SLEEP AID- diphenhydramine hydrochloride tablet, film coated
Velocity Pharma LLC

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.

Sleep Aid

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 imprinted with "SAFETY SEAL®" is broken or missing or blister unit is torn or broken**

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

C5288ar

Drug Facts (continued)

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: sodium 0.5mg, calcium 25mg, magnesium 0.2mg
- Store between 20–25°C (67–77°F). Avoid high humidity.
- Protect from light.

Inactive ingredients
carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide.

Questions or comments?
Call: 1-855-314-1950

Drug Facts (continued)

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 a serious underlying medical illness.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Do not use if safety seal under cap is broken

Overdose warning: In the case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222).

NDC 76168-015-07

Helps you to get a restful night's sleep

Sleep Aid

Diphenhydramine HCl 25mg each Caplet USP
Nighttime Sleep Aid

36 Caplets

*Compares to active ingredients in Tylenol® Extra Strength

NDC 76168-015-07

Helps you to get a restful night's sleep

Sleep Aid

Diphenhydramine HCl
25mg each Caplet USP
Nighttime Sleep Aid

36 Caplets

76168 01507 2 3

LOT NO:

EXP:

Drug Facts

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

Uses: for the 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

Distributed by
VELOCITY PHARMA LLC
Farmingdale, NY 11735

SLEEP AID

diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76168-015
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 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
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	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	DB
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-015-07	1 in 1 CARTON	05/14/2018	
1		36 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:76168-015-12	1 in 1 CARTON	05/14/2018	
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 final	part338	05/14/2018	

Labeler - Velocity Pharma LLC (962198409)

Revised: 5/2018 Velocity Pharma LLC