

**SLEEP-AID DIPHENHYDRAMINE HCL- diphenhydramine hydrochloride capsule,
liquid filled**

Cardinal Health 110, LLC. DBA Leader

Sleep-Aid Diphenhydramine HCl

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

- for relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not use •for children under 12 years of age •with any other product containing diphenhydramine, even one used on skin •with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

Ask a doctor before use if you have •glaucoma •heart diseases •a breathing problem such as emphysema, asthma, or chronic bronchitis
•difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives, tranquilizers, or any other sleep aid

When using this product •avoid alcoholic beverages and other drugs that cause drowsiness. Be careful when driving a motor vehicle or operating machinery.

Stop use and ask a doctor if sleeplessness persists 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. Overdose warning: In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions

- take only one dose per day (24 hours)

adults and children 12 years and over	take 2 softgels at bedtime if needed or as directed by a doctor
children under 12 years	do not use

Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

Inactive ingredients

edible white ink, FD&C blue#1, FD&C red#40, gelatin, glycerin, isopropyl alcohol, medium chain triglycerides, polyethylene glycol, povidone, purified water, sorbitol sorbitan solution

Questions or comments?

1-888-577-8033 Monday-Friday 8am-4pm EST

LEADER™

Non-Habit Forming

Not for Treating Pain, Cold or Flu

COMPARE TO VICKS® ZZZQUIL® NIGHTTIME SLEEP-AID LIQUICAPS® active ingredient*

100% Money Back Guarantee

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark VICKS® ZzzQuil® NIGHTTIME SLEEP-AID LiquiCaps®.

All LEADER™ Brand Products Have A 100% Money Back Guarantee

Return to place of purchase if not satisfied.

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

CardinalHealth™

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

Essential to Care™ since 1979

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Product of UAE

Packaged and Quality Assured in the USA

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS SIGNS OF TAMPERING

Packaging



SLEEP-AID DIPHENHYDRAMINE HCL			
diphenhydramine hydrochloride capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0584
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	purple	Score	no score
Shape	OVAL (oblong)	Size	15mm
Flavor		Imprint Code	779
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0584-1	1 in 1 CARTON	09/15/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	09/15/2021	

Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)