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

<table>
<tr><td colspan="2" align="center"><u>**DIPHENHYDRAMINE HYDROCLORIDE USP 25MG SOFT GELATIN CAPSULES**</u>
<u>**(PURPLE TRANSPARENT)**</u>
Each Soft Gelatin Capsule Contains:
(Diphenhydramine Hydrochloride USP 25mg)</td><td>**IMPRINT**</td></tr>
</table>

Batch No.	:			
Gross Wt	:	NDC No	:	35916 - 0436 - 2
Net Wt	:	Mfg Date	:	
Quantity	:	Exp Date	:	

<div align="center">

<u>WARNING</u>
Keep out of reach of children

</div>

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

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THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.
CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE
WITHTHE F.D. & C ACT AND REGULATIONS.

</div>

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

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CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKAGING"

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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 (676666501)

Revised: 1/2026

SOFTGEL HEALTHCARE PRIVATE LIMITED