

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

Diphenhydramine Hydrochloride Capsules, USP 25 mg

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. (1-800-222-1222)

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

Propylene Glycol, Polyethylene Glycol 400, Gelatin, Glycerin, Sorbitol Sorbitan Solution, Purified water.

NDC 35916-0435-1

Diphenhydramine Hydrochloride USP 25 mg | Antihistamine

Sneezing
Runny Nose
Itchy, Watery Eyes
Itchy Throat

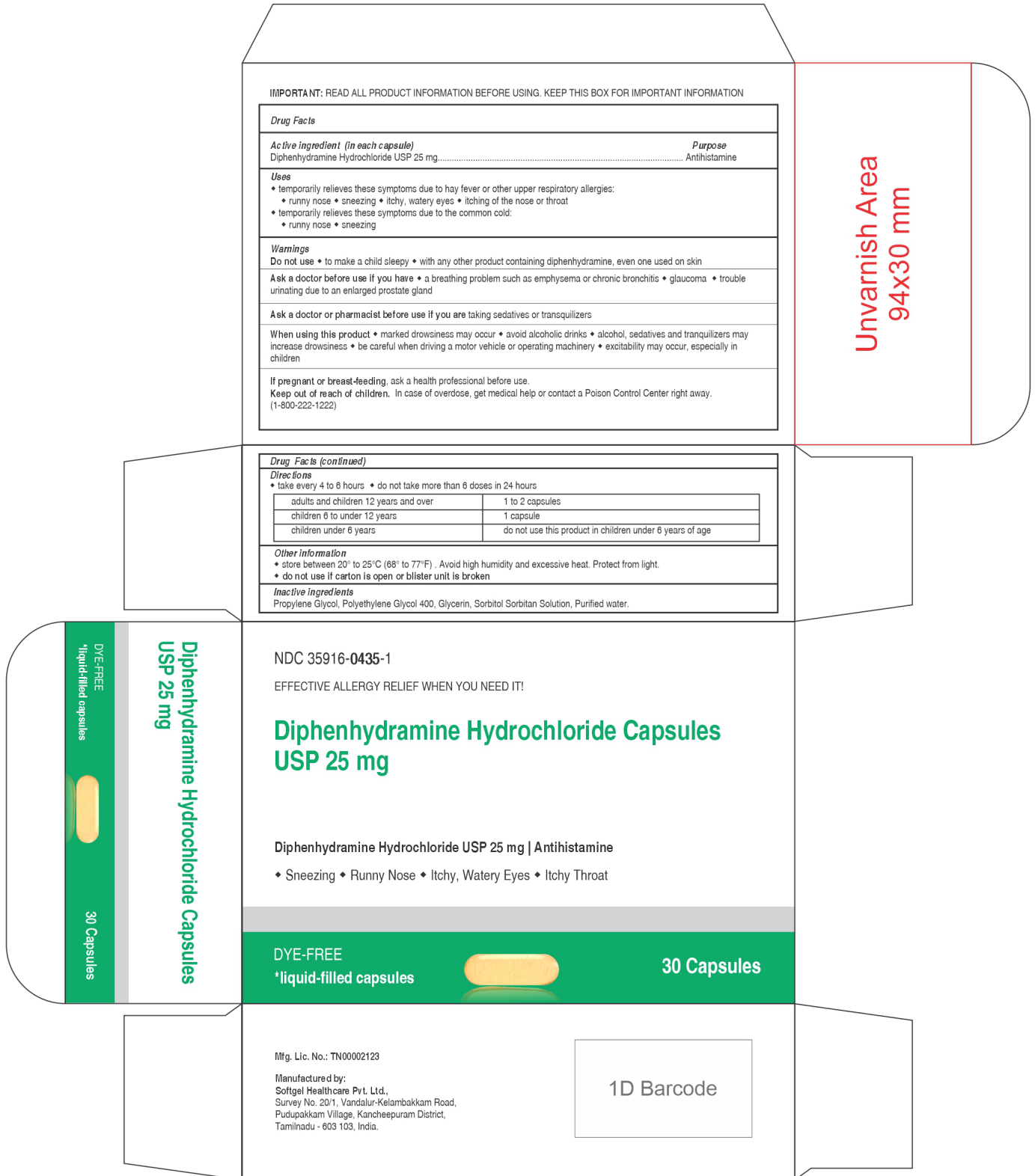
DYE-FREE

*liquid-filled capsules

Actual Size

BAR CODE

30 CAPSULES



IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THIS BOX FOR IMPORTANT INFORMATION

Drug Facts

Active ingredient (in each capsule)
Diphenhydramine Hydrochloride USP 25 mg..... **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. (1-800-222-1222)

Drug Facts (continued)

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
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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
Propylene Glycol, Polyethylene Glycol 400, Glycerin, Sorbitol Sorbitan Solution, Purified water.

NDC 35916-0435-1

EFFECTIVE ALLERGY RELIEF WHEN YOU NEED IT!

Diphenhydramine Hydrochloride Capsules USP 25 mg

Diphenhydramine Hydrochloride USP 25 mg | Antihistamine

• Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat

DYE-FREE

*liquid-filled capsules



30 Capsules

Mfg. Lic. No.: TN00002123

Manufactured by:
Softgel Healthcare Pvt. Ltd.,
Survey No. 20/1, Vandalur-Kelambakkam Road,
Pudupakkam Village, Kancheepuram District,
Tamilnadu - 603 103, India.

1D Barcode

Unvarnish Area
94x30 mm

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	

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 (675584180)

Establishment

Name	Address	ID/FEI	Business Operations
SOFTGEL HEALTHCARE PRIVATE LIMITED		675584180	manufacture(35916-0435)

Revised: 3/2024

SOFTGEL HEALTHCARE PRIVATE LIMITED