BANOPHEN- diphenhydramine hydrochloride liquid Atlantic Biologicals Corps Reference Label Set Id: 23e653b4-30f4-4038-82ce-78863c3f3101

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Banophen

Drug Facts

Active ingredient (in each teaspoonful (5 mL))

Diphenhydramine HCl USP 12.5 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, including one applied topically.

Ask a doctor before use if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours

adults and children 12 years and over	2 - 4 teaspoonsful (25 mg to 50 mg)
children 6 to under 12 years	1 - 2 teaspoonsful (12.5 mg to 25 mg)
children 2 to 5 years of age	do not use unless directed by a doctor_
children under 2 years of age	do not use

Other information

- each teaspoonful (5 mL) contains: sodium 7 mg
- store at room temperature 20°-25°C (68°-77°F)

Inactive ingredients

artificial cherry flavor, citric acid, D&C Red #33, FD&C Red #40, glycerin, polysorbate 20, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol solution

Questions or comments?

(800) 616-2471

HOW SUPPLIED

Product: 17856-5174 NDC: 17856-5174-2 5 mL in a CUP NDC: 17856-5174-1 10 mL in a CUP, UNIT-DOSE

BANOPHEN (DIPHENHYDRAMINE HYDROCHLORIDE) LIQUID

12.5 MG/S ML SUGAR-FREE, ALCOHOL-FREE, CHERRY FLAVOR UNIT DOSE DELIVERS 5 ML SUGAR-FREE, ALCOHOL-FREE, CHERRY FLAVOR UNIT DOSE DELIVERS 5 ML SUGAR FREALCOHOL, FREE DELIVERS 5 ML SUGAR FREALCOHOL, FREE DELIVERS 5 ML SUBAR FREALCOHOL, FREE DELIVERS 5 ML SUBAR FREALCOHOL, FREE DELIVERS 5 ML SUBAR FREAL ALCOHOL, FREE DELIVERS 5 ML SUBAR FREALCHOLO, FREE DELIVERS 5 ML SUBAR FREALCHOLO, FREE DELIVERS 5 ML SUBAR FREALCHOLO, FREE DELIVERS 5 ML Subar ML DELIVERS 5 ML Subar ML Subar ML DELIVERS 7 ML Subar ML	
(DEPREDIMPORADIDATE MCL.) UNIT DOSE DELIVERS 5 ML 12.3 MG, 78 MC, 78 M	
SWGAR FREE-ALCOHOL FREE Serving size per cup: 5 mL Cup(s) per Case: 72 Distribution Boologicus Codes See package insert for complete prescribing information. Obstrainuted by AtLANTIC Boologicus Codes See package insert for complete prescribing information. Other Information: *###92270518 ##posts at Manoa Lotre coccccs See to complete prescribing information. Other Information: *###92270518 See to complete prescribing information. Other Information: *###92270518 See to complete prescribing information. Other Information: *###9270518 See to complete prescribing information.	
BEOLOGICALS CORP. tax.de/23/2018 Unit and tax.de/23/2018 Unit and tax.de/23/2018 Unit and tax.de/23/2018 Unit and tax.de/23/2018 Each beaspoonful (5 mL) contains; sodium 7 mg Fig by 805 Spore at noon temperature 20-25°C (48-77%).	
twy-twy-20/2018 LiveF313333 Wg-DST av Muxoe Lora xxxxxxx Each beaspoonful (5 mL) contains; sodium 7 mg Pag by 805 Score at room temperature 20-25°C (48-77%).	
Hyperse and Andrew Adde Lotte account of the aspoonthal (5 mil) contains; sodium 7 mg Pig by 696 Store at noom temperature 20-25°C (68-77%).	
KEEP BANOPHEN ORAL SOLUTION AND ALL	
MEDICINES OUT OF THE REACH OF CHILDREN	
(DIPHENHYDRAMINE HCL) Major Pharmaceuticals (DIPHENHYDRAMINE HCL) Uvona, M1 48150	
ORAL SQLUTION	
SUGAR PRECALCONOL PREE DISTRIBUTED BY ATLANTIC Repackaged by Unit Dose Solutions, Inc. Morrisville, NC 27560 Distributed by: Atlantic Biologicals Corp. 2010 J. N.E. 16th Place Miamr, FL 33179	
BIOLOGICALS CORP. * Retain box label and package insert for drug information.	
Higher and the formation of the second secon	
UDS Lot No: XXXXXX	
MFG Lot No: XXXXXX	
Exp. Date: XX/XX/XXXX	
17856517402	
1/0301/402	
BANOPHEN	
diphenhydramine hydrochloride liquid	

