

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine  
hydrochloride capsule  
A-S Medication Solutions**

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**0835&0836(box unit)-Major**

**Active Ingredient (in each banded capsule)**

Diphenhydramine HCl... 25 mg

Diphenhydramine HCl... 50 mg

**Purpose**

Antihistamine

**Use**

25 MG

- Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itchy throat and nose
- Temporarily relieves these symptoms due to the common cold:
  - runny nose
  - sneezing

50 MG

- Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies and common cold
  - sneezing
  - runny nose
  - itchy, watery eyes
  - itchy throat and nose

**WARNINGS**

**Do not use**

25 MG

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

50 MG

- to make a child sleepy

- with any other product containing diphenhydramine, including one applied topically

**Ask a doctor before use if you have**

25 MG

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

50 MG

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

**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 REACH OF CHILDREN**

In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- Take every 4-6 hours
- Do not take more than 6 doses in 24 hours

**25 MG**

adults and children 12 years of age and over	1 to 2 capsules
children 6 years to under 12 years of age	1 capsule
children under 6 years of age	do not use this product in children under 6 years of age

## 50 MG

adults and children 12 years of age and over	1 capsule
children 6 years to under 12 years of age	Ask a doctor, the proper dosage strength is not available in this package**

\*\*Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.

### Other Information

- Store at 20°C – 25°C (68°F – 77°F); excursions permitted to 15° – 30°C (59° – 86°F) [See USP Controlled Room Temperature]
- Protect from moisture
- Contains lactose

### Inactive Ingredients

D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.

### Questions?

Questions or comments? (800) 616-2471

### Distributed by

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233,

Livonia, MI 48152

### HOW SUPPLIED

Product: 50090-3867

NDC: 50090-3867-1 28 CAPSULE in a BOTTLE

NDC: 50090-3867-0 30 CAPSULE in a BOTTLE

### Diphenhydramine Hydrochloride

CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

**Patient First**<sup>®</sup>

WARNING: KEEP OUT OF CHILDREN'S REACH. DISPENSE IN THIS LIGHT RESISTANT CONTAINER.

STORE AT ROOM TEMPERATURE, USP  
PROTECT FROM MOISTURE

LOT#

**BANOPHEN**  
DIPHENHYDRAMINE HCL  
25 MG  
28 CAPSULES  
NDC 50090-3867-1  
PRODUCT # 8340-1

ACTIVE INGREDIENT (IN EACH BANDED CAPSULE)  
DIPHENHYDRAMINE HCL 25 MG  
PURPOSE: ANTIHISTAMINE  
SRC NDC: 0904-5306-61

AFFIX LABEL HERE

AFFIX LABEL HERE

GTIN: 00350090386714  
LOT:  
EXP:  
S/N:

Packaged Exclusively By:  
**A-S MEDICATION SOLUTIONS LLC**<sup>™</sup>  
Libertyville, IL 60048

## DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-3867(NDC:0904-5306)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

### Product Characteristics

<b>Color</b>	pink (half pink and half clear with white powder inside)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	CPC;835
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-3867-1	28 in 1 BOTTLE; Type 0: Not a Combination Product	11/27/2018	
2	NDC:50090-3867-0	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/27/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/02/2009	

**Labeler** - A-S Medication Solutions (830016429)

## Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3867) , REPACK(50090-3867)

Revised: 12/2023

A-S Medication Solutions