

NIGHTTIME SLEEP-AID - diphenhydramine hcl tablet
Geri-Care Pharmaceutical Corp

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.

Active ingredient (in each caplet)

Diphenhydramine Hydrochloride 25mg

Purpose

Nighttime Sleep-aid

Uses

- relieves occasional sleeplessness

Warnings

Do not use

- in children under 12 years
- with any other product containing diphenhydramine, including one used on skin

Ask a doctor before use if you have

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

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

When using this product

- avoid alcoholic beverages
- drowsiness will occur
- avoid driving a motor vehicle or operating machinery

Stop use and ask a doctor if • sleeplessness persists continuously for more than two 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and over: take two caplets at bedtime if needed, or as directed by a doctor
- do not exceed recommended dose

Other information

- **each caplet contains:** calcium 85mg
- store at room temperature 15°C - 30°C (59°F - 86°F)

Inactive ingredients

calcium phosphate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, silica.

package label

NDC 57896-785-72

Health Star

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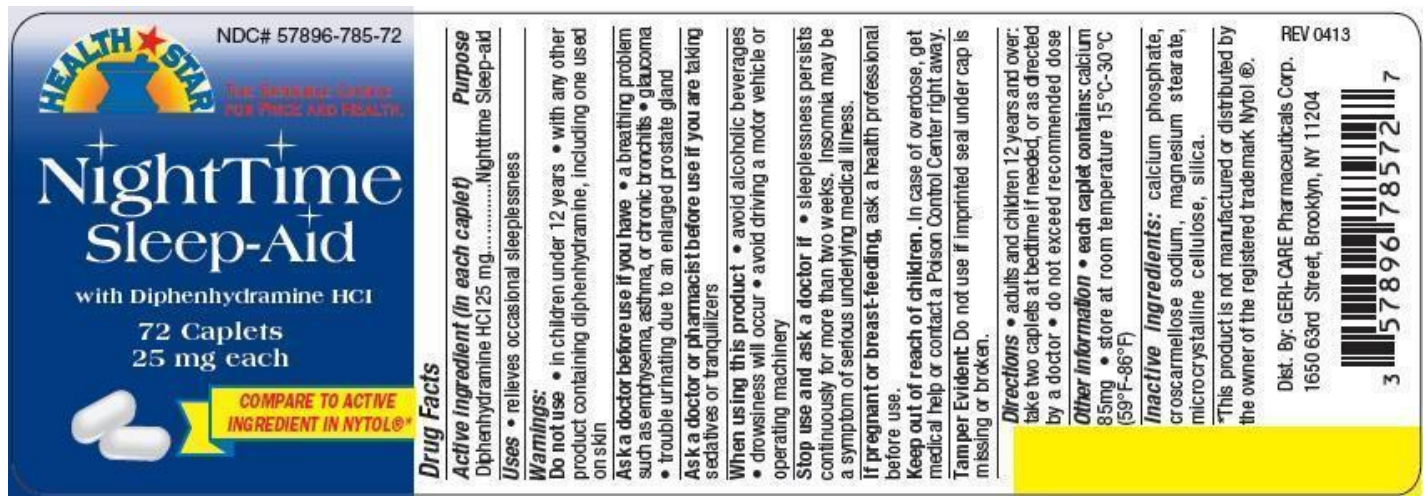
NightTime Sleep-Aid

with Diphenhydramine HCl

72 Caplets

25 mg each

Compare to active ingredient in Nytol



NIGHTTIME SLEEP-AID			
diphenhydramine hcl tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-785
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	93XF;57344
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-785-72	72 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	01/01/2004	

Labeler - Geri-Care Pharmaceutical Corp (611196254)**Registrant** - Geri-Care Pharmaceutical Corp (611196254)

Revised: 12/2013

Geri-Care Pharmaceutical Corp