

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

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**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<sup>®</sup>  
 25mg hydroxyzine

**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

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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:  
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 sleeplessness persist 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**



Lot No. \_\_\_\_\_  
 Exp. Dt. \_\_\_\_\_

**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, Talk.

**Questions or Comments?** Call toll free 1-732-688-5070 Mon to Fri 9am - 5pm.

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

**.5" Glue Area**

**SLEEP AID**

diphenhydramine hcl 25 mg tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72090-020
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	S5
<b>Contains</b>			

### 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)