

SLEEP AID- diphenhydramine hcl capsule, liquid filled
Allegiant Health

410-Sleep Aid Diphenhydramine HCl 50mg

Active ingredient(s)

Diphenhydramine HCl 50mg

Purpose

Nighttime sleep aid

Use(s)

for relief of occasional sleeplessness

Warnings

Do not use

for children under 12 years of age

- with any other products containing diphenhydramine, even one used on skin

Ask a doctor before use if

- 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.

Pregnancy/Breastfeeding

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 (1-800-222-

1222) right away.

Directions

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

Other information

- do not use if imprinted safety seal under cap is broken or missing or
- do not use if blister unit is torn or open

Storage

store at room temperature 15° to 30°C (59° to 86°F) and avoid excessive heat

Inactive ingredients

FD&C blue #1, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution, white ink

Questions

Principal Display Panel

The image shows the principal display panel for Sleep Aid capsules. On the left is the product box, which is blue and white with a starry background. It features the HealthA2Z logo, the product name 'SleepAid', the active ingredient 'Diphenhydramine HCl 50mg', and '250 Softgels'. To the right of the box is a detailed information panel with the following sections:

- Drug Facts**
 - Active ingredient (in each softgel):** Diphenhydramine HCl 50mg
 - Purpose:** Nighttime sleep aid
 - Use:** for relief of occasional sleeplessness
 - Warnings:** Do not use for 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; 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 (1-800-222-1222) right away.
 - Directions:** adults and children 12 years and over: 1 softgel (50mg) at bedtime if needed, or as directed by a doctor
 - Other information:** store at room temperature 15° to 30°C (59° to 86°F) and avoid excessive heat; do not use if imprinted safety seal under cap is broken or missing; you may report side effects to 1-888-952-0050
 - Inactive ingredients:** FD&C blue #1, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution, white ink
- Barcode:** 3 69168 41003 9
- Lot:** UNVARNISHED
- Exp:**
- Manufacturer:** Allegiant Health, Deer Park, NY 11729

Sleep Aid

SLEEP AID

diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-410
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: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-410-09	10 in 1 CARTON; Type 0: Not a Combination Product	11/09/2020	
2	NDC:69168-410-03	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/09/2020	
3	NDC:69168-410-32	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2022	
4	NDC:69168-410-98	200 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	11/09/2020	

Labeler - Allegiant Health (079501930)

