

**ALLERGY RELIEF- 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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**Nighttime SLEEP AID**

**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:
  - o runny nose
  - o sneezing
  - o itchy, watery eyes
  - o itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
  - o runny nose
  - o 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
- trouble urinating due to 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 or any other sleep aid

**When using this product**

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if** sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

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

**Keep out of reach of children.**

**Overdose warning**

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours

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

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**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: **1-855-215-8180**

**PRINCIPAL DISPLAY PANEL - Carton Label**

PuraVation Allergy Relief

Diphenhydramine HCl - 25 mg EACH

12 LIQUID-FILLED SOFTGELS

NDC 51013-108-02



## ALLERGY RELIEF

diphenhydramine hydrochloride capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-108
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: 059QF0K00R)	
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 13-108-02	1 in 1 CARTON	05/12/2014	
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	05/12/2014	

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

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(510 13-108) , analysis(510 13-108)

Revised: 6/2016

PuraCap Pharmaceutical LLC