## SLEEP AID- diphenhydramine hydrochloride tablet, film coated Publix Super Markets Inc

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.

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### Publix Super Markets, Inc. 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 may 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**

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

#### Other information

- each caplet contains: calcium 15 mg
- store at 68-77°F (20-25°C). Avoid high humidity. Protect from light.
- do not use if blister unit is broken or torn

#### **Inactive ingredients**

carnauba wax, crospovidone, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, stearic acid, titanium dioxide

## **Principal Display Panel**

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sleep aid

DIPHENHYDRAMINE HCl 25 mg

**ACTUAL SIZE** 

Nighttime Sleep Aid

- Does not Contain Pain Reliever
- For a restful night's sleep
- Safe, Non-Habit Forming

24 CAPLETS

Compare to Simply Sleep® Nighttime Sleep Aid active ingredient





NDC 56062-431-62

## sleepaid

DIPHENHYDRAMINE HCI 25 mg



ACTUAL SIZE



- Does Not Contain Pain Reliever
- · For a restful night's sleep
- Safe, Non-Habit Forming

**24** CAPLETS

Compare to Simply Sleep® Nighttime Sleep Aid active ingredient\*

# 43162 63 C8

## Drug Facts Active ingredient

Purpose

(in each caplet)
Diphenhydramine HCl 25 mg......Nigh time sleep-aid

Use for relief of occasional sle eplessness

#### Warnings

Do not use

- in children under 12 years of age with an yother product containing diph enhydramine, even one used on skin

#### Ask a doctor before use if you have

- a breathing problem such as emphyse ma or ch ronic b ron chitis
- glaucom a
- trouble uninating due to an enlarged prostate gland

Aska doctor or pharmacist before use if you are taking sedatives or tranquilizers

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

#### Drug Facts (continued)

Keep out of reach of children . O verdose 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 ove r	take 2 caple ts at bed time if needed, or as directed by a doctor
children under 12 vears	do not use

#### Other information

- ea ch c aplet contains: calcium 15 mg
- store at 68-77 °F (20-25°C). Avoid high hum idity. Protect from light.
- do notuse if blisterunit isbroken or torn

#### Inactive in gredients

camau ba wax, crospovidone, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, FD&Cblue #2 alu minu m lake, hyprome llose, magnesium steara te, microcrysta lli ne cellu lose, polyethyle ne glycol, polysorbate 80, pregel atin ized starch, stearicacid, titanium dioxide



INFORMATION

Publix.





\*This product is not manufactured or distributed by the owner of the registered trademark Simply Sleep®.

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## **SLEEP AID**

diphenhydramine hydrochloride tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-431	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)			
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics				
Color	BLUE (Light Blue)	Score	no score	
Shape	OVAL	Size	11mm	
Flavor		Imprint Code	L431	
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:56062-431- 62	12 in 1 CARTON	05/09/2002	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:56062-431- 78	1 in 1 CARTON	08/29/2011	
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	07/24/2001	

## **Labeler -** Publix Super Markets Inc (006922009)

Revised: 5/2022 Publix Super Markets Inc