ALLERGY RELIEF- diphenhydramine hcl 25 mg tablet NUVICARE LLC

Active Ingredient (in each tablet)

Diphenhydramine HCl 25mg

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
- temporarily relieves these symptoms due to the common cold:
- runny nose
- sneezing

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

- glaucoma
- troble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product ■ drowsiness may occur ■avoid alcoholic drinks ■alcohol, sedatives, and tranquilizers may increase drowsiness ■be careful when driving a motor vehicle or operating machinery ■excitability may occur, especially in children.

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 (1-800-222-1222) right away.

DIRECTIONS

- Take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours.
- Adults and children 12 years and over: 1 to 2 tablets
- Children 6 years to under 12 years: 1 tablet
- Children under 6 years: Do not use

OTHER INFORMATION

Each tablet contains: ■Calcium 24mg ■Store between 20º-25ºC (68º-77ºF). Avoid high humidity. Protect from moisture and light.

INACTIVE INGREDIENTS

Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Colloidal Silicon Dioxide, Magnesium Stearate, Opadry-II 85G540006 Pink

QUESTIONS OR COMMENTS?

Call 1 (718) 337-8733 or visit: support@nuvicare.com





NuviCare Allergy Relief - 300 Count - 6 x 2

Approval Signature:

ALLERGY RELIEF

diphenhydramine hcl 25 mg tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84324-004	
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		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)			

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

MAGNESIUM STEARATE (UNII: 70097M6I30)

Product Characteristics				
Color	pink	Score	no score	
Shape	OVAL	Size	11mm	
Flavor		Imprint Code	S4	
Contains				

ı	Packaging				
4	# Item Code Package Description		Marketing Start Date	Marketing End Date	
:	NDC:84324-004-	300 in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2024		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	07/17/2024		

Labeler - NUVICARE LLC (119257565)

Registrant - NUVICARE LLC (119257565)

Establishment				
Name	Address	ID/FEI	Business Operations	
ELYSIUM PHARMACEUTICALS LIMITED		915664486	manufacture(84324-004)	

Establishment				
Name	Address	ID/FEI	Business Operations	
MAK Pharma USA		109960731	pack(84324-004)	

Revised: 7/2024 NUVICARE LLC