

DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule
NuCare Pharmaceuticals, Inc.

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.**

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

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.

Caution/Instructions:

Take _____ every _____ hours
_____ times a day.

GTIN 00368071335248
Serial# 000000000003
Exp. Date 00-00
LOT#: 000000

Rev. 01/01/19



8
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Diphenhydramine HCl 25mg
#4 Capsules Serial# 000000000003
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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-3352(NDC:66424-020)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	PH014
Contains			

Packaging

#	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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/27/2010	

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment

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

Revised: 7/2024

NuCare Pharmaceuticals, Inc.