

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine
hydrochloride capsule
CVS Pharmacy, Inc**

5347K-CVS

Drug Facts

Active ingredient (in each mini-capsule)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Use

for relief of occasional sleeplessness

- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
- 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 beverages.

Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a 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 (1-800-222-1222) right away.

Directions

- **adults and children 12 years and over:** take 2 mini-capsules (50 mg) at bedtime if needed, or as directed by a doctor

Other information

- store in a dry place at 15° – 30°C (59° – 86°F)
- use by expiration date on package
- protect from moisture

anhydrous citric acid, corn starch, FD&C blue #1, FD&C red #3, gelatin, lactose monohydrate, magnesium stearate, polysorbate 80, potassium sorbate, sodium lauryl sulfate, titanium dioxide.

Questions or comments?

1-800-231-4670

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
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CVS.com® 1-800-SHOP CVS

Product of China. Manufactured and packaged in the U.S.A. using domestic and imported ingredients.

V-34571

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TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING OR IF BLUE BAND AROUND CAPSULE IS BROKEN OR MISSING.

Compare to the active ingredient in Unisom® SleepMinis®*

Nighttime
DIPHENHYDRAMINE HCl, 25 mg
Nighttime sleep-aid
Non-habit forming

120 MINI-CAPSULES



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51316-347 |
| 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 |
|---|----------|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| GELATIN (UNII: 2G86QN327L) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |

| | |
|---|--|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| FD&C RED NO. 3 (UNII: PN2ZH5LOQY) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | blue | Score | no score |
| Shape | CAPSULE | Size | 14mm |
| Flavor | | Imprint Code | 5347 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:51316-347-05 | 1 in 1 CARTON | 02/02/2023 | |
| 1 | | 120 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:51316-347-06 | 365 in 1 BOTTLE; Type 0: Not a Combination Product | 04/20/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M010 | 02/02/2023 | |

Labeler - CVS Pharmacy, Inc (062312574)

Revised: 2/2024

CVS Pharmacy, Inc