

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

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**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

<b><u>DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES USP 50 MG</u></b> <b><u>(DYE AND PROPYLENE GLYCOL FREE)</u></b> Each Soft Gelatin Capsule Contains: (Diphenhydramine Hydrochloride USP 50mg)		IMPRINT
BATCH NO :	NDC NO :	35916-0470-1
MFG DATE :	GROSS WT :	
EXP DATE :	NET WT :	
QUANTITY :	SHIPPER NO. :	
<b><u>WARNING</u></b> <b>KEEP OUT OF REACH OF CHILDREN.</b>		
<b><u>STORAGE</u></b> 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, REPACKED AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS.		
<b>MANUFACTURED BY:</b> <b>SOFTGEL HEALTHCARE PVT. LTD.,</b> SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM, CHENGALPATTU, TAMILNADU 603 103, INDIA (IND) LABELLER CODE: 35916 LIC NO:XXXXX		<b>MANUFACTURED FOR</b>
<b>CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”</b>		

**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35916-0470	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	50 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)				
WATER (UNII: 059QF0KO0R)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
SORBITOL (UNII: 506T60A25R)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
<b>Product Characteristics</b>				
<b>Color</b>	white (Clear Transparent)	<b>Score</b>	no score	
<b>Shape</b>	OVAL (Oval)	<b>Size</b>	13mm	
<b>Flavor</b>		<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:35916-0470-1	1000 in 1 BAG; Type 0: Not a Combination Product	04/22/2025	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC Monograph Drug	M010	04/22/2025		

**Labeler** - Softgel Healthcare Pvt Ltd (676666501)

Revised: 1/2026

Softgel Healthcare Pvt Ltd