

SIMPLY SLEEP- diphenhydramine hydrochloride tablet, film coated
Johnson & Johnson Consumer Inc.

Simply Sleep

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
- 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
- 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.

Overdose warning

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 and over	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 15 mg**
- store between 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- **do not use if carton tape or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing**

Inactive ingredients

carnauba wax, croscarmellose sodium, dibasic calcium phosphate, FD&C Blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments?

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

FROM THE MAKERS OF
TYLENOL® PM

NDC 50580-843-12
Non-habit Forming

Simply
Sleep®

Diphenhydramine HCl
Nighttime Sleep Aid
Does NOT Contain Pain Reliever
*Capsule-Shaped Tablets

Actual Size

100 Caplets*

TIPS FOR A MORE Restful Night



Read a book or listen to soothing music to help you relax before bed



Keep your room cool and dark to prepare your body for sleep



Establish a sleep routine and keep a consistent bedtime schedule



Avoid caffeine in the late afternoon and evening

FROM THE MAKERS OF
TYLENOL[®]PM

NDC 50580-843-12

Non-habit Forming

Simply Sleep[®]

Actual Size

Diphenhydramine HCl

Nighttime Sleep Aid

Does NOT Contain Pain Reliever *Capsule-Shaped Tablets

100 Caplets^{*}

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children.
Over dose warning: 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 and over	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 15 mg
- store between 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- do not use if carton tape or foil inner seal imprinted with "SAFETY SEAL[®]" is broken or missing

Inactive ingredients carnauba wax, croscarmellose sodium, dibasic calcium phosphate, FD&C Blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments? call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

Active ingredient made in Japan

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

McNeil Consumer Healthcare Division

Fort Washington, PA 19054 USA

© J&J 2020

3 0047802



Tamper
area



Active ingredient (in each caplet) *Purpose*
Diphenhydramine HCl 25 mg, 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
- glaucoma
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

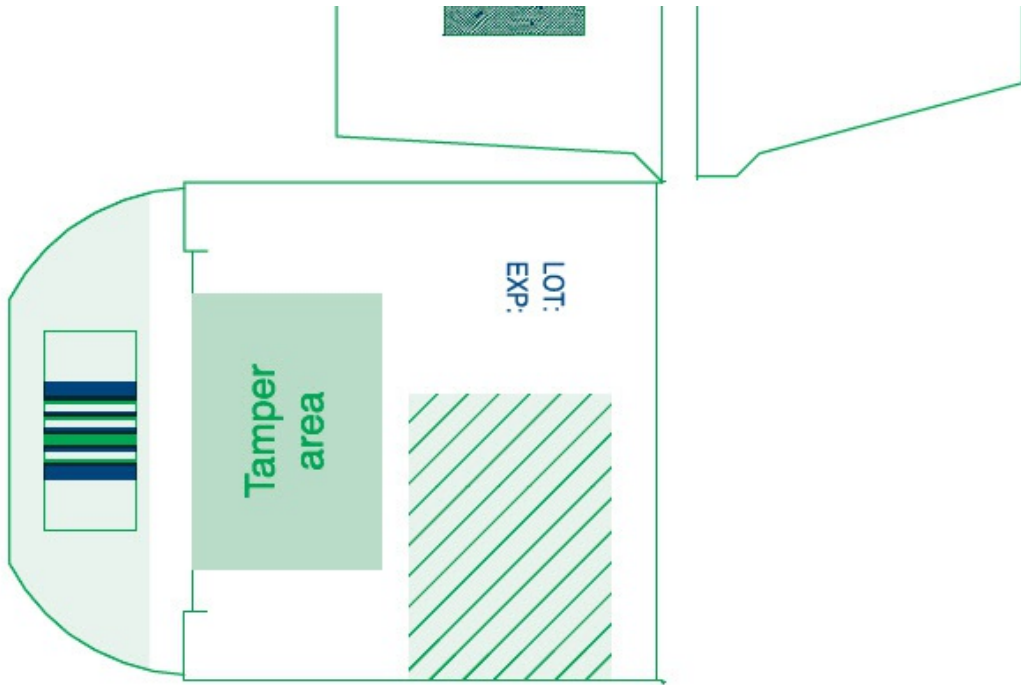
When using this product

- avoid alcoholic drinks
- drowsiness will occur
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- sleepiness persists continuously for more than 2 weeks.
- Insomnia may be a symptom of serious underlying medical illness.

Tamper
area



SIMPLY SLEEP

diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-843
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color		blue (Light blue)	Score	no score
Shape		OVAL	Size	13mm
Flavor			Imprint Code	SL
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-843-11	2 in 1 CARTON	09/26/2013	12/31/2020
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-843-12	1 in 1 CARTON	04/10/2013	
2		100 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 Drug		M010	02/01/2004	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024

Johnson & Johnson Consumer Inc.