

**DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule**  
**NuCare Pharmaceuticals, Inc.**

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**0836-Major(100C/1000C)**

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

Diphenhydramine Hydrochloride 50 mg

**Purpose**

Antihistamine

**Use**

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

**Do not use**

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

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

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

adults and children 12 years of age and over	Take 1 capsule (50 mg)
children 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 in a dry place at 15° – 30°C (59° – 86°F).
- Do not use if either capsule band or imprinted safety seal under cap is broken or missing
- 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? 1-800-231-4670

Distributed by: MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

[www.majorpharmaceuticals.com](http://www.majorpharmaceuticals.com)

### **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



GTIN 00368071365047  
 Serial# 0000000002  
 Exp. Date 00-00  
 LOT#: 00000

Rev. 01/01/19

Take \_\_\_\_\_ every \_\_\_\_\_ hours

**Patient Instructions:**

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

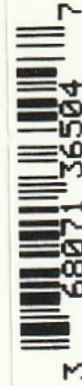
Packaged By: NuCare Pharmaceuticals, Inc. Orange, CA 92667

Distributed by: Major Pharmaceuticals Indianapolis, IN 46268

**NDC: 68071-3650-4**  
**Diphenhydramine HCl 50mg #4 Capsules**

Oblong clear pink with red band capsule imprint with "CPC" on cap and "836" on body. Each banded capsule contains Diphenhydramine HCl 50mg Antihistamine. Warnings: Do not use, to make a child sleepy, with any other product containing Diphenhydramine, even one used on skin. Ask a doctor before use if you have, a breathing problem such as emphysema or chronic bronchitis, glaucoma, trouble urinating due to an enlarged 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. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Product #: P0779004ER**



Diphenhydramine HCl 50mg #4 Capsules Serial# 0000000002 Lot: 00000 NDC: 68071-3650-04 Exp.: 00-00 MFR NDC: 0904-5307-60

**WARNING: KEEP OUT OF REACH OF CHILDREN STORE AT CONTROLLED TEMPERATURE 59-86°F.**

**DIPHENHYDRAMINE HCL**

diphenhydramine hcl capsule

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68071-3650(NDC:0904-5307)
<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	50 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</b> (UNII: 2G86QN327L)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

**Product Characteristics**

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	CPC;836
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-3650-4	4 in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/02/2009	

**Labeler** - NuCare Pharmaceuticals, Inc. (010632300)

## Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc		010632300	repack(68071-3650)

Revised: 7/2024

NuCare Pharmaceuticals, Inc.