## SLEEP AID NIGHTTIME- diphenhydramine hcl tablet Family Dollar (FAMILY WELLNESS)

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.

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#### **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

- 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 a serious underlying medical illness

#### If pregnant of 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

#### **Principal Display Panel**

COMPARE TO THE ACTIVE INGREDIENT IN TYLENOL® SIMPLY SLEEP®†

**NIGHTTIME** 

Sleep-Aid

Diphenhydramine HCI, 25 mg / Nighttime sleep aid

- Safe, Non Habit-Forming
- Does not Contain Pain Reliever
- Fall Asleep Fast & Wake Up Rested

#### **CAPLETS**

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 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: MIDWOOD BRANDS, LLC 10611 MONROE RD., MATTHEWS, NC 28105

**Product label** 

Exp. Date:

Lot No.:

SKU 0901496

NOT 100% SATISFIED? Return package and store for a refund (with receipt) or exchange. unused product within 30 days to any Family Dollar

**DISTRIBUTED BY: MIDWOOD BRANDS, LLC** 10611 MONROERD., MATTHEWS, NC 28105

# **Drug Facts** (continued)

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**Drug Facts** 

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**Orug Facts** (continued)

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COMPARE TO THE ACTIVE INGREDIENT IN TYLENOL® SIMPLY SLEEP®

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Diphenhydramine HCl. 25 mg/Nighttime Sleep-Aid

- Safe, Non Habit-Forming
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FAMILY ■ Wellness™

NDC 55319-800-01

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#### **FAMILY WELLNESS Nighttime Sleep-Aid**

#### **SLEEP AID NIGHTTIME**

diphenhydramine hcl tablet

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-800

**Route of Administration** ORAL

#### **Active Ingredient/Active Moiety**

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Ingredient Name	<b>Basis of Strength</b>	Strength
	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)	
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
NDC:55319- 800-01	1 in 1 BOX	07/31/2016	04/26/2024

1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:55319- 800-24	24 in 1 CARTON	07/31/2016	04/26/2024
2		1 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 final	part338	07/31/2016	04/26/2024

### Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 10/2021 Family Dollar (FAMILY WELLNESS)