

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

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**DIPHENHYDRAMINE HYDROCHLORIDE capsules, liquid filled**

**Drug Facts**

**Active ingredient (in each softgel)**

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

**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 of age & 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 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 : 53345-027-01

IMPORTANT:

Inspect immediately upon receipt.

This is a bulk shipment, intended for further processing only.

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

Store at 15-30°C (59-86°F)

CAUTION : "FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING"

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**Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.**

No. 99, 2nd Shendun Road, East Lake New Technology Development District,  
Wuhan, Hubei 430226, P. R. China

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**NDC No.: 53345-027-01**

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**Product:**

**Diphenhydramine HCl Capsules 25 mg**

Each softgel contains: Diphenhydramine HCl 25 mg

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

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**Product Code:**

43-01654

**Quantity:**

20000 Capsules

**Lot Number:**

XXXXXXXX

**Manufacturing Date:**

xx/yyyy

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**Box No.:**

**IMPORTANT:**

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.
4. Store at 15-30°C (59-86°F)

**MADE IN CHINA**

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REV-00  
08/2014

**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53345-027
<b>Route of Administration</b>	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: 059QF0KO0R)	
<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>	654
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-027-01	1 in 1 BOX	10/14/2014	
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	10/14/2014	

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

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-027)