

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine  
hydrochloride capsule, liquid filled  
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.**

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**DIPHENHYDRAMINE HYDROCHLORIDE 25 mg capsule, liquid filled**

**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.

**Directions**

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

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	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 special and white edible ink

manufactured by:

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

Wuhan, Hubei

430206, China

**PRINCIPAL DISPLAY PANEL - Shipping Label**

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, 25 mg

Quantity : 20000 Capsules

NDC. No : 53345-007-01

IMPORTANT:

Inspect immediate upon receipt.

This is a bulk shipment intended for further processing only.

Protect from heat, humidity, and light. Do not refrigerate.

CAUTION : "FOR FURTHER MANUFACTURING, PROCESSING OR REPACKING"

# Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

No. 99, 2<sup>nd</sup> Shendun Road, East Lake New Technology Development District,  
Wuhan, Hubei 430206, P. R. China

NDC No.: 53345-007-01

Product:

## DIPHENHYDRAMINE HYDROCHLORIDE

### CAPSULES, 25 mg

Each softgel contains: Diphenhydramine Hydrochloride USP, 25 mg

**CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING**

Product Code: 40-00005	Quantity: 20000 Capsules
Lot No.: 0000000	Manufacturing Date: 00/0000
Box No.: X	<b>IMPORTANT:</b> 1. Inspect immediately upon receipt. 2. This is a bulk shipment intended for further processing only. 3. Protect from heat, humidity, and light. Do not refrigerate.
<b>MADE IN CHINA</b>	

REV - 00  
01/2013

## DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-007
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
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>	yellow (clear)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (OBLONG)	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	PC4
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-007-01	1 in 1 BOX	09/15/2013	
1		20000 in 1 BAG; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/15/2013	

**Labeler** - Humanwell PuraCap Pharmaceutical (Wuhan), Ltd. (421293287)

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-007)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.