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 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. Manufactured by: SDA Laboratories, Inc., Greenwich, CT 06830 Packaged By: NuCare Pharmaceuticals, Inc. Orange, CA 92887 NDC: 66267-080-20 Patient Instructions: Diphenhydramine HCI 25mg Diphenhydramine HCI 25mg Lot: 000000 NDC: 66267-0080-20 MFR NDC: 66424-020-01 Exp.: 00-00 #20 Capsules times a day. 86267008020*20*0000000000000 Diphenhydramine HCI 25mg Each capsule contains Lot: 000000 NDC: 66267-0080-20 Diphenhydramine HCl 25mg.... Antihistamine USP Warnings. Do MFR NDC: 66424-020-01 Exp.: 00-00 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, GTIN 00366267080200 Serial# 00000000002 if you are taking sedatives or tranquilizers. When using this product, avoid alcoholic drinks, marked drowsiness may occur, excitability may Exp. Date 00-00 occur, especially in children, alcohol, sedatives & tranquilizers may increase occur, especially in children, arconol, securities a manquincers 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 LOT#: 000000 drowsiness, be careful when driving a motor vehicle or operating machinery. Clear Pink Cap/Clear Body w/Red Band Capsule Imprinted "PH014" on body and Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. Product #: P0080020 Rev 01/01/19 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:66267-080(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		
D&C RED NO. 28 (UNII: 767IP0Y5NH)			
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)			
FERROSOFERRIC OXIDE (UNII: XM0M87F357)			

Product Characteristics					
ColorpinkScoreno score					
Shape	CAPSULE	Size	14mm		
Flavor		Imprint Code	PH014		

Contains

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:66267- 080-15	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2016		
2	NDC:66267- 080-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2016		
3	NDC:66267- 080-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2016		
4	NDC:66267- 080-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2016		
5	NDC:66267- 080-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2016		
6	NDC:66267- 080-24	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2016		

Marketing Information					
Marketing Category	Application Number or Monograph Marketing Start Marketing End Citation Date 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(66267-080)	

Revised: 8/2022 NuCare Pharmaceuticals, Inc.