GOOD SENSE SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled
L. Perrigo Company

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.

Perrigo Sleep Aid Softgels 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 persists 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 (1-800-222-1222).

Directions

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

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

edible ink*, FD&C blue #1, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution *may contain this ingredient

Questions or comments?

1-800-719-9260

Principal Display Panel

Non-Habit Forming

One Softgel Per Dose

Sleep Aid Softgels

Diphenhydramine HCl Softgels, 50 mg

Nighttime Sleep-Aid

Actual Size

Compare to active ingredient of Unisom® SleepGels®

100% SATISFACTION GUARANTEED

32 Softgels

GOOD SENSE SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0113-1909
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 (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	BLUE (clear to light blue)	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	5V6
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0113-1909-64	1 in 1 CARTON	05/30/2019	
1		32 in 1 BOTTLE; 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	05/30/2019	

Labeler - L. Perrigo Company (006013346)

Revised: 6/2019 L. Perrigo Company