

**NIGHTTIME SLEEP-AID SOFTGEL- diphenhydramine hydrochloride capsule,
liquid filled
CVS PHARMACY, INC**

Nighttime Sleep-Aid Softgel

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

- for relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not use • for children under 12 years of age • with any other product containing diphenhydramine, even one used on skin • with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

Ask a doctor before use if you have • glaucoma • heart diseases • a breathing problem such as emphysema, asthma, 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, tranquilizers, or any other sleep aid

When using this product avoid alcoholic beverages and other drugs that cause drowsiness. Be careful when driving a motor vehicle or operating 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. Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions

- take only one dose per day (24 hours)
- adults and children 12 years and over: take 2 softgels at bedtime if needed or as directed by a doctor
- children under 12 years: do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

FD&C blue#1, FD&C red#40, gelatin, glycerin, isopropyl alcohol, medium chain triglycerides, polyethylene glycol, povidone, purified water, sorbitol sorbitan solution, white ink

Questions or comments?

1-888-577-8033 Monday-Friday 9am-4:30pm EST

Compare to the active ingredient in Vicks® ZzzQuil™ NIGHTTIME SLEEP-AID LiquidCaps™**

Non-habit forming

Not for treating pain, cold or flu

**This product is not manufactured or distributed by The Proctor & Gamble Company, owner of the registered trademark VICKS® ZzzQuil™ NIGHTTIME SLEEP-AID LiquiCaps™.

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS SIGNS OF TAMPERING

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Product of UAE

Packaged and Quality Assured in the USA

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive

Woonsocket, RI 02895

© 2021 CVS/pharmacy

CVS.com®

1-800-SHOP CVS

Packaging



SEAL AREA
INK FREE AREA



Drug Facts READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

Uses for relief of occasional sleeplessness
reduces time to fall asleep if you have difficulty falling asleep

Warnings Do not use for children under 12 years of age with any other product containing diphenhydramine, even one used on skin with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

Ask a doctor before use if you have glaucoma heart diseases breathing problem such as emphysema, asthma, 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, tranquilizers, or any other sleep aid

When using this product avoid alcoholic beverages and other drugs that cause drowsiness. Be careful when driving a motor vehicle or operating 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. Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions take only one dose per day (24 hours)
adults and children take 2 softgels at bedtime if needed or as directed by a doctor
children under 12 years do not use

Other information store at 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F) protect from light

Inactive ingredients edible white ink, FD&C blue#1, FD&C red#40, gelatin, glycerin, isopropyl alcohol, medium chain triglycerides, polyethylene glycol, povidone, purified water, sorbitol sorbitan solution

Questions or comments?
1-888-577-8033 Monday-Friday 8am-4pm EST

Nighttime
Sleep-Aid
DIPHENHYDRAMINE
HCl, 25 mg
Nighttime sleep-aid
Non-habit forming

**This product is not manufactured or distributed by The Procter & Gamble Company. ZzzQuil™ is a trademark of The Procter & Gamble Company.

50844 ORG012072708
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

CT5131677924
REV.00-062021
#918867
FPO 80%
UPC# 050428266328
X XXXXXXX XXXXXX X



Drug Facts READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

Uses for relief of occasional sleeplessness
reduces time to fall asleep if you have difficulty falling asleep

Warnings Do not use for children under 12 years of age with any other product containing diphenhydramine, even one used on skin with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

Ask a doctor before use if you have glaucoma heart diseases breathing problem such as emphysema, asthma, 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, tranquilizers, or any other sleep aid

When using this product avoid alcoholic beverages and other drugs that cause drowsiness. Be careful when driving a motor vehicle or operating 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. Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions take only one dose per day (24 hours)
adults and children take 2 softgels at bedtime if needed or as directed by a doctor
children under 12 years do not use

Other information store at 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F) protect from light

Inactive ingredients edible white ink, FD&C blue#1, FD&C red#40, gelatin, glycerin, isopropyl alcohol, medium chain triglycerides, polyethylene glycol, povidone, purified water, sorbitol sorbitan solution

Questions or comments?
1-888-577-8033 Monday-Friday 8am-4pm EST

Nighttime
Sleep-Aid
DIPHENHYDRAMINE
HCl, 25 mg
Nighttime sleep-aid
Non-habit forming

**This product is not manufactured or distributed by The Procter & Gamble Company. ZzzQuil™ is a trademark of The Procter & Gamble Company.

