

DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule, liquid filled

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.

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.

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.	
<small>No. 99, 2nd Shendun Road, East Lake New Technology Development District, Wuhan, Hubei 430206, P. R. China</small>	
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: 40-00006	Quantity: 12000 Capsules
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 - 02
01/2018

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 final	part338	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) , analysis(53345-005)

Revised: 8/2019

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.