

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine
hydrochloride capsule, liquid filled
SOFTGEL HEALTHCARE PRIVATE LIMITED**

Diphenhydramine Hydrochloride Capsules, USP 25 mg (Dye and Propylene Glycol Free)

Active ingredient (in each softgel)

Diphenhydramine Hydrochloride USP 25mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
- runny nose
- sneezing

Warnings

Do not use

- to make a child sleepy
- 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

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness

- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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

- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours

adults and children 12 years and over	1 to 2 capsules
children 6 to under 12 years	1 capsule
children under 6 years	do not use this product in children under 6 years of age

Other Information

- store between 20° to 25°C (68° to 77°F). Avoid high humidity and excessive heat. Protect from light.

Inactive Ingredients

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

Bulk Package Label

<p align="center"><u>DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES USP 25 MG</u> <u>(DYE AND PROPYLENE GLYCOL FREE)</u> Each Soft Gelatin Capsule Contains: (Diphenhydramine Hydrochloride USP 25mg)</p>				<div>IMPRINT</div>
BATCH NO	:	NDC NO	:	35916-0471-1
MFG DATE	:	GROSS WT	:	
EXP DATE	:	NET WT	:	
QUANTITY	:	SHIPPER NO.	:	
<p align="center">WARNING KEEP OUT OF REACH OF CHILDREN.</p>				
<p align="center">STORAGE Store at 20° to 25°C (68° to 77°F), Avoid high humidity and excessive heat above 40°C (104°F).Protect from light</p>				
<p align="center">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.</p>				
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		
<p align="center">CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”</p>				

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0471
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (Clear Transparent)	Score	no score
Shape	CAPSULE (Oblong)	Size	16mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0471-1	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	M012	04/22/2025	

Labeler - SOFTGEL HEALTHCARE PRIVATE LIMITED (675584180)

Revised: 4/2025

SOFTGEL HEALTHCARE PRIVATE LIMITED