

**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



# Sleep-Aid

nighttime sleep-aid

**Diphenhydramine HCl  
 25mg**

- Does Not Contain Pain Reliever
- Non-Habit Forming



not actual size

**100 caplets**

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 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



X002ISYS5

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)<br>(DIPHENHYDRAMINE - UNII: 8GTS82S83M) | DIPHENHYDRAMINE<br>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: 3WJQ05DW1A) |  |
| <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)