

**UNISOM SLEEPGELS NIGHTTIME SLEEP-AID- diphenhydramine hcl capsule, liquid filled
Chattem, Inc.**

Unisom SleepGels Nighttime

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 persist 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: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Inactive ingredients

blue 1, gelatin, glycerin, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, sorbitol, titanium dioxide, water (309-153)

PRINCIPAL DISPLAY PANEL

Unisom
SleepGels
Diphenhydramine HCl
SoftGels, 50 mg
#1 Pharmacist Recommended Brand*
NIGHTTIME SLEEP-AID
32 SoftGels
One SoftGel per dose

UNISOM SLEEPGELS NIGHTTIME SLEEP-AID

diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0061
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: PDC6A3C00X)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	UNISOM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0061-0	1 in 1 CARTON	01/01/2007	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41167-0061-1	2 in 1 CARTON	01/01/2007	
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41167-0061-3	1 in 1 CARTON	01/01/2007	
3		32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:41167-0061-6	1 in 1 CARTON	01/01/2007	
4		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:41167-0061-2	1 in 1 CARTON	09/15/2017	
5		100 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:41167-0061-5	1 in 1 CARTON	01/01/2007	
6		40 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 Drug	M010	01/01/2007	

Labeler - Chattem, Inc. (003336013)

Revised: 10/2023

Chattem, Inc.