ALLERGY RELIEF- diphenhydramine hydrochloride capsule, liquid filled FOODHOLD U.S.A., LLC

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.

Allergy Relief

Drug Facts

Active ingredient (in each softgel)

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
- 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

- 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
- do not take more than 6 doses in 24 hours

adults and children 12 years and over	1 to 2 softgels
children 6 to under 12 years	1 softgel
children under 6 years	do not use this product in children under 6 years of age

Other information

- store at room temperature 15°-30°C (59°-86°F) in a dry place
- protect from heat, humidity, and light

Inactive ingredients

gelatin, glycerin, polyethylene glycol, purified water, sorbitol special and white edible ink

Questions or comments?

Call: 1-855-215-8180

PRINCIPAL DISPLAY PANEL - Carton Label

CAREONE Allergy Relief

Diphenhydramine HCl 25 mg 24 softgels

NDC 41520-996-04

 * Compare to the active ingredient in Benadryl[®] Dye-Free Allergy Liqui-Gels[®]



ALLERGY RELIEF

diphenhydramine hydrochloride capsule, liquid filled

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-996			
Route of Administration	ORAL					

Active Ingredien	Active Ingredient/Active Moiety							
Ingredient Name			Basis of Strength		Strength			
DIPHENHYDRAMINE HYDRO CHL O RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE UNII:8GTS82S83M)			-		25 mg			
Inactive Ingredie	nts							
	Ingredient Name			St	Strength			
GELATIN (UNII: 2G86	QN327L)							
GLYCERIN (UNII: PDC	6A3C0OX)							
POLYETHYLENE GL	YCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)							
WATER (UNII: 059QF	OKOOR)							
SORBITOL (UNII: 506T60A25R)								
Product Characte	eristics							
Color	yellow (clear)	yellow (clear) Score		no score				
Shape	capsule (oblong) S	Size 15		15mm	.5mm			
Flavor	L.	Imprint Code PC		PC4	°C4			
Contains								
Packaging								
# Item Code	Package Description	Mar	keting Start Date	Marketing	g End Date			
1 NDC:41520-996-04	2 in 1 CARTON	10/0	3/2016					
1	12 in 1 BLISTER PACK; Type 0: Not a Combination Product							
Marketing Information								
Marketing Categor	Application Number or Monograph Citation		rketing Start Date Marketin		End Date			
OTC monograph final	part341	10/03/	/03/2016					

Labeler - FOODHOLD U.S.A., LLC (809183973)

Establishment							
Name	Address	ID/FEI	Business Operations				
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(41520-996), analysis(41520-996)				

Revised: 11/2019

FOODHOLD U.S.A., LLC