

**SLEEP AID NIGHTTIME- diphenhydramine hcl tablet
EQUATE (Wal-Mart 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.

Drug Facts

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

For relief of occasional sleeplessness

Warnings

Do not use

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

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 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 right away. (1-800-222-1222)

Directions

- take only one dose (2 caplets) per day (24 hours)
- 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 25 mg
- store between 20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

carnauba wax*, colloidal silicon dioxide*, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call **1-888-287-1915**

Principal Display Panel

**Compare to the active ingredient in Tylenol® Simply Sleep®†

Nighttime SLEEP-AI

Diphenhydramine HCl, 25 mg

Does not contain pain reliever

Fall asleep fast

Wake up rested

Non habit-forming

Caplets

**This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademarks Tylenol® and Simply Sleep®.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT

INFORMATION.

Distributed by: Wal-Mart Stores, Inc.,
Bentonville, AR 72716 © Wal-Mart Stores, Inc.

Product Label

Exp. Date: _____
Lot No.: _____
PLD-833F
F0005254

<p>Drug Facts Active ingredient (in each caplet) Diphenhydramine HCl 25 mg.....</p> <p>Use For relief of occasional sleeplessness.</p> <p>Warnings Do not use</p> <ul style="list-style-type: none"> ■ in children under 12 years of age ■ with any other products containing diphenhydramine, even one used on skin <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to an enlarged prostate gland <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</p> <p>When using this product, avoid alcoholic drinks.</p> <p>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.</p>	<p>Drug Facts (continued) Questions or comments? 1-888-287-1915</p> <p style="color: red; font-weight: bold; font-size: small;">TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.</p> <p style="color: red; font-weight: bold; font-size: small;">KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.</p>	<p>Drug Facts (continued) If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In the case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)</p> <p>Directions</p> <ul style="list-style-type: none"> ■ take only one dose (2 caplets) per day (24 hours) ■ 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 <p>Other information</p> <ul style="list-style-type: none"> ■ each caplet contains: calcium 25 mg ■ store between 20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F) <p>Inactive ingredients carnauba wax*, colloidal silicon dioxide*, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1, aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide *contains one or more of these ingredients</p>
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Product of India

GV 2014.0688



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NDC 49035-808-10
**Compare to the active ingredient in Tylenol® Simply Sleep®

Nighttime Sleep-Aid

Diphenhydramine HCl 25 mg

Does NOT contain pain reliever
Fall asleep fast
Wake up rested
Non habit-forming

100 Caplets



Actual Size

EQUATE Nighttime Sleep-Aid

SLEEP AID NIGHTTIME

diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-808
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	T129;S25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-808-10	1 in 1 BOX	09/07/2018	07/26/2024
1		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	09/07/2018	07/26/2024

Labeler - EQUATE (Wal-Mart Stores, Inc.) (051957769)

Revised: 10/2021

EQUATE (Wal-Mart Stores, Inc.)