

NIGHTTIME SLEEP AID- diphenhydramine hydrochloride tablet
Chain Drug Marketing Association

QCH - 1019- 2019-1004

Drug Facts

Active ingredient (in each tablet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Use

helps to reduce difficulty falling asleep

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

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.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years of age and over: take two tablets at bedtime if needed, or as directed by a doctor

Other information

- each tablet contains: **calcium 85 mg**
- store at room temperature 15-30°C (59-86°F)
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate, FD&C blue #1, magnesium stearate, microcrystalline cellulose

PRINCIPAL DISPLAY PANEL

NDC 63868-611-32

QUALITY CHOICE

†Compare to SOMINEX® active ingredient

Nighttime Sleep Aid

Original Formula

Diphenhydramine HCl, 25mg

Get to sleep safely, wake up refreshed

32 Tablets



NIGHTTIME SLEEP AID

diphenhydramine hydrochloride tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-611 |
| 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) | |
| CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|------------|
| Color | blue | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | 93XF;57344 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63868-611-32 | 4 in 1 CARTON | 06/25/2007 | 04/30/2027 |
| 1 | | 8 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 Drug | M010 | 06/25/2007 | 04/30/2027 |

Labeler - Chain Drug Marketing Association (011920774)