

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine
hydrochloride capsule, liquid filled
Softgel Healthcare Pvt Ltd**

Diphenhydramine Hydrochloride Capsules USP 50 mg

Active ingredient

(in each softgel)

Diphenhydramine Hydrochloride USP 50 mg

Nighttime sleep-aid

Uses

for relief of occasional sleeplessness

Do not use

for children under 12 years of age

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

avoid alcoholic drinks

Stop use and ask a doctor if

sleeplessness persist continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.

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

adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Inactive ingredients

Propylene Glycol, Polyethylene Glycol 600, Polyethylene Glycol 400, Gelatin, Glycerin, Sorbitol Sorbitan Solution, FD & C Blue No.1, Purified Water

Bottle Label


Compare to the active ingredient **Unisom® SleepGels®**

SleepGels NDC 35916-0438-1

Diphenhydramine Hydrochloride Capsules USP 50 mg

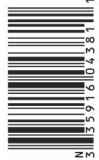
NIGHTTIME SLEEP-AID

- fall asleep fast
- sleep soundly
- safe, non-habit forming

100 SoftGels ** 

**liquid-filled capsules one softgel per dose

Drug Facts	Purpose
<p>Active ingredient (in each softgel) Diphenhydramine Hydrochloride USP 50 mg.....Nighttime sleep-aid</p> <p>Use</p> <ul style="list-style-type: none"> for relief of occasional sleeplessness <p>Warnings</p> <ul style="list-style-type: none"> Do not use for children under 12 years of age with any other product containing diphenhydramine, even one used on skin <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> a breathing problem such as emphysema or chronic bronchitis glaucoma trouble urinating due to an enlarged prostate gland <p>Ask a doctor or pharmacist before use if you are taking</p> <p>sedatives or tranquilizers</p> <p>When using this product, avoid alcoholic drinks</p> <p>Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.</p> <p>Directions</p> <ul style="list-style-type: none"> adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor <p>Inactive ingredients propylene glycol, polyethylene glycol 600, polyethylene glycol 400, gelatin, glycerin, sorbitol sorbitan solution, FD & C blue No.1, purified water</p>	<p>Drug Facts</p> <p>Active ingredient (in each softgel) Diphenhydramine Hydrochloride USP 50 mg.....Nighttime sleep-aid</p> <p>Use</p> <ul style="list-style-type: none"> for relief of occasional sleeplessness <p>Warnings</p> <ul style="list-style-type: none"> Do not use for children under 12 years of age with any other product containing diphenhydramine, even one used on skin <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> a breathing problem such as emphysema or chronic bronchitis glaucoma trouble urinating due to an enlarged prostate gland <p>Ask a doctor or pharmacist before use if you are taking</p> <p>sedatives or tranquilizers</p> <p>When using this product, avoid alcoholic drinks</p> <p>Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.</p> <p>Directions</p> <ul style="list-style-type: none"> adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor <p>Inactive ingredients propylene glycol, polyethylene glycol 600, polyethylene glycol 400, gelatin, glycerin, sorbitol sorbitan solution, FD & C blue No.1, purified water</p>



Mfg. Lic. No.: TN00002123

Manufactured by:
Softgel Healthcare Pvt. Ltd.
Survey No. 201,
Vandalur-Keimbakkam Road,
Pudupakkam Village,
Kanchipuram District,
Tamilnadu - 603103,
India.

NVZ

LH - 26x15 mm

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0438
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	blue ((Transparent))	Score	score with uneven pieces
Shape	CAPSULE ((Oval))	Size	13mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0438-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2024	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	01/10/2024	

Labeler - Softgel Healthcare Pvt Ltd (675584180)

Establishment

Name	Address	ID/FEI	Business Operations
SOFTGEL HEALTHCARE PRIVATE LIMITED		675584180	manufacture(35916-0438)

Revised: 3/2024

Softgel Healthcare Pvt Ltd