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

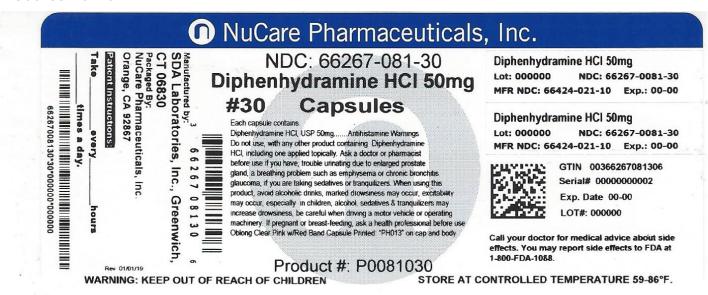
Other information:

- 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



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

I	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
	DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg	

Inactive Ingredients				
Ingredient Name	Strength			
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)				
D&C RED NO. 28 (UNII: 767IP0 Y5NH)				
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 DIO XIDE (UNII: ETJ7Z6 XBU4)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				

Product Characteristics				
Color	pink	Score	no score	
Shape	CAPSULE	Size	14mm	
Flavor		Imprint Code	PH0 13	
Contains				

P	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	0 1/27/20 10	

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

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

Revised: 1/2021 NuCare Pharmaceuticals, Inc.