

NIGHTTIME SLEEP AID- diphenhydramine hcl tablet
We Care Distributor Inc

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 tablet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

provides relief of occasional sleeplessness

Warnings

Do not use

- with any other products containing diphenhydramine, even one used on skin
- in children under 12 years of age

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operating a 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.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- do not take more than directed
- adults and children 12 years of age and over - take 2 tablets at bedtime if needed or as directed by a doctor
- children under 12 years of age: do not use

Other Information

- each caplet contains; calcium 25 mg
- store at controlled room temperature 15°-30°C (59°-86°F)
- avoid excessive heat and humidity

Inactive Ingredients

Colloidal silicon dioxide, Croscarmellose sodium, Dicalcium phosphate, FD&C Blue #1, FD&C Blue #2, Magnesium stearate, Microcrystalline cellulose, Polyethylene glycol, Polyvinyl alcohol, Talc, Titanium dioxide

Questions or comments?

Call: 1-800-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

Principal Display Panel

NDC: 70005-014-25



NIGHTTIME SLEEP AID

COMPARE TO ACTIVE INGREDIENT IN

Tylenol® Simply Sleep®*

TABLETS

Diphenhydramine HCl, 25 mg
Helps You Fall Asleep

• Easy To Swallow • Non-Habit Forming

Does not contain pain reliever

*This product is not manufactured or distributed by McNeil Consumer HealthCare, owner of the registered trademarks Tylenol® and Simply Sleep®.



25 Pouches of 2 Coated Tablets

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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Diphenhydramine HCl 25 mg	Nighttime sleep-aid

Uses provides relief of occasional sleeplessness

Warnings

Do not use

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- in children under 12 years of age

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- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate 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 right away.

Directions

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Questions or Comments
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Manufactured For / Distributed By:
We Care Distributor Inc.
Hermitage, TN 37076
www.wecaredistributor.com

DO NOT USE IF POUCH IS BROKEN OR TORN

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NIGHTTIME SLEEP AID

diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-014
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	EC
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-014-25	25 in 1 BOX		
1		4 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70005-014-50	50 in 1 BOX		
2		4 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70005-014-02	2 in 1 BOX		
3		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/04/2016	

Labeler - We Care Distributor Inc (079832998)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuthical Ltd.		915664486	manufacture(70005-014)

Revised: 2/2016

We Care Distributor Inc