

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine
hydrochloride capsule, liquid filled
Softgel Healthcare Pvt Ltd**

Diphenhydramine Hydrochloride Capsules USP 50 mg (Dye-free)

Active ingredient
(in each softgel)

Diphenhydramine Hydrochloride USP 50 mg

Purpose

Nighttime sleep-aid

Uses

- for relief of occasional sleeplessness

Warnings

Do not use

- for children under 12 years of age
- 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 a 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

Inactive ingredients

gelatin, glycerin, polyethylene glycol 400, polyethylene glycol 600, propylene glycol, purified water, sorbitol sorbitan solution

Bulk Package Label

<u>Diphenhydramine Hydrochloride Capsules USP 50mg (Dye Free)</u>			
<u>Each Soft Gelatin Capsule Contains:</u> (Diphenhydramine Hydrochloride USP 50mg)			
Batch No.	:		<div>IMPRINT</div>
Gross Wt	:	NDC No : 35916-0472-1	
Net Wt	:	Mfg Date :	
Quantity	:	Exp Date :	
<u>WARNING</u> KEEP OUT OF REACH OF CHILDREN			
STORE BETWEEN 20° - 25°C (68° to 77°F). AVOID HIGH HUMIDITY AND EXCESSIVE HEAT. PROTECT FROM LIGHT.			
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE F.D. & C ACT AND REGULATIONS.			
MANUFACTURED BY: SOFTGEL HEALTHCARE PVT. LTD., SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM VILLAGE, KANCHEEPURAM, TAMILNADU 603 103, INDIA (IND) LABELLER CODE : 35916 LIC NO : XXXX		MANUFACTURED FOR:	
CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKAGING"			

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0472
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
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITOL (UNII: 506T60A25R)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics			
Color	white (Clear transparent)	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0472-1	1000 in 1 BAG; Type 0: Not a Combination Product	04/08/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	04/08/2025	

Labeler - Softgel Healthcare Pvt Ltd (675584180)

