

**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 capsule)**

Diphenhydramine HCl 25 mg

**Purpose**

Nighttime sleep-aid

**Uses**

- for the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

**Warnings**

**Do not use**

- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
- with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products
- do not use with NyQuil

**Ask a doctor before use if you have**

- a breathing problem such as asthma, emphysema, or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease

**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 only one dose per day (24 hours) - see Overdose warning

adults & children 12 yrs & over	One dose = TWO 25 mg softgels (50 mg) at bedtime if needed or as directed by a doctor
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### Other information

- store at room temperature 15°-30°C (59°-86°F)
- avoid excessive heat above 40°C (104°F) and high humidity
- protect from light

### Inactive ingredients

FD&C blue #1, FD&C red #40, 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 : 53345-002-02

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.: 53345-002-02**

Product:

## Diphenhydramine HCl CAPSULES, 25 mg

Each softgel contains: Diphenhydramine HCl USP, 25 mg

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

Product Code: <b>40-00014</b>	Quantity: <b>20000 Capsules</b>
Lot No.: <b>0000000</b>	Manufacturing Date: <b>00/0000</b>
Box No.: <b>X</b>	<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 - 01  
01/2013

## DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-002
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>	purple	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (oblong)	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	PC11
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-002-02	1 in 1 BOX	04/15/2013	
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	M010	04/15/2013	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-002)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.