

NIGHT TIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled
Harmon Stores

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

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

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on skin
- for children under 12 years of age
- with other drugs that cause drowsiness such as antihistamines, nighttime cold/flu products, and other nighttime sleep-aids

Ask a doctor before use if you have

- a breathing problem such as asthma, emphysema, or chronic bronchitis
- glaucoma
- heart disease
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers or any other sleep-aid.

When using this product

- drowsiness will occur
- 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 serious underlying medical illness.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take only one dose per day (24 hours) - see Overdose warning
- swallow whole; do not crush, chew, or dissolve
- adults & children 12 yrs & over
 - one dose= TWO 25 mg softgels (50 mg) at bedtime if needed or as directed by a doctor

Other information

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

Inactive ingredients

edible white ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol 400, propylene glycol*, purified water, sorbitan, sorbitol

*may contain this ingredient

Questions or comments?

Call 1-877-753-3935 Monday- Friday 9AM-5PM EST

Principal Display Panel

Compare Ours to the active ingredient in ZZZQUIL®†

Nighttime Sleep-Aid

Diphenhydramine HCl 25 mg

Non Habit- Forming

Not for treating cold or flu

See warnings

Failure to follow these warnings could result in serious consequences.

Softgels

†This product is not manufactured or distributed by The Procter & Gamble Company. ZZZQUIL® is a registered trademark of The Procter & Gamble Company.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

Distributed by

Harmon Stores, Inc

650 Liberty Ave, Union, NJ 07083 USA

www.facevalues.com

Product Label

0 3 3 1 2 8 0 1



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Drug Facts (continued)

Active ingredient
Diphenhydramine HCl 25 mg.....Nighttime sleep-aid

Purpose

Warnings

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- for children under 12 years of age
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- trouble urinating due to an enlarged prostate gland

When using this product

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- avoid alcoholic beverages and other drugs that cause drowsiness
- be careful when driving a motor vehicle or operating machinery

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Drug Facts

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"may contain this ingredient"

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Night Time Sleep-Aid

Non-Habit Forming

Diphenhydramine HCl 25 mg

HARMON® FACEVALUES™

Compare Ours to the Active Ingredient in ZZZQUIL®!

Night Time Sleep-Aid

Non-Habit Forming

Diphenhydramine HCl 25 mg



Actual Size

24 Softgels

Not for treating Cold or Flu See Warnings

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Lot No.:
Exp. Date:



Harmon Night Time Sleep Aid Softgels

NIGHT TIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-404
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: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	A1;602
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:63940-404-24	24 in 1 CARTON	02/28/2015	12/31/2021
1		1 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 FINAL	part338	02/28/2015	12/31/2021

Labeler - Harmon Stores (804085293)

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Harmon Stores