

## **BANOPHEN- diphenhydramine hcl liquid**

### **A-S Medication Solutions**

*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.*

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## **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<sup>®</sup> PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

**HOW SUPPLIED**

Product: 50090-2935

NDC: 50090-2935-0 118 mL in a BOTTLE / 1 in a CARTON

**Diphenhydramine HCl**



# BANOPHEN

diphenhydramine hcl liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-2935(NDC:0904-1228)
<b>Route of Administration</b>	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

<b>Color</b>	red (Bluish-Red)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-2935-0	1 in 1 CARTON	03/28/2017	
1		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** - A-S Medication Solutions (830016429)

## Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-2935)

Revised: 2/2019

A-S Medication Solutions