

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



GTIN 0036626779043
 Serial# 00000000004
 Exp. Date 00-00
 Lot#: 000000

Rev. 01/01/19

Take _____ every _____ hours
 _____ times a day.
 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.

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

NDC: 66267-779-04
Diphenhydramine HCl 50mg
#4 Capsules

Each capsule contains Diphenhydramine HCl 50mg USP.....
 Antihistamine 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 w/Red Band Capsule Printed: "PH013" on cap and body
Product #: P0779004ER



Diphenhydramine HCl 50mg
 #4 Capsules Serial# 00000000004
 Lot: 000000 NDC: 66267-0779-04
 Exp.: 00-00 MFR NDC: 66424-021-01

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:66267-779(NDC:66424-021)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 28 (UNII: 7671P0Y5NH)	
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
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Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	PH013
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66267-779-06	6 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2017	

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(66267-779)

Revised: 8/2024

NuCare Pharmaceuticals, Inc.