

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

Directions

□ 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 1 to 2 capsules

children 6 to
under 12 years of age 1 capsule

children under 6 years of age do not use this product
in children under 6 years of age

Other information

□ 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.

NuCare Pharmaceuticals, Inc.

NDC: 68071-2924-3
Diphenhydramine HCl 25mg
#30 Capsules

Each harded capsule contains Diphenhydramine HCl 25mg. Antihistamine 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, 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, excitability may occur, especially in children. If pregnant or breast-feeding, ask a health professional before use. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-722-1222). Oblong clear pink cap/clear body/wired band capsule imprinted "CPC" on cap and "835" on body.

Product #: P0080030

Major Pharmaceuticals Indianapolis, IN 46268
Packaged By: NuCare Pharmaceuticals, Inc. Orange, CA 92867

Distributed by: 3 68071 29243 5

Take _____ every _____ hours _____ times a day.

88071292403*30*00000*00000

Now 11/30/11

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 59-86°F.

Diphenhydramine HCl 25mg
Lot: 00000 NDC: 68071-2924-03
MFR NDC: 0904-7237-60 Exp.: 00-00
Serial# 0000000002

Diphenhydramine HCl 25mg
Lot: 00000 NDC: 68071-2924-03
MFR NDC: 0904-7237-60 Exp.: 00-00
Serial# 0000000002

GTIN 00368071292435
Serial# 0000000002
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.

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

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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part341	04/14/2022	
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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.