

REST SIMPLY- diphenhydramine hydrochloride tablet, coated
DISCOUNT DRUG MART

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-DDM-2021-1124

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

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

Other information

- **each caplet contains:** calcium 45 mg
- store at room temperature 20-25°C (68-77°F)
- retain carton for complete product information

Inactive ingredients

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

PRINCIPAL DISPLAY PANEL

DISCOUNT drug mart FOOD FAIR

NDC 53943-191-01

Helps You Fall Asleep

Rest Simply

Nighttime Sleep-Aid

Contains:

Diphenhydramine HCl

* Non-Habit Forming, Use As Directed

† Compare to the active in SIMPLY SLEEP® Caplets

24 CAPLETS | 25 MG EACH





Drug Facts
 Diphenhydramine HCl 25 mg.....Nighttime sleep-aid
Active ingredient (in each caplet) Purpose
 Use 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
 ■ 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
 ■ drowsiness will occur
 ■ do not drive a motor vehicle or operate machinery
 Stop use and ask a doctor if

Drug Facts (continued)
 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
 take 2 caplets at bedtime if needed, or as directed by a doctor
 children under 12 years
 do not use
Other information
 ■ each caplet contains: calcium 45 mg
 ■ store between 20-25°C (68-77°F)
 ■ retain carton for complete product information
Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Product is not manufactured or
 sold by McNeil Consumer
 Care, distributor of Simply
 Caplets

**DO NOT USE IF BLISTER UNITS
 ARE CRACKED OR BROKEN**

Distributed by:
 Drug Mart - Food Fair
 211 Commerce Drive
 Medina, OH 44256

Rest Nighttime Sleep-Aid
Simply

Contains:
 Diphenhydramine HCl

* Non-Habit Forming, Use As Directed

24 CAPLETS | 25 MG EACH

† Compare to the active ingredient in SIMPLY SLEEP® Caplets

Rest Nighttime Sleep-Aid
Simply

NDC 53943-191-01

Helps You Fall Asleep

Contains:
 Diphenhydramine HCl

* Non-Habit Forming, Use As Directed

24 CAPLETS | 25 MG EACH

† Compare to the active ingredient in SIMPLY SLEEP® Caplets

REST SIMPLY
 diphenhydramine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-191
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
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

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
1	NDC:53943-191-01	4 in 1 PACKAGE	01/27/2010	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:53943-191-03	1 in 1 CARTON	07/10/2019	
2		100 in 1 BOTTLE, PLASTIC; 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	01/27/2010	

