DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule NuCare Pharmaceuticals, Inc.

Drug Facts

Active ingredient(in each capsule)

Diphenhydramine HCL 50 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 capsule | |
|--------------------------------------|--------------|--|
| Children under 12 years | ask a doctor | |

^{**25} mg strength is not available in this package. Do not attempt to break capsules

Other information:

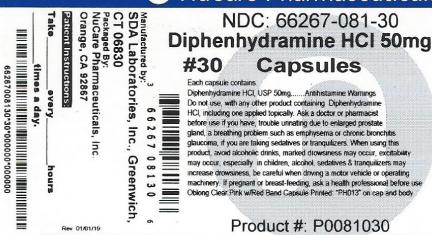
- Store at room temperature 15-30 degrees C (59-86 degrees F)
- Protect from excessive moisture

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

Questions? Adverse drug event call:

1-800-687-0176

• NuCare Pharmaceuticals, Inc.



Diphenhydramine HCI 50mg
Lot: 000000 NDC: 66267-0081-30
MFR NDC: 66424-021-10 Exp.: 00-00

Diphenhydramine HCl 50mg Lot: 000000 NDC: 66267-0081-30 MFR NDC: 66424-021-10 Exp.: 00-00



GTIN 00366267081306 Serial# 00000000002 Exp. Date 00-00 LOT#: 000000

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

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 59-86°F.

DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66267-081(NDC:66424-021)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)
(DIPHENHYDRAMINE - UNII:8GTS82S83M)

DIPHENHYDRAMINE HYDROCHLORIDE

50 mg

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| D&C RED NO. 28 (UNII: 767IP0Y5NH) | | |
| FERROSOFERRIC OXIDE (UNII: XM0M87F357) | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | |
| GELATIN (UNII: 2G86QN327L) | | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | |

| Product Characteristics | | | |
|-------------------------|---------|--------------|----------|
| Color | pink | Score | no score |
| Shape | CAPSULE | Size | 14mm |
| Flavor | | Imprint Code | PH013 |

Contains

| ı | Packaging | | | | |
|---|-----------|----------------------|--|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:66267- 081-30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/30/2016 | |

| Marketing Information | | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC Monograph Drug | M012 | 01/27/2010 | | |
| | | | | |

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

| Establishment | | | |
|------------------------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| NuCare Pharmaceuticals, Inc. | | 010632300 | repack(66267-081) |

Revised: 8/2024 NuCare Pharmaceuticals, Inc.