Product Information					
1 router mornation					
roduct TypeHUMAN OTC DRUGItem Code (Source)			NDC:17856-5174(NDC:0904-5174)		
Route of Administration	ORAL				
Active Ingredient/Active Moi	ety				
Ingredient Name Basis of Strengt					
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE DIPHENH - UNII:8 GTS82S83M) HYDROC				E 12.5 mg in 5 mL	
- 01411.001302303141)			HYDROCHLORIDE	III J IIIL	
Inactive Ingredients					
Inactive Ingredients	Ingredient Nan	16		Strength	
Inactive Ingredients SODIUM CITRATE, UNSPECIFIED FO	0			Strength	
	DRM (UNII: 1Q73Q2JULR)			Strength	
SO DIUM CITRATE, UNSPECIFIED FO	DRM (UNII: 1Q73Q2JULR)			Strength	
SODIUM CITRATE, UNSPECIFIED FC Citric Acid Monohydrate (UNII: 2968	PRM (UNII: 1Q73Q2JULR) PHW8QP)			Strength	
SODIUM CITRATE, UNSPECIFIED FC Citric Acid Monohydrate (UNII: 2968 Sorbitol (UNII: 506T60A25R)	PRM (UNII: 1Q73Q2JULR) PHW8QP)			Strength	
SODIUM CITRATE, UNSPECIFIED FC Citric Acid Monohydrate (UNII: 2968 Sorbitol (UNII: 506T60A25R) FD&C Red no. 40 (UNII: WZB9127XO	PRM (UNII: 1Q73Q2JULR) PHW8QP)			Strength	
SODIUM CITRATE, UNSPECIFIED FC Citric Acid Monohydrate (UNII: 2968 Sorbitol (UNII: 506T60A25R) FD&C Red no. 40 (UNII: WZB9127XO. Glycerin (UNII: PDC6A3C0OX)	PRM (UNII: 1Q73Q2JULR) PHW8QP)			Strength	
SODIUM CITRATE, UNSPECIFIED FC Citric Acid Monohydrate (UNII: 2968 Sorbitol (UNII: 506T60A25R) FD&C Red no. 40 (UNII: WZB9127XO) Glycerin (UNII: PDC6A3C0OX) Polysorbate 20 (UNII: 7T1F30V5YH)	PRM (UNII: 1Q73Q2JULR) PHW8QP)			Strength Strength	
SODIUM CITRATE, UNSPECIFIED FC Citric Acid Monohydrate (UNII: 2968 Sorbitol (UNII: 506T60A25R) FD&C Red no. 40 (UNII: WZB9127XO Glycerin (UNII: PDC6A3C0OX) Polysorbate 20 (UNII: 7T1F30V5YH) Cherry (UNII: BUC519595W)	A)			Strength	

D	D&C Red no. 33 (UNII: 9DBA0SBB0L)						
D	Product Characteristics						
			PINK	Score			
Shape							
	lavor		CHERRY	Size			
	ontains			Imprint Code	:		
C	ontains						
Packaging							
-	ackaging						
#	Item Code		Package Description		Marketing Start Date	Marketing End Date	
#		72 in 1 CASE					
#	Item Code NDC:17856-5174-			nbina tio n	Date		
# 1	Item Code NDC:17856-5174-	5 mL in 1 CU		nbinatio n	Date		
# 1	Item Code NDC:17856-5174-	5 mL in 1 CU		nbina tio n	Date		
# 1 1	Item Code NDC:17856-5174-	5 mL in 1 CU Product	P, UNIT-DOSE; Type 0: Not a Cor	nbinatio n	Date		
# 1 1	Item Code NDC:17856-5174-2	5 mL in 1 CU Product	P, UNIT-DOSE; Type 0: Not a Cor		Date 09/17/2019	Date	
# 1 1	Item Code NDC:17856-5174- 2	5 mL in 1 CU Product	P, UNIT-DOSE; Type 0: Not a Cor D D pplication Number or Monog		Date 09/17/2019	Date	

Labeler - Atlantic Biologicals Corps (047437)	707)
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Establishment					
Name	Address	ID/FEI	Business Operations		
Atlantic Biologicals Corps		047437707	RELABEL(17856-5174), REPACK(17856-5174)		

Revised: 9/2019

Atlantic Biologicals Corps