50844 ORG012072708
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

CT5131677924
REV.00-062021
#918867
FPO 80%
UPC# 050428266328
X XXXXXXX XXXXXX X

Compare to the active ingredient in Vicks® ZzzQuil™ LiquiCaps™**

NDC 51316-779-24

Nighttime Sleep-Aid
DIPHENHYDRAMINE HCl, 25 mg

Nighttime sleep-aid
Non-habit forming

Not for treating pain, cold or flu



Actual Size

24 SOFTGELS

GLUE - NO COATING

SEAL AREA
INK FREE AREA

SEAL AREA
INK FREE AREA



Drug Facts READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

Uses for relief of occasional sleeplessness
reduces time to fall asleep if you have difficulty falling asleep

Warnings Do not use for children under 12 years of age with any other product containing diphenhydramine, even one used on skin with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

Ask a doctor before use if you have glaucoma heart diseases breathing problem such as emphysema, asthma, 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, tranquilizers, or any other sleep aid

When using this product avoid alcoholic beverages and other drugs that cause drowsiness. Be careful when driving a motor vehicle or operating 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. Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions take only one dose per day (24 hours)
adults and children take 2 softgels at bedtime if needed or as directed by a doctor
children under 12 years do not use

Other information store at 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F) protect from light

Inactive ingredients edible white ink, FD&C blue#1, FD&C red#40, gelatin, glycerin, isopropyl alcohol, medium chain triglycerides, polyethylene glycol, povidone, purified water, sorbitol sorbitan solution

Questions or comments?
1-888-577-8033 Monday-Friday 8am-4pm EST

Nighttime
Sleep-Aid
DIPHENHYDRAMINE
HCl, 25 mg
Nighttime sleep-aid
Non-habit forming

**This product is not manufactured or distributed by The Procter & Gamble Company. ZzzQuil™ is a trademark of The Procter & Gamble Company.

50844 ORG012072722
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

CT5131677948
REV.00-062021
#933379
FPO 80%
UPC# 050428347577
X XXXXXXX XXXXXX X



Drug Facts READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

Uses for relief of occasional sleeplessness
reduces time to fall asleep if you have difficulty falling asleep

Warnings Do not use for children under 12 years of age with any other product containing diphenhydramine, even one used on skin with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

Ask a doctor before use if you have glaucoma heart diseases breathing problem such as emphysema, asthma, 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, tranquilizers, or any other sleep aid

When using this product avoid alcoholic beverages and other drugs that cause drowsiness. Be careful when driving a motor vehicle or operating 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. Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions take only one dose per day (24 hours)
adults and children take 2 softgels at bedtime if needed or as directed by a doctor
children under 12 years do not use

Other information store at 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F) protect from light

Inactive ingredients edible white ink, FD&C blue#1, FD&C red#40, gelatin, glycerin, isopropyl alcohol, medium chain triglycerides, polyethylene glycol, povidone, purified water, sorbitol sorbitan solution

Questions or comments?
1-888-577-8033 Monday-Friday 8am-4pm EST

Nighttime
Sleep-Aid
DIPHENHYDRAMINE
HCl, 25 mg
Nighttime sleep-aid
Non-habit forming

**This product is not manufactured or distributed by The Procter & Gamble Company. ZzzQuil™ is a trademark of The Procter & Gamble Company.

50844 ORG012072722
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

CT5131677948
REV.00-062021
#933379
FPO 80%
UPC# 050428347577
X XXXXXXX XXXXXX X

Compare to the active ingredient in Vicks® ZzzQuil™ LiquiCaps™**

NDC 51316-779-48

Nighttime Sleep-Aid
DIPHENHYDRAMINE HCl, 25 mg

Nighttime sleep-aid
Non-habit forming

Not for treating pain, cold or flu



Actual Size

48 SOFTGELS

GLUE - NO COATING

SEAL AREA
INK FREE AREA

NIGHTTIME SLEEP-AID SOFTGEL

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-779
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	purple	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	779
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-779-24	2 in 1 CARTON	07/23/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51316-779-48	4 in 1 CARTON	07/23/2021	
2		12 in 1 BLISTER PACK; 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	07/23/2021	

Labeler - CVS PHARMACY, INC (062312574)

Revised: 1/2025

CVS PHARMACY, INC