

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

Diphenhydramine Hydrochloride Capsules, USP 25 mg (Purple Transparent)

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.
- **do not use if carton is open or blister unit is broken**

Inactive Ingredients

FD & C blue no.1, FD & C red no.40, gelatin, glycerin, polyethylene glycol 400, propylene glycol, purified water, sorbitol sorbitan solution

Bulk Package Label

<u>DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES USP 25 MG</u>				IMPRINT
<u>(PURPLE TRANSPARENT)</u>				
Each Soft Gelatin Capsule Contains: (Diphenhydramine Hydrochloride USP 25mg)				
BATCH NO	:	NDC NO	:	35916-0436-2
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. 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.				
MANUFACTURED BY:		MANUFACTURED FOR		
SOFTGEL HEALTHCARE PVT. LTD.,				
SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD,				
PUDUPAKKAM VILLAGE, KANCHEEPURAM,				
TAMILNADU 603 103, INDIA (IND)				
LABELLER CODE: 35916				
LIC NO:XXXXXX				
CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”				

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0436
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	purple (Transparent)	Score	no score
Shape	CAPSULE (Oblong)	Size	15mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0436-2	1000 in 1 BAG; Type 0: Not a Combination Product	04/07/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/07/2025	

Labeler - SOFTGEL HEALTHCARE PRIVATE LIMITED (675584180)