfg for: AiPing Pharmaceutical, Inc. Hauppauge, NY 11788 Mfg by: Anshi Pharmaceutical (Zhongshan) Inc., P.R. China	

BENZONATATE benzonatate capsule						
Product Information						
Product Type	HUMAN PRES	SCRIPTION DRUG	ltem Co	de (Source)) NDC:	11788-028
Route of Administration	ORAL					
Active Ingredient/Acti	ve Moiety					
In	gredient Nan	ne		Basis of S	Strength	Strength
BENZONATATE (UNII: 5P4DHS	6ENR) (BENZONA	TATE - UNII:5P4DHS6	ENR)	BENZONATAT	Ē	100 mg
Inactive Ingredients						
	Ingredien	t Name			Str	ength
D&C YELLOW NO. 10 (UNII: 3	55W5USQ3G)					
GELATIN (UNII: 2G86QN327L)						
GLYCERIN (UNII: PDC6A3C0OX)					
WATER (UNII: 059QF0KO0R)						
METHYLPARABEN (UNII: A2180	C7HI9T)					
PROPYLPARABEN (UNII: Z8IX2						
PROPYLENE GLYCOL (UNII: 6	DC9Q167V3)					
SHELLAC (UNII: 46N107B710)						
TITANIUM DIOXIDE (UNII: 15F	IX9V2JP)					
Product Characteristi	cs					
Color	rellow	Score			no score	
Shape	CAPSULE	Size			9mm	
Flavor		Imprint Cod	е		Logo;28	
Contains						

Pa	Packaging								
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date					
1	NDC:11788-028- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2019						
2	NDC:11788-028- 05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2019						
Μ	Marketing Information								
	Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date					
AN	IDA	ANDA210562	03/14/2019						

BENZONATATE						
benzonatate capsule						
.						
Product Information						
Product Type	HUMAN PR	ESCRIPTION DRUG	Item Co	de (Source)	NDC:	11788-029
Route of Administration	ORAL					
Active Ingredient/Act	ive Moiety					
I	ngredient Na	me		Basis of Str	rength	Strength
BENZONATATE (UNII: 5P4DH	S6ENR) (BENZON	IATATE - UNII:5P4DHS6	ENR)	BENZONATATE		150 mg
Inactive Ingradiante						
Inactive Ingredients	Ingradia	nt Name			C+r	ength
D&C YELLOW NO. 10 (UNII:					30	engtn
GELATIN (UNII: 2G86QN327L)						
GLYCERIN (UNII: PDC6A3C00						
WATER (UNII: 059QF0KO0R)						
METHYLPARABEN (UNII: A218	BC7HI9T)					
PROPYLPARABEN (UNII: Z8I)	(2SC10H)					
PROPYLENE GLYCOL (UNII: (6DC9Q167V3)					
SHELLAC (UNII: 46N107B710)					
TITANIUM DIOXIDE (UNII: 15	FIX9V2JP)					
Product Characterist	ics					
Color	yellow	Score		r	no score	
Shape	CAPSULE	Size		1	L0mm	
Flavor		Imprint Cod	е	L	_ogo;29	
Contains						

