

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.

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.

NDC: 66267-081-30
**Diphenhydramine HCl 50mg
#30 Capsules**

Each capsule contains
Diphenhydramine HCl, USP 50mg.....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 #: P0081030

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

Diphenhydramine HCl 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.

Manufactured by: SDA Laboratories, Inc., Greenwich, CT 06830
Packed By: NuCare Pharmaceuticals, Inc. Orange, CA 92867

Take _____ every _____ hours
_____ times a day.

Rev 01/01/19

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	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: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
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			

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 final	part341	01/27/2010	

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

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