

PREMIER VALUE NIGHTTIME SLEEP AID SOFTGELS- diphenhydramine hydrochloride capsule, gelatin coated
Chain Drug Consortium

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.

PREMIER VALUE SLEEP-AID SOFTGELS

Drug Facts

Active ingredients (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

- 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

- a breathing problem such as asthma, emphysema, or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease

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

When using this product

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- 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

adults & children 12 yrs & over	One dose = TWO 25 mg Softgels (50 mg) at bed time if needed or as directed by a doctor
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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, methylparaben, polyethylene glycol, propylparaben, purified water, sorbitol, titanium dioxide

Failure to follow these warnings could result in serious consequences

TAMPER EVIDENT: This package is safety sealed & child resistant. Use only if blisters are intact. If difficult to open, use scissors.

Distributed by:

Chain Drug Consortium LLC.

3301 N.W. Boca Raton Blvd.

Suite 101, Boca Raton FL 33431

*This product is not manufactured or distributed by Procter & Gamble, the distributor of ZzzQuil® Liquicaps.

PRINCIPAL DISPLAY PANEL

Premier Value

Nighttime

Sleep-Aid Softgels

Diphenhydramine HCl

Non Habit Forming

Not for treating Cold or Flu

See Warnings

Compare to ZzzQuil® Liquicaps® active ingredient*

24 SOFTGELS

Nighttime Sleep-Aid Softgels

24 SOFTGELS

NDC 68016-218-25

COMPARE TO ZZZQUIL® LIQUICAPS® ACTIVE INGREDIENT*



Nighttime Sleep-Aid Softgels

Diphenhydramine HCl
Non-Habit Forming

24 SOFTGELS See Warnings Not for treating Cold or Flu



LOT:

EXP:

Nighttime Sleep-Aid Softgels

Nighttime Sleep-Aid Softgels

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 If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.



PREMIER VALUE NIGHTTIME SLEEP AID SOFTGELS
diphenhydramine hydrochloride capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-218
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 in 2

Inactive Ingredients

Ingredient Name	Strength
FD&C Blue No. 1 (UNII: HBR47K3TBD)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
gelatin (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
polyethylene glycols (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sorbitol (UNII: 506T60A25R)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	R060
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-218-25	12 in 1 CARTON	11/14/2014	
1		2 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	11/14/2014	

Labeler - Chain Drug Consortium (101668460)