

SOUND BODY SLEEP AID- diphenhydramine hcl 25 mg tablet, coated

Allegiant Health

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.

SoundBody Sleep Aid

Active ingredient (in each caplet)

Diphenhydramine HCl 25mg

Purpose

Nighttime Sleep aid

Uses

for relief of occasional sleeplessness

Warnings

Do not use

- in 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 beverages
- drowsiness will occur
- do not drive a motor vehicle or operate machinery

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,

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

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Overdose Warning: 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: take 2 caplets at bedtime if needed or as directed by a doctor

children under 12 years of age: do not use

Other information

- store at room temperature store between 20-25°C (68-77°F)
- **do not use if blister unit is torn or open**

Inactive ingredients

croscarmellose sodium, FD&C blue #1 aluminum lake, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide

Principal Display Panel

SOUNDBODY™

Compare to the Active Ingredients in Simply Sleep®*

For Nighttime Use

Sleep Aid

Diphenhydramine HCl 25 mg

- Does not contain Pain Reliever

24 Caplets

(pill image) Actual Size

Distributed by: **Allegiant Health**

Deer Park, NY 11729

V#5003620 ITEM#FP064

LB1307

R0617

Questions or Comments?

1-888-952-0050



Sleep Aid 24 ct.

SOUND BODY SLEEP AID

diphenhydramine hcl 25 mg tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-910	
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	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
Product Characteristics				
Color	BLUE	Score	no score	
Shape	CAPSULE	Size	11mm	
Flavor		Imprint Code	AZ;263	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-910-93	2 in 1 CARTON	03/03/2015	
1		12 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	03/03/2015		

Labeler - Allegiant Health (079501930)