

**REVASOL SLEEP AID- diphenhydramine hcl liquid**

**Rnv LLC**

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**Revasol Sleep Aid**

**Active ingredient (in each 30 mL dose cup) Purpose**

Diphenhydramine HCl 50mg..... Nighttime sleep-aid

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 emphysema or chronic bronchitis
- glaucoma
- 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**

- avoid alcoholic beverages

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

**Directions**

- take only one dose (30 mL) per day (24 hours)
- only use dose cup provided

<b>Age</b>	<b>Dose</b>
adults and children 12 years and over	30 mL at bedtime if needed or as directed by a doctor
children under 12 years	do not use

**Other information**


- **each 30 mL dose cup contains:** sodium 4 mg
- store between 15-30°C (59-86°F).

• **TAMPER-EVIDENT FEATURE:** Do not use if printed safety seal is torn, broken or missing.

**Inactive ingredients** anhydrous citric acid, FD&C Blue #1, FD&C Red #40, flavor, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose.

**Questions or comments 1-888-446-4753**

Monday - Friday (9 AM - 5 PM EST)

Drug Facts		Drug Facts (continued)	
<b>Active ingredient (in each 30 mL dose cup)</b> Diphenhydramine HCl 50mg.....	<b>Purpose</b> Nighttime sleep-aid	<b>Age</b>	<b>Dose</b>
<b>Uses</b> • for the relief of occasional sleeplessness • reduces time to fall asleep if you have difficulty falling asleep		adults and children 12 years and over	30 mL at bedtime if needed or as directed by a doctor
<b>Warnings</b> <b>Do not use</b> • 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 <b>Ask a doctor before use if you have</b> • a breathing problem such as emphysema or chronic bronchitis • glaucoma • difficulty in urination due to enlargement of the prostate gland <b>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</b> <b>When using this product</b> • avoid alcoholic beverages <b>Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks.</b> Insomnia may be a symptom of serious underlying medical illness. <b>If pregnant or breast-feeding, ask a health professional before use.</b> <b>Keep out of the reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).		children under 12 years	do not use
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		<b>Made in USA</b> Distributed by: RNV LLC 14501 NW 60 Ave, Miami Lakes, FL 33014 *This product is not manufactured or distributed by Procter and Gamble, the distributor of ZzzQuil™ Nighttime Sleep-Aid. Rev. 1	 8 60012 31355 6 <b>Lot:</b> <b>Exp:</b>

## REVASOL SLEEP AID

diphenhydramine hcl liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84379-284
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SORBITOL SOLUTION 70%</b> (UNII: 8KW3E207O2)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>CITRIC ACID</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	

### Product Characteristics

<b>Color</b>		<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:84379-284-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	02/03/2025	

**Labeler** - Rnv LLC (118917568)

**Registrant** - Rnv LLC (118917568)

### Establishment

Name	Address	ID/FEI	Business Operations
Rnv LLC		118917568	manufacture(84379-284)

Revised: 3/2025

Rnv LLC