	ackaging							
#	Item Code	· · · · · · · · · · · · · · · · · · ·				ing Start ate		eting End Date
	NDC:11788-029- 01	100 in 1 BOTT Product	LE; Type 0: Not a Co	mbination	03/14/2019)		
2 NDC:11788-029- 05 500 in 1 PACKA Product			AGE; Type 0: Not a C	03/14/2019)			
Μ	arketing l	nformat	ion					
Marketing Application Number or Monograph Category Citation			Marketing Start Marketing Date Date					
٩N	DA	ANDA210562	2		03/14/20	19		
	ENZONATA							
e	nzonatate cap	sule						
P	roduct Infor	mation						
Pr	oduct Type		HUMAN PRESCRIPTIO	ON DRUG	Item Co	de (Source)	NDC:	11788-027
	oute of Admini	stration	ORAL					
Ac	tive Ingredi	ent/Active	Moiety					
40	ctive Ingredi		Moiety dient Name			Basis of St	rength	Strengt
		Ingre	-	JNII:5P4DHS6E	:NR)	Basis of St BENZONATATE	-	Strengt 200 mg
		Ingre	dient Name	JNII:5P4DHS6E	ENR)		-	-
ΒE	NZONATATE (UN	ing re III: 5P4DHS6EN	dient Name	JNII:5P4DHS6E	NR)		-	-
3 E		ing re III: 5P4DHS6EN	e dient Name R) (BENZONATATE - U		ENR)		-	200 mg
3E	NZONATATE (UN	Ingre III: 5P4DHS6EN dients	edient Name R) (BENZONATATE - U Ingredient Nam		INR)		-	-
BE In	AC YELLOW NO.	Ingre III: 5P4DHS6EN dients 10 (UNII: 35SW	edient Name R) (BENZONATATE - U Ingredient Nam		ENR)		-	200 mg
BE In D& GE	AC YELLOW NO.	Ingre III: 5P4DHS6EN dients 10 (UNII: 35SW 6QN327L)	edient Name R) (BENZONATATE - U Ingredient Nam		INR)		-	200 mg
BE In D& GE	AC YELLOW NO. LATIN (UNII: 2G8 YCERIN (UNII: PD	Ingre III: 5P4DHS6EN dients 10 (UNII: 35SW 6QN327L) C6A3C0OX)	edient Name R) (BENZONATATE - U Ingredient Nam		ENR)		-	200 mg
BE In D& GE GL	AC YELLOW NO. LATIN (UNII: 2G8 YCERIN (UNII: PD ATER (UNII: 059Q)	Ingre III: 5P4DHS6EN dients 10 (UNII: 35SW 6QN327L) C6A3C0OX) F0KO0R)	dient Name R) (BENZONATATE - U Ingredient Nam 5USQ3G)		INR)		-	200 mg
BE In GE GL	AC YELLOW NO. LATIN (UNII: 2G8 YCERIN (UNII: PD ATER (UNII: 059Q)	Ingre III: 5P4DHS6EN dients 10 (UNII: 35SW 6QN327L) C6A3C0OX) F0KO0R) (UNII: A2I8C7HI	edient Name R) (BENZONATATE - (Ingredient Nam (5USQ3G)		ENR)		-	200 mg
BE In GE GL W/	AC YELLOW NO. LATIN (UNII: 2G8 YCERIN (UNII: PD ATER (UNII: 059Q) CHYLPARABEN (OPYLPARABEN (Ingre III: 5P4DHS6EN dients 10 (UNII: 35SW 6QN327L) C6A3C0OX) F0KOOR) (UNII: A2I8C7HIS UNII: Z8IX2SC1	edient Name R) (BENZONATATE - (Ingredient Nam 5USQ3G) PT) OH)		ENR)		-	200 mg
BE In D& GE GL W/ ME PR	AC YELLOW NO. LATIN (UNII: 2G8 YCERIN (UNII: PD ATER (UNII: 059Q) THYLPARABEN (OPYLENE GLYCO	Ingre III: 5P4DHS6EN dients 10 (UNII: 35SW 6QN327L) (C6A3C0OX) F0KOOR) (UNII: A2I8C7HI UNII: Z8IX2SC1 DL (UNII: 6DC90	edient Name R) (BENZONATATE - (Ingredient Nam 5USQ3G) PT) OH)		ENR)		-	200 mg
BE In GE GL W/ ME PR SH	AC YELLOW NO. C YELLOW NO. LATIN (UNII: 2G8 YCERIN (UNII: PD ATER (UNII: 059QI CHYLPARABEN (OPYLENE GLYCO ELLAC (UNII: 46N	Ingre III: 5P4DHS6EN dients 10 (UNII: 355W 6QN327L) C6A3C0OX) FOKOOR) (UNII: A2I8C7HIS UNII: Z8IX2SC1 DL (UNII: 6DC90 I107B710)	edient Name R) (BENZONATATE - (Ingredient Nam 5USQ3G) 9T) OH) 2167V3)		ENR)		-	200 mg
