

**DIPHENHYDRAMINE HCL- diphenhydramine hcl solution**  
**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.*

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**Major 44-015-DSP**

***Active ingredient (in each teaspoonful (5 mL))***

Diphenhydramine HCl 12.5 mg

***Purpose***

Antihistamine

***Uses***

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat

***Warnings***

**Do not use**

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

**Ask a doctor before use if you have**

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

**Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers.

**When using this product**

- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- marked drowsiness may occur
- use caution 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**

- do not take more than 6 doses in 24 hours
- mL = milliliter; FL OZ = fluid ounce
- find right dose on chart below
- take every 4 to 6 hours, or as directed by a doctor

<b>Age</b>	<b>Dose</b>
adults and children 12 years and over	2 - 4 teaspoonsful (25 mg to 50 mg)
children 6 to 11 years	1 - 2 teaspoonsful (12.5 mg to 25 mg)
children 2 to 5 years	do not use unless directed by a doctor
children under 2 years	do not use

**Other information**

- **each teaspoonful (5 mL) contains:** sodium 5 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

**Inactive ingredients**

anhydrous citric acid, D&C red #33, FD&C red #40, flavors, glycerin, high fructose corn syrup, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sucrose

**Questions or comments?**

**(800) 616-2471**

**Principal display panel**

# NuCare Pharmaceuticals, Inc.

NDC: 68071-2862-4  
Diphenhydramine HCl 12.5mg/5mL

**4oz Oral Soln.**

See manufacturer's label  
for full list of ingredients.

Diphenhydramine HCl 12.5mg/5mL  
Lot: 00000 NDC: 68071-2862-04  
MFR NDC: 0904-6985-20 Exp.: 00-00  
Serial# 000000002

Diphenhydramine HCl 12.5mg/5mL  
Lot: 00000 NDC: 68071-2862-04  
MFR NDC: 0904-6985-20 Exp.: 00-00  
Serial# 000000002



GTIN 00368071286243  
Serial# 000000002  
Exp. Date 00-00  
LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Take \_\_\_\_\_ teaspoonful(s) every \_\_\_\_\_ hours \_\_\_\_\_ times a day.  
Patient Instructions:  
Packed By: NuCare Pharmaceuticals, Inc. Orange, CA 92867  
Major Pharmaceuticals Livonia, MI 48152  
Distributed by: 3 68071 2862 4 3

88071286204\*4\*00000\*00000

Rev 01/01/19  
Product #: R0257004  
WARNING: KEEP OUT OF REACH OF CHILDREN STORE AT CONTROLLED TEMPERATURE 68-77°F.

## DIPHENHYDRAMINE HCL

diphenhydramine hcl solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-2862(NDC:0904-6985)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCROSE (UNII: C151H8M554)	

### Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2862-4	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/26/2022	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/27/2019	

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

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-2862)

Revised: 10/2022

NuCare Pharmaceuticals, Inc.