REST SIMPLY- diphenhydramine hydrochloride tablet, coated Chain Drug Marketing Association

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 - QCH - 2014-1028

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.

Directions

adults and children	take 2 caplets at bedtime if
12 years of age and	needed, or as directed by a
over	doctor
children under 12 years of age	do 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

NDC 63868-772-24

QUALITY CHOICE

†Compare to Active Ingredient in SIMPLY SLEEP®

Rest Simply

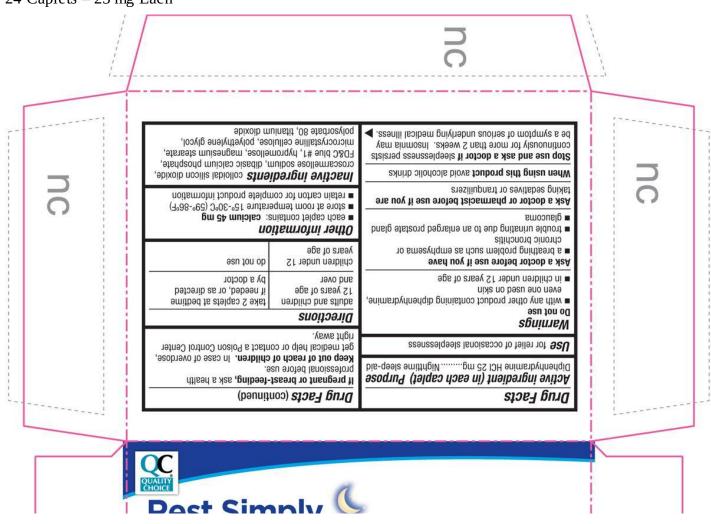
Nighttime Sleep Aid

Diphenhydramine HCl

Safe and Non-Habit Forming

Does Not Contain Pain Reliever

24 Caplets – 25 mg Each





REST SIMPLY

diphenhydramine hydrochloride tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-772	
Route of Administration	ORAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		

MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

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

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-772- 24	2 in 1 CARTON	06/13/2014	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63868-772- 10	1 in 1 CARTON	06/13/2014	
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	06/13/2014		

Labeler - Chain Drug Marketing Association (011920774)

Revised: 12/2018 Chain Drug Marketing Association