

EZ NITE SLEEP NIGHTTIME SLEEP-AID- diphenhydramine hydrochloride capsule, liquid filled

QUALITY CHOICE (Chain Drug Marketing Association)

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 a 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

FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol-sorbitan solution, titanium dioxide

Questions or comments?

Call **1-248-449-9300** Monday-Friday 9AM-5PM EST

Principal Display Panel

*Compare to the active ingredient in ZZZQUIL®

EZ Nite Sleep

Nighttime Sleep-Aid

Diphenhydramine HCl 25 mg

Non Habit-Forming

Not for Treating Cold or Flu | See Warnings

Softgels**

(**Liquid-filled capsules)

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Novi, MI 48376-0995

www.qualitychoice.com

Product of Canada

Failure to follow these warnings could result in serious consequences.

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.

Product Label

<p>Drug Facts</p> <p>Active ingredient (in each softgel) Diphenhydramine HCl 25 mg.....Nighttime sleep-aid</p> <p>Purpose</p> <p>for the relief of occasional sleeplessness</p> <p>reduces time to fall asleep if you have difficulty falling asleep</p> <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> a breathing problem such as asthma, emphysema, or chronic bronchitis glaucoma heart disease trouble urinating due to an enlarged prostate gland <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep-aid.</p> <p>When using this product</p> <ul style="list-style-type: none"> drowsiness will occur avoid alcoholic beverages and other drugs that cause drowsiness be careful when driving a motor vehicle or operating machinery <p>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.</p>	<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> 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 <p>Other information</p> <ul style="list-style-type: none"> store at 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F) and high humidity protect from light <p>Inactive ingredients FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol-sorbitan solution, titanium dioxide</p> <p>Questions or comments?</p> <p>Call 1-248-449-9300 Monday-Friday 9AM-5PM EST</p> <p>This product is not manufactured or distributed by The Procter & Gamble Company. WICKS®, LIQUICAPS®, and ZZZQUIL® are registered trademarks of The Procter & Gamble Company.</p>
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EZ Nite Sleep

Diphenhydramine HCl 25 mg
Non Habit-Forming

NDC 63868-014-48



*Compare to the active ingredient in ZZZQUIL®

EZ Nite Sleep

Nighttime Sleep-Aid

Diphenhydramine HCl 25 mg
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Not for Treating Cold or Flu | See Warnings



48 Softgels



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PLD-B
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Lot No.:
Exp. Date:

EZ NITE SLEEP NIGHTTIME SLEEP-AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-014
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)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	A41
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-014-48	4 in 1 CARTON		
1		12 in 1 BLISTER PACK		
2	NDC:63868-014-24	2 in 1 CARTON		
2		12 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	03/11/2013	

Revised: 3/2013

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