

ONLY FOR SLEEP- diphenhydramine hcl tablet
O4 Global Trading Usa, Llc

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.

Only For- SLEEP

DRUG FACTS

Active ingredient (in each caplet)

Diphenhydramine HCL 25mg

Purpose

Nighttime 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 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 medical illness.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children

Overdose Warning: In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions:

- take with a full glass of water
- **do not take more than directed**

| | |
|--|--|
| adults and children 12 years of age and over | 2 caplets at bedtime if needed, or as directed by a doctor |
| children under 12 years of age | do not use |

Other Information:

- Store at room temperature between 20-25°C (68-77°F)
- Avoid high humidity • Protect from light

Inactive Ingredients:

Croscarmellose sodium, D&C blue #4 aluminium lake, dibasic calcium phosphate, hydroxy propyl methyl cellulose, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, titanium dioxide.

Questions Or Comments ?

1-833-665-9444.

NDC: 73006-111-41

NIGHTTIME SLEEP-AID

Distributed By: O4 GLOBAL TRADING USA LLC., 2241 S Watson RD, Suite 121 Arlington, TX 76010.

www.onlyfor.com

Packaged By: Strive Pharmaceuticals Inc., East Brunswick, NJ 08816.

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF A BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING.

Tear along perforation push product through foil

Packaging

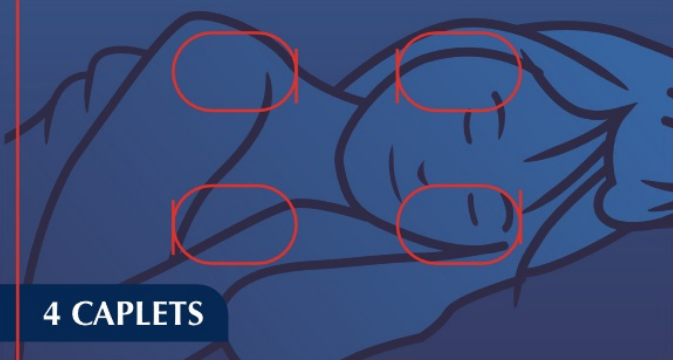


NDC: 73006-111-41

Only For™

SLEEP NIGHTTIME SLEEP-AID

Diphenhydramine HCl 25mg / Sleep aid



4 CAPLETS



LOT: K002A

EXP: 05/20

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www.onlyfor.com

CT2DMR4-REV.102018

ONLY FOR SLEEP

diphenhydramine hcl tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73006-111 |
| 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 |
|--|----------|
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| D&C BLUE NO. 4 (UNII: 0KSY80VYS3) | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |
| HYPROMELLOSE 2910 (5 MPAS) (UNII: R75537T0T4) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| MAGNESIUM PALMITOSTEARATE (UNII: R4OXA9G5BV) | |
| MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|----------|---------------|--------------|----------|
| Color | blue | Score | no score |
| Shape | OVAL (CAPLET) | Size | 12mm |
| Flavor | | Imprint Code | S1 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:73006-111-41 | 1 in 1 CARTON | 03/29/2019 | |
| 1 | | 4 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part338 | 03/29/2019 | |

Labeler - O4 Global Trading Usa, Llc (081226861)

Revised: 4/2019

O4 Global Trading Usa, Llc