

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.

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.
- **do not use if carton is open or blister unit is broken**

Inactive ingredients

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

Questions or comments?

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL

Allergy Relief

Diphenhydramine HCl 25 mg 24 softgels

NDC 51013-199-04

*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:51013-199 |
| 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) | |
| SORBITAN (UNII: 6O92ICV9RU) | |

Product Characteristics

| | | | |
|----------|------------------------|--------------|----------|
| Color | yellow (clear natural) | 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 13-199-04 | 2 in 1 CARTON | 07/14/2017 | |
| 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 | 07/14/2017 | |

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

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|--|
| Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd. | | 421293287 | manufacture(510 13-199) , analysis(510 13-199) |