#### ALLERGY RELIEF- diphenhydramine hydrochloride capsule, liquid filled Topco Associates 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

- glaucoma
- trouble urinating due to an 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.

# 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)
- protect from heat, humidity, and light

#### **Inactive ingredients**

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

#### **Questions or comments?**

Call toll free: 1-888-423-0136

## PRINCIPAL DISPLAY PANEL

Allergy Relief

Diphenhydramine HCl 25 mg 100 softgels

#### NDC 36800-436-24

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



|--|

#### **ALLERGY RELIEF** diphenhydramine hydrochloride capsule, liquid filled **Product Information Product Type** HUMAN OTC DRUG NDC:36800-436 Item Code (Source) ORAL **Route of Administration Active Ingredient/Active Moiety** Strength **Ingredient Name Basis of Strength** DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE - DIPHENHYDRAMINE 25 mg UNII:8GTS82S83M) HYDROCHLORIDE **Inactive Ingredients Ingredient** Name Strength GELATIN (UNII: 2G86QN327L) GLYCERIN (UNII: PDC6A3C0OX) POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A) WATER (UNII: 059QF0KO0R) SORBITOL (UNII: 506T60A25R) SORBITAN (UNII: 6092ICV9RU) **Product Characteristics** Color yellow (clear) no score Score CAPSULE (oblong) 15mm Shape Size PC4 Flavor Imprint Code Contains Packaging Marketing Start Date Marketing End Date # Item Code **Package Description**

**1** NDC:36800-436-24 100 in 1 BOTTLE; Type 0: Not a Combination Product 05/29/2018

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part341	05/29/2018					

Labeler - Topco Associates LLC (006935977)

# Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(36800-436) , analysis(36800-436)

Revised: 3/2019

Topco Associates LLC