

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

DIPHENHYDRAMINE HYDROCHLORIDE 50 mg capsule, liquid filled

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

- for the relief of occasional sleeplessness

Warnings

- **do not give to children under 12 years of age**
- **do not use** 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 avoid alcoholic drinks.

Stop use and ask a doctor if

- sleeplessness persist 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **adults and children 12 years of age and over:** 1 softgel (50 mg) at bedtime if

needed, or as directed by a doctor.

Other information

- store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

FD&C blue #1, 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, 50 mg

Quantity : 12000 Capsules

NDC. No : 53345-005-01

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 nd Shendun Road, East Lake New Technology Development District, Wuhan, Hubei 430206, P. R. China	
NDC No.: 53345-005-01	
Product:	
DIPHENHYDRAMINE HYDROCHLORIDE	
CAPSULES, 50 mg	
Each softgel contains: Diphenhydramine HCl USP, 50 mg	
CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING	
Product Code:	Quantity:
40-00006	12000 Capsules
Lot No.:	Manufacturing Date:
0000000	00/0000
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.
X	
MADE IN CHINA	

REV - 02
01/2013

Humanwell PuraCap Pharmaceuticals (Wuhan) Co.,Ltd

NDC #: 53345-005-01

PLD Item: BK000529



BK000529



DIPHENHYDRAMINE HCL 50MG SOFTGEL PUR BULK

LOT # XXXXXXX

MFG DATE: MM/DD/YY



XXXXXX



MM/DD/YY

QTY/Case: 12,000 capsules

CAUTION: FOR FUTURE MANUFACTURING, PROCESSING OR REPACKAGING	IMPORTANT: 1. Protect from heat, humidity, and light. 2. Store at 15-30°C (59-86°F) and avoid excessive heat above 40°C (104°F) .
Made in China	

COMMENTS:
PO#:

REV-00
08/2019

PRINCIPAL DISPLAY PANEL - Shipping Label

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, 50 mg

Quantity : 80 Bottles

NDC. No : 53345-005-02

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, 2nd Shendun Road, East Lake New Technology Development District,
Wuhan, Hubei 430206, P. R. China

NDC No.: 53345-005-02

Product:

Diphenhydramine HCl Capsules, 50 mg

Each softgel contains: Diphenhydramine HCl USP, 50 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

32 Capsules Per Bottle

Product Code: 41-10007	Quantity: 80 Bottles
Lot No.: 0000000	Manufacturing Date: 00/0000
Box No.: X	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.
MADE IN CHINA	

REV - 00
12/2013

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE (oval)	Size	13mm
Flavor		Imprint Code	PC5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-005-01	1 in 1 BOX	04/15/2013	
1		12000 in 1 BAG; Type 0: Not a Combination Product		
2	NDC:53345-005-02	80 in 1 BOX	04/15/2013	
2		32 in 1 BOTTLE, PLASTIC; 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)

Registrant - Epic Pharma, LLC (827915443)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-005)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.