

SLEEP AID- diphenhydramine hcl capsule, liquid filled
Allegiant Health

431 - Sleep Aid Diphenhydramine HCl 25mg

Active ingredient(s)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Use(s)

- for the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not use

- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
- with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

Ask a doctor before use if

- a breathing problem such as asthma, emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease

Ask a doctor or pharmacist before use if

you are taking sedatives or tranquilizers or any other sleep aid

When using this product

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

if sleeplessness persists continuously for more than 2 weeks.

- Insomnia may be a symptom of serious underlying medical illness.

If Pregnant or Breastfeeding,

ask a health professional before use.

Keep out of reach of children

Overdose warning: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

take only one dose per day (24 hours) - see Overdose warning

Adults and children 12 years and over: ONE dose = TWO 25 mg softgels (50 mg) at bed time if needed or as directed by a doctor

Other information

Do not use if blister unit is torn or open.

Do not use if imprinted safety seal under cap is broken or missing.

Storage

- store at 15-30° C (59-86° F)
- avoid excessive heat above 40° C (104° F) and high humidity
- Protect from light

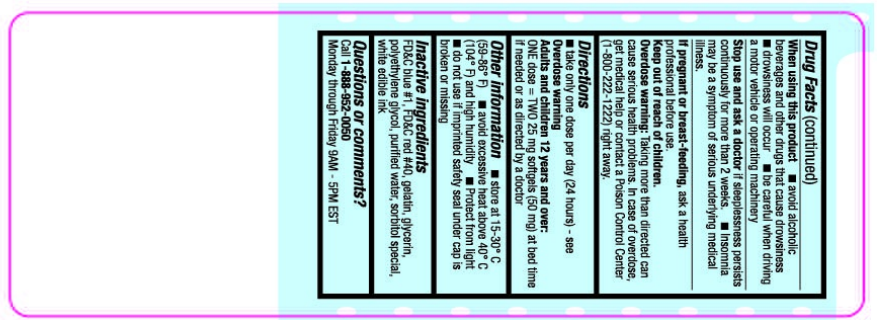
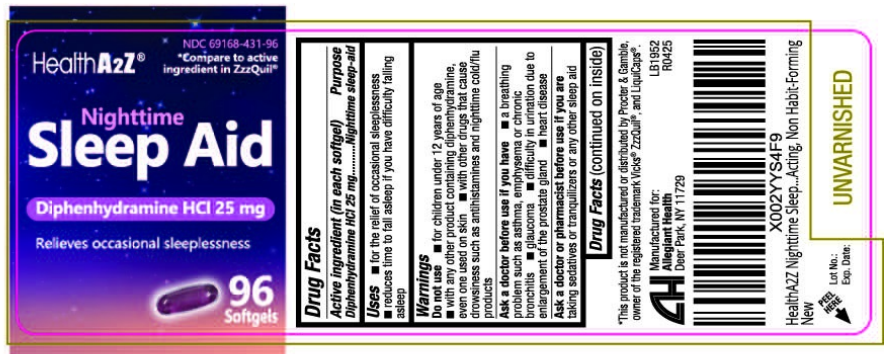
Inactive ingredients

FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol special, white edible ink

Questions

Call 1-888-952-0050 Monday through Friday 9AM - 5PM EST

Principal Display Panel



Sleep Aid

SLEEP AID

diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-431
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	

SORBITOL (UNII: 506T60A25R)

Product Characteristics

Color	purple	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	PC11
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-431-96	96 in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2021	
2	NDC:69168-431-86	1 in 1 CARTON	09/21/2021	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:69168-431-03	250 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M011	09/21/2021	

Labeler - Allegiant Health (079501930)

Revised: 8/2021

Allegiant Health