

## **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.*

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### **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**

DISTRIBUTED BY: CARDINAL HEALTH

DUBLIN, OHIO 43017

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

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**LEADER NIGHTTIME SLEEP-AID**

diphenhydramine hydrochloride liquid

**Product Information**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Product Characteristics**

<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**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	

