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:

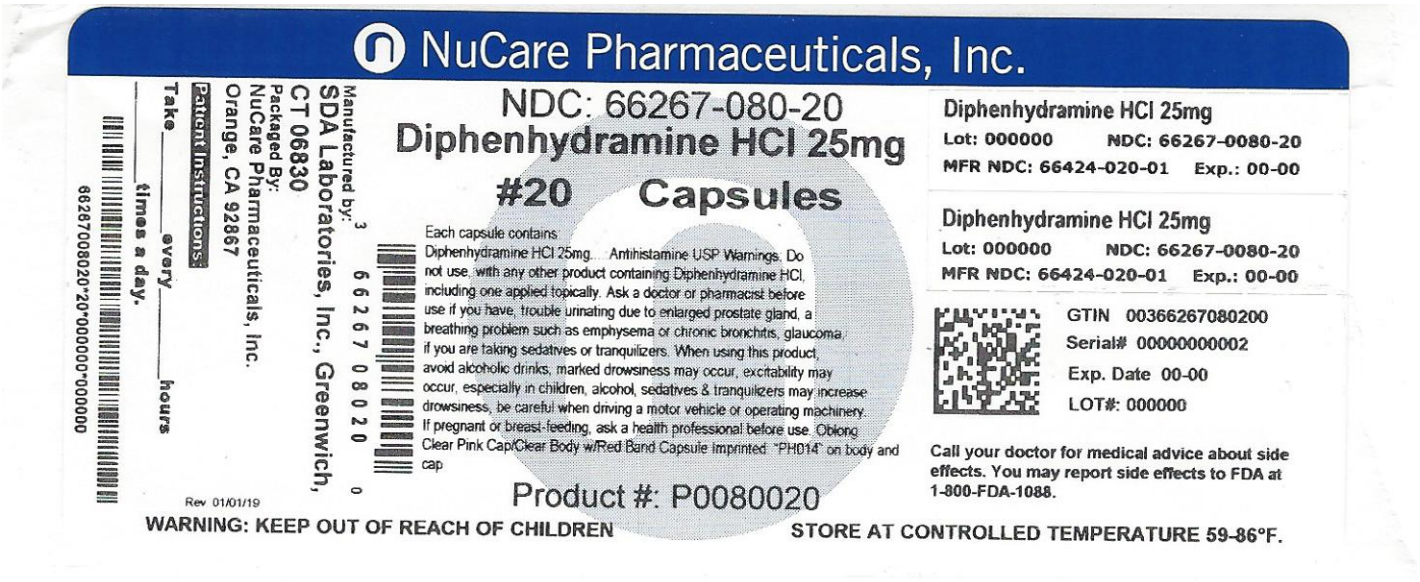
- Take every 4-6 hours
- Do not take more than 6 doses in 24 hours.

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



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			
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: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 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(66267-080)

Revised: 8/2022 NuCare Pharmaceuticals, Inc.