BANOPHEN- diphenhydramine hcl liquid
Major Pharmaceuticals

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™ Allergy

Drug Facts

Active ingredient (in each 5 mL)

Diphenhydramine HCl USP 12.5 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms of 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
- a sodium restricted diet
- 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
- use caution 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 (1-800-222-1222).

Directions

- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours
- use only with enclosed dosing cup. Do not use with any other device
- find right dose on chart below
- mL = milliliter

adults and children 12 years and over	10-20mL (25 mg to 50 mg)
children 6 to under 12 years	5-10mL (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 (5 mL) contains: **sodium 7 mg**
- **TAMPER-EVIDENT:** Do not use this product if inner foil seal over the mouth of the bottle is cut, torn, broken or missing
- 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, saccharin sodium, sodium benzoate, sodium citrate, sorbitol solution

Questions or comments?

(800) 616-2471

Distributed by:
MAJOR ® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

MAJOR ®
NDC 0904-1228-00
TAMPER-EVIDENT

Banophen™
ALLERGY

Antihistamine
12.5 mg Diphenhydramine HCl USP

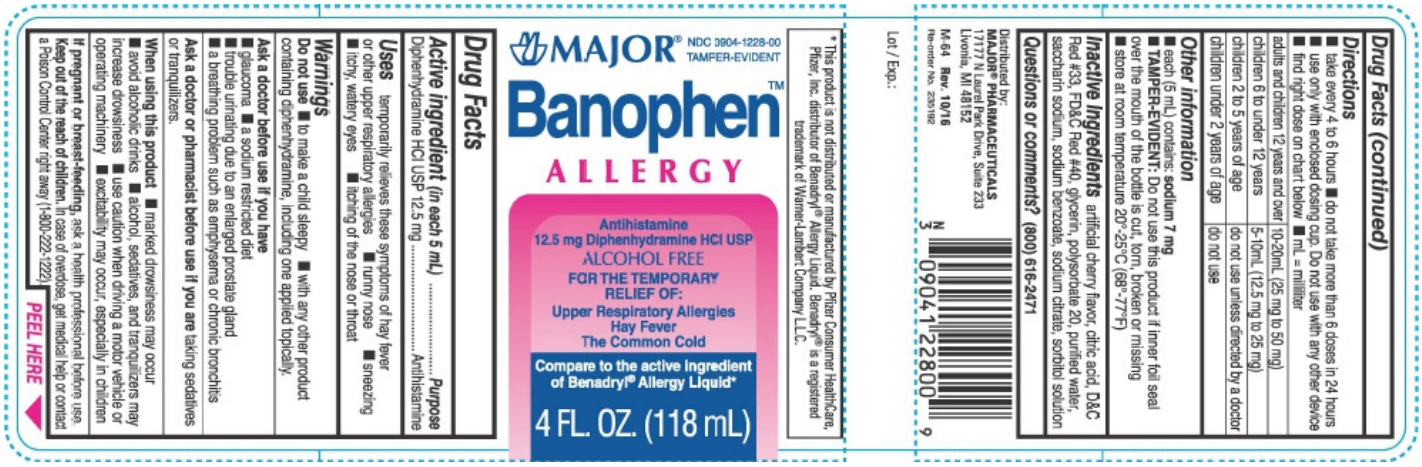
ALCOHOL FREE

FOR THE TEMPORARY
RELIEF OF:
Upper Respiratory Allergies
Hay Fever

The Common Cold

Compare to the active ingredient of Benadryl ® Allergy Liquid*

4 FL. OZ. (118 mL)



BANOPHEN

diphenhydramine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-1228
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**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CHERRY (UNII: BUC5I9595W)	

Product Characteristics			
Color	red (Bluish-Red)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-1228-20	1 in 1 CARTON	11/20/2006	01/31/2021
1	NDC:0904-1228-00	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/20/2006	

Labeler - Major Pharmaceuticals (191427277)

Revised: 9/2019 Major Pharmaceuticals