

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

Diphenhydramine Hydrochloride Capsules, USP 25 mg (Dye 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

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, propylene glycol, purified water, sorbitol sorbitan solution

Diphenhydramine Hydrochloride Capsules USP 25mg (Dye Free)			
Each Soft Gelatin Capsule Contains: (Diphenhydramine Hydrochloride USP 25mg)			
Batch No.	:	NDC No	: 35916-0435-5
Gross Wt	:	Mfg Date	:
Net Wt	:	Exp Date	:
Quantity	:		
WARNING 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, Chengalpattu Tamilnadu -603 103, India (IND). Labeller code : 35916 Lic no. : XXXX			
CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKAGING"			

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0435
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)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

SORBITOL (UNII: 506T60A25R)

WATER (UNII: 059QF0KO0R)

Product Characteristics

Color	white ((Clear))	Score	score with uneven pieces
Shape	CAPSULE ((Oblong))	Size	15mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0435-1	3 in 1 CARTON; Type 0: Not a Combination Product	08/07/2023	
2	NDC:35916-0435-3	1000 in 1 BAG; Type 0: Not a Combination Product	04/22/2025	
3	NDC:35916-0435-4	2 in 1 BOX	06/11/2025	
3		3000 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:35916-0435-5	2 in 1 BOX	01/24/2026	
4		1500 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/07/2023	

Labeler - SOFTGEL HEALTHCARE PRIVATE LIMITED (676666501)

Revised: 1/2026

SOFTGEL HEALTHCARE PRIVATE LIMITED