

SIMPLY SLEEP- diphenhydramine hydrochloride tablet, film coated
Kenvue Brands LLC

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

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 (btl-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

Drug Facts

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

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

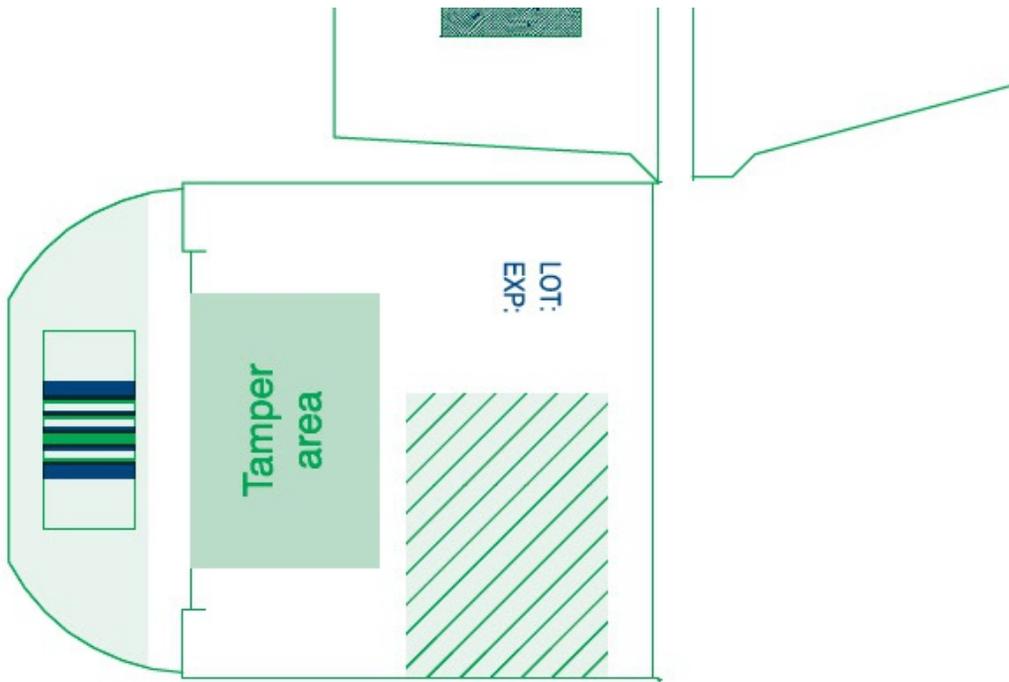
Tamper area

USA
697109
0907

3 0045-0843-104

Tamper area

001



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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELOSE 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)	

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 - Kenvue Brands LLC (118772437)

Revised: 6/2025

Kenvue Brands LLC