

NIGHTTIME SLEEP AID MAXIMUM STRENGTH- diphenhydramine hydrochloride 50 mg capsule, liquid filled
EQUATE (Walmart Stores, Inc.)

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.

Nighttime Sleep-Aid

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

- for the relief of occasional sleeplessness

Warnings

Do not use

- for 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.

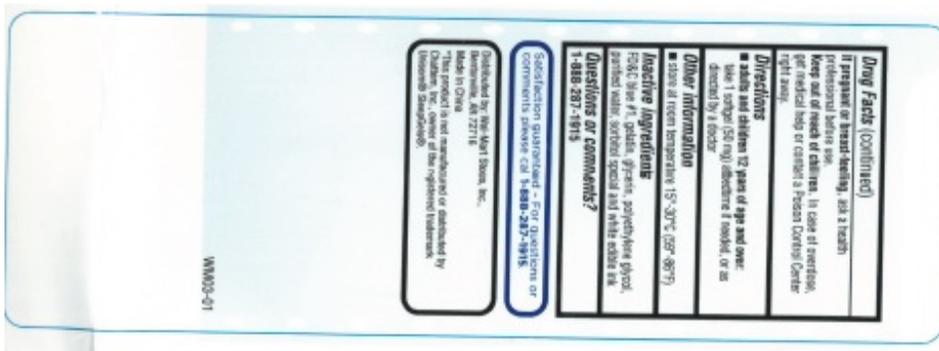
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years of age and over: take 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Other information

- store at 15°-30°C (59°-86°F)



NIGHTTIME SLEEP AID MAXIMUM STRENGTH

diphenhydramine hydrochloride 50 mg capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49035-237 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------|----------|
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 50 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GELATIN (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| WATER (UNII: 059QF0K00R) | |
| SORBITOL (UNII: 506T60A25R) | |

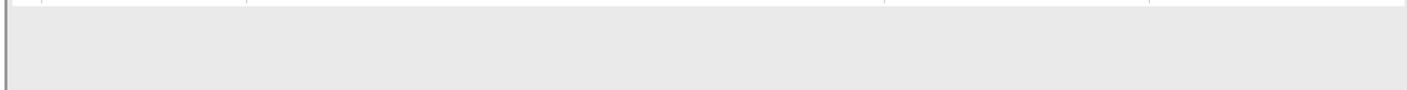
Product Characteristics

| | | | |
|-----------------|------------------|---------------------|----------|
| Color | blue | Score | no score |
| Shape | CAPSULE (oblong) | Size | 13mm |
| Flavor | | Imprint Code | PC5 |
| Contains | | | |

Packaging

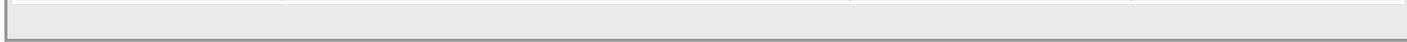
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:49035-237-16 | 1 in 1 CARTON | 10/31/2013 | |
| 1 | | 32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

| | | | |
|---|------------------|--|------------|
| 2 | NDC:49035-237-96 | 96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/31/2013 |
|---|------------------|--|------------|



Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 10/31/2013 | |



Labeler - EQUATE (Walmart Stores, Inc.) (051957769)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|--|
| Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd | | 421293287 | MANUFACTURE(49035-237) , ANALYSIS(49035-237) |

Revised: 11/2019

EQUATE (Walmart Stores, Inc.)