# SLEEP AID- diphenhydramine hcl capsule EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART 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.

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#### **Drug Facts**

### Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

## **Purpose**

Nighttime sleep-aid

#### Use

for 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 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**

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

#### Other information

• store at 15-30°C (59°-86°F)

#### **Inactive ingredients**

edible white ink, FD&C blue #1, gelatin, glycerin, light mineral oil\*, polyethylene glycol, purified water, sorbitol-sorbitan

\*may contain this ingredient

## **Principal Display Panel**

#### Compare to Unisom® SleepGels® Active Ingredient\*\*

Maximum Strength

Sleep-Aid Softgels

Diphenhydramine HCI 50 mg

Nighttime sleep-aid

- Fall asleep fast
- Sleep soundly
- Wake up refreshed

Liquid Filled

Safe, Non Habit-Forming

One softgel per dose

**SOFTGELS** 

For Questions or comments or to report an undesired reactionor side effect, please call **1-888-287-1915.** 

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

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

\*\*This product is not manufactured or distributed by Chattem, Inc., distributor of Unisom® SleepGels®.

**DISTRIBUTED BY: Walmart Inc.,** 

Bentonville, AR 72716

#### Package Label



#### **SLEEP AID** diphenhydramine hcl capsule **Product Information HUMAN OTC DRUG** NDC:49035-935 **Product Type** Item Code (Source) **Route of Administration** ORAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength **DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6JAD40) **DIPHENHYDRAMINE** 50 mg **HYDROCHLORIDE** (DIPHENHYDRAMINE - UNII:8GTS82S83M)

Inactive Ingredients			
Ingredient Name	Strength		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
WATER (UNII: 059QF0KO0R)			
SORBITAN (UNII: 6092ICV9RU)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE	Size	13mm	
Flavor		Imprint Code	P50;A99;AP018	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:49035- 935-32	1 in 1 BOX	02/28/2018	12/27/2024		
1		32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
2	NDC:49035- 935-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/28/2018	12/27/2024		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part341	02/28/2018	12/27/2024		

Labeler - EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC) (051957769)

Revised: 9/2022 EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC)