REST SIMPLY- diphenhydramine hydrochloride tablet, coated Marc Glassman, Inc.

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.

1091 - MAR - 2022-1005

Drug Facts

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Use

for relief of occasional sleeplessness

Warnings

Do not use

- with any other product containing diphenhydramine, even 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
- trouble urinating due to an enlarged prostate gland
- glaucoma

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.

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	take 2 caplets at bedtime
	if needed, or as directed
of age and over	by a doctor
children under	do not use
12 years of age	uo not use

Other information

- each caplet contains: calcium 45 mg
- store at room temperature 15°-30°C (59°-86°F)
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate, FD&C blue #1, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

PRINCIPAL DISPLAY PANEL

Marc's®

NDC 68988-091-01

†Compare to the active ingredient in Simply Sleep® Caplets

Rest Simply

Diphenhydramine HCl

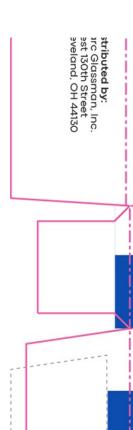
NIGHTTIME SLEEP-AID

Helps you fall asleep

Actual Size

24 CAPLETS - 25 MG EACH





asu fon ob	children under 12 years
take 2 caplets at bedtime if needed, or as directed by a doctor	adults and children 12 years and over
	nirections

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).

Drug Facts (continued)

Ask a doctor before use if you have

even one used on skin

in children under 12 years of age
 with any other product containing diphenhydramine,

Warnings Do not use

USE for relief of occasional sleeplessness

Active ingredient (in each caplet) Purpose Diphenhydramine HCl 25 mg........ Nighttime sleep-aid

Drug Facts



109101MAR



Rest Simply

Marc's.

NDC 68998-091-01

†Compare to the active ingredient in Simply Sleep® Caplets

Rest Simply

Diphenhydramine HCI

NIGHTTIME SLEEP-AID

Helps you fall asleep

Actual Size

24 CAPLETS - 25 MG EACH

JC

REST SIMPLY

diphenhydramine hydrochloride tablet, coated

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:68998-091

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

20

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

DIPHENHYDRAMINE HYDROCHLORIDE

25 mg

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYSORBATE 80 (UNII: 60ZP39ZG8H)				

Product Characteristics					
Color	blue	Score	no score		
Shape	OVAL	Size	11mm		
Flavor		Imprint Code	25;052		
Contains					

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
NDC:68998- 091-01	2 in 1 CARTON	12/31/2008				
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	12/31/2008		

Labeler - Marc Glassman, Inc. (094487477)

Revised: 10/2022 Marc Glassman, Inc.