DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride 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.

0835K- Major

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine HCl 25 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
] 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] trouble urinating due to an enlarged prostate gland
Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers
When using this product
] marked drowsiness may occur
] avoid alcoholic drinks] alcohol, sedatives and tranquilizers may increase drowsiness
] be careful when driving a motor vehicle or operating machinery
nexcitability may occur, especially in children

In case of overdose, get medical help or contact a Poison Control Center right away (1-

If pregnant or breast-feeding, ask a health professional before use.

Directions

800-222-1222).

Keep out of reach of children.

□ take every 4 to 6 hours, or as directed by a doctor
□ do not take more than 6 doses in 24 hours

adults and children
12 years of age and over
children 6 to
under 12 years of age

children under 6 years of age

do not use this product

in children under 6 years of age

Other information

 \square store in a dry place at 15° – 30°C (59° – 86°F)

corn starch, D&C red #28, FD&C blue #1, FD&C red #40, gelatin, lactose monohydrate, magnesium stearate, sodium lauryl sulfate

Questions or comments?

1-800-616-2471

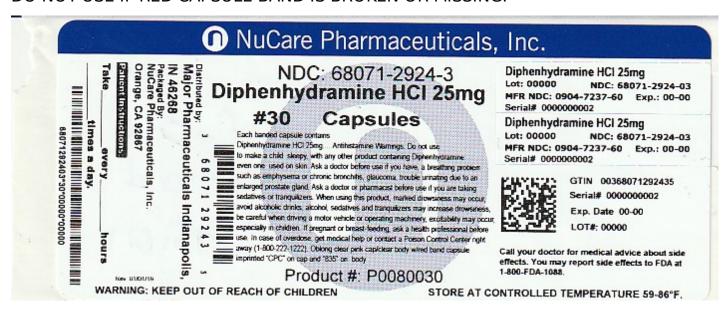
Distributed by: MAJOR® PHARMACEUTICALS, Indianapolis, IN 46268

Product of China. Manufactured and packaged in the USA using domestic and imported ingredients.

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Benadryl®.

To preserve quality and freshness, keep bottle tightly closed.

KEEP OUT OF REACH OF CHILDREN. DO NOT USE IF PRODUCT APPEARS TO BE TAMPERED WITH OR IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING. DO NOT USE IF RED CAPSULE BAND IS BROKEN OR MISSING.



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-2924(NDC:0904-7237)		
Route of Administration	ORAL				

	Active Ingredient/Active Moiety				
ı	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)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
GELATIN (UNII: 2G86QN327L)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
STARCH, CORN (UNII: O8232NY3SJ)				

Product Characteristics				
Color	pink (Half pink and half clear with white powder inside and sealed with red band)	Score	no score	
Shape	CAPSULE	Size	14mm	
Flavor		Imprint Code	CPC;835	
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68071- 2924-5	15 in 1 BOTTLE; Type 0: Not a Combination Product	01/30/2023		
2	NDC:68071- 2924-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/30/2023		
3	NDC:68071- 2924-4	24 in 1 BOTTLE; Type 0: Not a Combination Product	01/30/2023		

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	
Category	Citation	Date	Date	

OTC monograph final	part341	04/14/2022

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment				
Name	Address	ID/FEI	Business Operations	
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-2924)	

Revised: 6/2023 NuCare Pharmaceuticals,Inc.