

**DYE-FREE ALLERGY- diphenhydramine hydrochloride capsule, liquid filled**  
**PuraCap Pharmaceutical 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.*

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**DYE-FREE ALLERGY**

**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 toll free: **1-800-833-6278**

**PRINCIPAL DISPLAY PANEL**

DYE-FREE ALLERGY 24 SOFTGELS

Diphenhydramine HCl 25mg

NDC 51013-144-04

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



DYE-FREE ALLERGY			
diphenhydramine hydrochloride capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-144
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
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

**Product Characteristics**

Color	yellow (clear)	Score	no score
Shape	capsule (oblong)	Size	15mm
Flavor		Imprint Code	PC4
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-144-04	2 in 1 CARTON	06/27/2016	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/27/2016	

**Labeler** - PuraCap Pharmaceutical LLC (962106329)**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(510 13-144) , analysis(510 13-144)