

LEADER NIGHTTIME SLEEP-AID- diphenhydramine hydrochloride liquid CARDINAL HEALTH

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.

Leader Nighttime Sleep Aid Diphenhydramine HCl Berry Flavor 12 FL OZ 354mL

Drug Facts

Active ingredient (in each 30 mL dose cup)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

- for the 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

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

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep- aid.

When using this product

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur

- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if sleeplessness persists continuously for more than two 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:

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. 1-800-222-1222

Directions

- take only one dose per day (24 hours) - see Overdose warning
- Measure with dosing cup provided.

adults & children 12 yrs & over	One Dose = 30 mL (2 tablespoons) at bed time if needed or as directed by a doctor
Children under 12 yrs	Do not use

Other information

- each 30 mL dose contains: **sodium 23 mg**
- store at room temperature
- protect from light. Does not meet USP <671>

Inactive ingredients

anhydrous citric acid, FD&C blue 1, FD&C red 40, flavor, glycerin, potassium citrate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

Questions or comments?

1-866-467-2748

PRINCIPAL DISPLAY PANEL

LEADER

NDC **70000-0174-1**

Nighttime Sleep-aid

Diphenhydramine HCl

COMPARE TO ZZZQUIL® active ingredient*

100% money Back Guarantee

Non-habit forming

Berry flavor

Naturally & Artificially Flavored

Non-habit forming

12 FL OZ (354 mL)

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Failure to follow these warnings could result in serious consequences.

TAMPER EVIDENT: Do not use if printed shrink band is missing or broken

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DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

*This product is not manufactured or distributed by Procter & Gamble, the owner of the registered trademark ZzzQuil®.

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LEADER

NDC 70000-0174-1

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Diphenhydramine HCl

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LOT: 7002DRR

EXP: 7002DRR

24136 E9 F2

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LEADER NIGHTTIME SLEEP-AID

diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0174
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0174-1	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/17/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	01/17/2017	

