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

BANOPHEN

diphenhydramine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-5174(NDC:0904-5174)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Sorbitol (UNII: 506T60A25R)	
FD&C Red no. 40 (UNII: WZB9127XOA)	
Glycerin (UNII: PDC6A3C0OX)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Cherry (UNII: BUC5I9595W)	
Water (UNII: 059QF0KO0R)	
Sodium Benzoate (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

D&C Red no. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics			
Color	PINK	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-5174-2	72 in 1 CASE	09/17/2019	
1		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	08/24/2012	

Labeler - Atlantic Biologicals Corps (047437707)

Establishment

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

Revised: 9/2019 Atlantic Biologicals Corps