BE In GE GL W/ ME PR SH	AC YELLOW NO. LATIN (UNII: 2G8 YCERIN (UNII: PD ATER (UNII: 059Q) THYLPARABEN (OPYLENE GLYCO	Ingre III: 5P4DHS6EN dients 10 (UNII: 355W 6QN327L) C6A3C0OX) FOKOOR) (UNII: A2I8C7HIS UNII: Z8IX2SC1 DL (UNII: 6DC90 I107B710)	edient Name R) (BENZONATATE - (Ingredient Nam 5USQ3G) 9T) OH) 2167V3)		ENR)		-	200 mg
BE In GE GL W/ ME PR SH	AC YELLOW NO. C YELLOW NO. LATIN (UNII: 2G8 YCERIN (UNII: PD ATER (UNII: 059QI CHYLPARABEN (OPYLENE GLYCO ELLAC (UNII: 46N	Ingre III: 5P4DHS6EN dients 10 (UNII: 355W 6QN327L) C6A3C0OX) FOKOOR) (UNII: A2I8C7HIS UNII: Z8IX2SC1 DL (UNII: 6DC90 I107B710)	edient Name R) (BENZONATATE - (Ingredient Nam 5USQ3G) 9T) OH) 2167V3)		ENR)		-	200 mg
BE D& GE GL W/ PR SH	AC YELLOW NO. C YELLOW NO. LATIN (UNII: 2G8 YCERIN (UNII: PD ATER (UNII: 059QI CHYLPARABEN (OPYLENE GLYCO ELLAC (UNII: 46N	Ingre III: 5P4DHS6EN dients 10 (UNII: 35SW 6QN327L) C6A3C0OX) F0KOOR) (UNII: A2I8C7HIS UNII: Z8IX2SC1 DL (UNII: 6DC90 1107B710) : (UNII: 15FIX9V	edient Name R) (BENZONATATE - (Ingredient Nam 5USQ3G) 9T) OH) 2167V3)		ENR)		-	200 mg
BE In D& GE GL W/ PR SH TIT	ACTIVE INGRE ACTIVE INGRE ACTIVE INGRE ACTIVE INGRE ACTIN (UNII: 2G8 YCERIN (UNII: 2	Ingre III: 5P4DHS6EN dients 10 (UNII: 355W 6QN327L) C6A3C0OX) FOKOOR) (UNII: A2I8C7HIS UNII: Z8IX25C1 DL (UNII: 6DC90 1107B710) : (UNII: 15FIX9V Acteristics	edient Name R) (BENZONATATE - (Ingredient Nam 5USQ3G) 9T) OH) 2167V3) 2JP)	e	ENR)		Stre	200 mg
BE In D& GE GL W/ PR SH TIT	AC YELLOW NO. AC YELLOW NO. LATIN (UNII: 2G8 YCERIN (UNII: 2G8 YCERIN (UNII: 9D) ATER (UNII: 059Q) THYLPARABEN (OPYLPARABEN (OPYLENE GLYCO ELLAC (UNII: 46N TANIUM DIOXIDE TODUCT Chara	Ingre III: 5P4DHS6EN dients 10 (UNII: 35SW 6QN327L) C6A3C0OX) F0KOOR) (UNII: A2I8C7HI9 UNII: Z8IX2SC1 DL (UNII: 6DC90 1107B71O) : (UNII: 15FIX9V Acteristics yellov	edient Name R) (BENZ ONATATE - (Ingredient Nam 5USQ3G) 9T) OH) Q167V3) 2JP) v S	ie	ENR)		no score	200 mg
BE D& GE GL W/ PR SH TIT Co Sh	ACTIVE INGRE ACTIVE INGRE ACTIVE INGRE ACTIN (UNII: 2G8 YCERIN (UN	Ingre III: 5P4DHS6EN dients 10 (UNII: 355W 6QN327L) C6A3C0OX) FOKOOR) (UNII: A2I8C7HIS UNII: Z8IX2SC1 DL (UNII: 6DC90 1107B710) : (UNII: 15FIX9V Acteristics	edient Name R) (BENZONATATE - (Ingredient Name /5USQ3G) PT) OH) Q167V3) 2JP) V S ULE S	ie Score		BENZONATATE	no score 11mm	200 mg
BE Jn SE GL W/ PR SH Fla	AC YELLOW NO. AC YELLOW NO. LATIN (UNII: 2G8 YCERIN (UNII: 2G8 YCERIN (UNII: 9D) ATER (UNII: 059Q) THYLPARABEN (OPYLPARABEN (OPYLENE GLYCO ELLAC (UNII: 46N TANIUM DIOXIDE TODUCT Chara	Ingre III: 5P4DHS6EN dients 10 (UNII: 35SW 6QN327L) C6A3C0OX) F0KOOR) (UNII: A2I8C7HI9 UNII: Z8IX2SC1 DL (UNII: 6DC90 1107B71O) : (UNII: 15FIX9V Acteristics yellov	edient Name R) (BENZONATATE - (Ingredient Name /5USQ3G) PT) OH) Q167V3) 2JP) V S ULE S	ie		BENZONATATE	no score	200 mg

Pa	Packaging							
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date				
	NDC:11788-027- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2019					
	NDC-11788-027-	500 in 1 BOTTLE; Type 0: Not a Combination	03/14/2019					
~	05	Product	00/11/2015					
2	05		00,11,2010					
2	05	Product Information						
2	05			Marketing End Date				

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

Revised: 10/2022

AiPing Pharmaceutical, Inc.