

SLEEP TABS FOR NIGHTTIME USE- diphenhydramine hcl tablets tablet Allegiant Health

Drug Facts

Active ingredient

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep aid

Uses

relief of occasional sleeplessness

Warnings

Do not use

- with any other products containing diphenhydramine, including one used on skin
- in children under 12 years of age

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

- marked drowsiness may occur
- avoid alcoholic beverages
- 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 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

In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately.

Directions

Adults and children 12 years and over	take 2 tablets at bedtime if needed or as directed by a doctor
Children under 12 years of age	do not use

Inactive Ingredients

croscarmellose sodium, dicalcium phosphate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide

Package/Label Principal Display Panel

3 69168 24724 6

Lot:

Exp:

Diphenhydramine HCl 25mg

SLEEP TABS FOR NIGHTTIME USE			
diphenhydramine hcl tablets tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-247
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	AZ247
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-247-24	24 in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product	04/28/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/28/2015	

Labeler - Allegiant Health (079501930)

Revised: 12/2018

Allegiant Health