

REST SIMPLY- diphenhydramine hydrochloride tablet, coated
Chain Drug Marketing Association

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.

1091 - QCH - 2014-1028

Drug Facts

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Use

for relief of occasional sleeplessness

Warnings

Do not use

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

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

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

Other information

- each caplet contains: **calcium 45 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, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

PRINCIPAL DISPLAY PANEL

NDC 63868-772-24

QUALITY CHOICE

†Compare to Active Ingredient in SIMPLY SLEEP®

Rest Simply

Nighttime Sleep Aid

Diphenhydramine HCl

Safe and Non-Habit Forming

Does Not Contain Pain Reliever

24 Caplets – 25 mg Each





REST SIMPLY

diphenhydramine hydrochloride tablet, coated

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-772 |
| 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) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |

| | |
|---|--|
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|-------------------------|------|--------------|----------|
| Color | blue | Score | no score |
| Shape | OVAL | Size | 11mm |
| Flavor | | Imprint Code | 25;052 |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:63868-772-24 | 2 in 1 CARTON | 06/13/2014 | |
| 1 | | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:63868-772-10 | 1 in 1 CARTON | 06/13/2014 | |
| 2 | | 100 in 1 BOTTLE, PLASTIC; 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 | 06/13/2014 | |

Labeler - Chain Drug Marketing Association (011920774)