

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

Diphenhydramine Hydrochloride Capsules USP 50 mg (Dye and Propylene Glycol 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, purified water, sorbitol sorbitan solution

Bulk Package Label

<u>DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES USP 50 MG</u>		<div>IMPRINT</div>		
<u>(DYE AND PROPYLENE GLYCOL FREE)</u>				
Each Soft Gelatin Capsule Contains: (Diphenhydramine Hydrochloride USP 50mg)				
BATCH NO	:	NDC NO	:	35916-0470-1
MFG DATE	:	GROSS WT	:	
EXP DATE	:	NET WT	:	
QUANTITY	:	SHIPPER NO.	:	
<u>WARNING</u> KEEP OUT OF REACH OF CHILDREN.				
<u>STORAGE</u> Store at 20° to 25°C (68° to 77°F), Avoid high humidity and excessive heat above 40°C (104°F).Protect from light				
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKEDAND LABELED IN STRICT CONFORMANCE WITH THE FD&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:XXXXX		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:35916-0470
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)	
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 (Oval)	Size	13mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0470-1	1000 in 1 BAG; Type 0: Not a Combination Product	04/22/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	04/22/2025	

Labeler - Softgel Healthcare Pvt Ltd (675584180)