

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

*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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**Drug Facts**

**Active ingredient(in each capsule)**

Diphenhydramine HCL 25 mg

**Purpose**

Antihistamine

**Uses:**

- Temporarily relieves these symptoms associated with the common cold, hay fever, or other respiratory allergies.
- Sneezing.
- Nasal congestion.
- Runny nose.
- Itchy, watery eyes.

**Warnings:**

**Do not use**

- With any other product containing Diphenhydramine HCL, including one applied topically.

**Ask a doctor or pharmacist before use**

If you have Trouble urinating due to enlarged prostate gland A breathing problem such as emphysema or chronic bronchitis Glaucoma If you are taking sedatives or tranquilizers

**When using this product**

- Avoid alcoholic drinks.
- Marked drowsiness may occur.
- Excitability may occur, especially in children.
- Alcohol, sedatives and tranquilizers may increase drowsiness.
- Be careful when driving a motor vehicle or operating machinery.

**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 or over | 1 to 2 capsule |
| Children 6 to under 12 years         | 1 capsule      |
| Children under 6 years               | ask a doctor   |

**Other information:**

- Store at room temperature 15-30 degrees C (59-86 degrees F)
- Protect from excessive moisture

**Inactive ingredients: Black Iron Oxide, D & C Red #28, FD & C Blue #1, FD & C Red #40, Gelatin, Lactose Monohydrate, Magnesium Stearate, Silicon Dioxide, Sodium Lauryl Sulfate**

**NuCare Pharmaceuticals, Inc.**



GTIN 00368071335248  
 Serial# 00000000003  
 Exp. Date 00-00  
 Lot#: 000000

Rev. 01/01/19

Take \_\_\_\_\_ every \_\_\_\_\_ hours \_\_\_\_\_ times a day.  
 Patient Instructions

Manufactured by:  
 SDA Laboratories, Inc., Greenwich, CT 06830

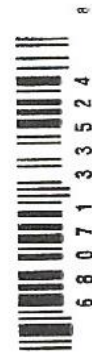
Packaged By:  
 NuCare Pharmaceuticals, Inc. Orange, CA 92667

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

**NDC: 68071-3352-4**  
**Diphenhydramine HCl 25mg**  
**#4 Capsules**

Each capsule contains Diphenhydramine HCl 25mg USP.....  
 Antihistamide Warnings: Do not use, with any other product containing Diphenhydramine HCl, including one applied topically.  
 Ask a doctor or pharmacist before use if you have, trouble urinating due to enlarged prostate gland, a breathing problem such as emphysema or chronic bronchitis, glaucoma, if you are taking sedatives or tranquilizers. When using this product, avoid alcoholic drinks, marked drowsiness may occur, excitability may occur, especially in children, alcohol, sedatives & tranquilizers may increase drowsiness, be careful when driving a motor vehicle or operating machinery. If pregnant or breast-feeding, ask a health professional before use. Oblong Clear Pink Cap/Clear Body w/Red Band Capsule Imprinted: "PH014" on cap and body

**Product #: P0778004ER**



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Diphenhydramine HCl 25mg  
 #4 Capsules Serial# 00000000003  
 Lot: 000000 NDC: 68071-3352-04  
 Exp.: 00-00 MFR NDC: 66424-020-01

**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:68071-3352(NDC:66424-020) |
| <b>Route of Administration</b> | ORAL           |                           |                               |

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

| Ingredient Name                                 | Strength |
|---|----------|
| <b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)  |          |
| <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>MAGNESIUM STEARATE</b> (UNII: 70097M6130)    |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XB4)        |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J) |          |

**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>                              | PH014                |                    |
|------------------------------|--|--|----------------------|--------------------|
| <b>Contains</b>              |  |  |                      |                    |
| <b>Packaging</b>             |  |  |                      |                    |
| #                            | Item Code                                | Package Description                              | Marketing Start Date | Marketing End Date |
| 1                            | NDC:68071-3352-4                         | 4 in 1 BOTTLE; Type 0: Not a Combination Product | 07/11/2017           |                    |
| <b>Marketing Information</b> |  |  |                      |                    |
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date                             | Marketing End Date   |                    |
| OTC monograph final          | part341                                  | 01/27/2010                                       |                      |                    |

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

### Establishment

| Name                        | Address | ID/FEI    | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| NuCarePharmaceuticals, Inc. |         | 010632300 | repack(68071-3352)  |

Revised: 2/2021

NuCare Pharmaceuticals, Inc.