

SLEEP AID- diphenhydramine hcl 25 mg tablet
Pioneer Life Sciences, LLC

Nighttime Sleep Aid

Active Ingredient (*in each caplet*)

Diphenhydramine HCl 25mg

Purpose

Night Time Sleep Aid

Uses:

for relief of occasional sleeplessness

Warnings:

Do not use:

■ in children under 12 years of age ■ with any other product containing diphenhydramine, even one used on skin.

Ask a doctor before use if you have:

- a breathing problem such as, emphysema 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 drinks
- drowsiness will occur
- do not drive a motorvehicle or operate machinery.

Stop use and ask a doctor if:

■ sleeplessness persist 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: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**(See overdose warning)

■ adults and children 12 years and over: take 2 caplets at bedtime if needed or as directed by doctor

■ children under 12 years: do not use

OTHER INFORMATION

■ each caplet contains: calcium 23.52 mg

■ store between 15-30°C (59-86°F).

■ Avoid high humidity.

■ Protect from light.

INACTIVE INGREDIENTS

Colloidal Silicon, Croscarmellose, Sodium, Dicalcium Phosphate, FD&C Blue#1, FD&C Blue#2, Lethicin, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol , Titanium Dioxide, Talc.

QUESTIONS OR COMMENTS?

Call toll free **1-732-698-5070** Mon to Fri 9am – 5pm.

PRINCIPAL DISPLAY PANEL

Prepare to SIMPLY SLEEP[®]
as the ingredient.

GenCare
generic healthcare

Sleep-Aid
nighttime sleep-aid

**Diphenhydramine HCl
25mg**

- Does Not Contain Pain Reliever
- Non-Habit Forming

100 caplets not actual size

TAMPER EVIDENT Do not use if safety seal under cap is broken or missing.

Drug Facts

Active Ingredient (in each caplet) **Purpose**
Diphenhydramine HCl 25mg Night Time Sleep Aid

Uses: for relief of occasional sleeplessness

Warnings: Do not use: ■ in children under 12 years of age ■ with any other product containing diphenhydramine, even one used on skin.

Ask a doctor before use if you have:
■ a breathing problem such as, emphysema 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 drinks ■ drowsiness will occur ■ 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 serious underlying

(continued under label)

Distributed by: **GenCare Consumer Products, LLC**
40E Cotters Ln, Suite A, East Brunswick, NJ 08816

PL0080-00

PEEL HERE

Peel Off Label - Inside part

Drug Facts (continued)

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. (1-800-222-1222).

Directions: ■ do not take more than directed (See overdose warning) ■ adults and children 12 years and over: take 2 caplets at bedtime if needed or as directed by doctor ■ children under 12 years: do not use

Other Information: ■ each caplet contains calcium 23.52 mg ■ store between 15-30°C (59-86°F). ■ Avoid high humidity. ■ Protect from light

Inactive Ingredients: Colloidal Silicon, Croscarmellose, Sodium Dicalcium Phosphate, FD&C Blue#1, FD&C Blue#2, Lefthion, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Titanium Dioxide, Talc.

Questions or Comments? Call toll free 1-772-688-5070 Mon to Fri 9am - 5pm.

†This product is not manufactured or distributed by Moheli Consumer Healthcare, owner of the Registered Trademark Tylenol® Simply Sleep®.

.5" Glue Area

SLEEP AID

diphenhydramine hcl 25 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72090-020
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TALC (UNII: 7SEV7J4R1U)				
Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE	Size	11mm	
Flavor		Imprint Code	S5	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-020-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010		06/29/2020	

Labeler - Pioneer Life Sciences, LLC (014092742)