

DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet, film coated

CVS Pharmacy, 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.

2834-CVS

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

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- use caution when driving a motor vehicle or operating machinery ■ drowsiness will occur
- avoid alcoholic beverages

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.

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

Directions

- do not take more than directed
- 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 37 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- use by expiration date on package

Inactive ingredients

croscarmellose sodium, dicalcium phosphate, FD&C blue #1 lake, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, silica, stearic acid, talc, titanium dioxide, triacetin

Questions or comments?

1-800-231-4670

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark

Simply Sleep®.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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V-34571

CVSHealth

Compare to the active ingredient in Simply Sleep®*

Nighttime

Sleep-Aid


DIPHENHYDRAMINE HCl, 25 mg

Nighttime sleep-aid

- Safe, non-habit forming
- Fall asleep fast, wake up rested
- Does not contain pain reliever

500 MINI-CAPLETS

VALUE SIZE 500 MINI-CAPLETS



Compare to the active ingredient in Simply Sleep[®] Mini-Caplets


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Money Back Guarantee

FEEL FREE 13254-07-18

PDP 2.25"

6.0"

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DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-834
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
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	CPC;2824
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-834-51	365 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2018	
2	NDC:69842-834-55	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	07/23/2018	

Labeler - CVS Pharmacy, Inc. (062312574)

Revised: 12/2020

CVS Pharmacy, Inc.