

**NIGHTTIME SLEEP AID- diphenhydramine hydrochloride liquid  
fred's, 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.*

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**Nighttime Sleep Aid**

***Drug Facts***

**Active ingredient (in each 30 mL or 2 tablespoons)**

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 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 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
- use dose cup or tablespoon

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adults & children 12 yrs & over	One Dose = 30 mL (2 tablespoons) at bed time if needed or as directed by a doctor
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### **Other information**

- **each 30 mL dose (2 tablespoons) contains:**  
sodium 21 mg
- store at room temperature
- protect from light. Does not meet USP <671>.

### **Inactive ingredients**

citric acid, ethyl alcohol, FD&C blue #1, FD&C red #40, flavors, glycerin, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol

### **Questions?**

**1-732-249-6363**

DISTRIBUTED BY: fred's, Inc.  
4300 NEW GETWELL RD, MEMPHIS, TN 38118

### **PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label**

**NDC 55315-003-12**

**fred's®**

**Warming**

**Berry Flavor**

**Nighttime**

**Sleep-Aid**

Diphenhydramine HCl

**Non-Habit Forming**

**Not for treating Cold  
or Flu**

Alcohol 10%

See Warnings

**6 FL OZ (177 mL)**

**fred's**

**LAB TESTED**

**Lab Tested for Quality**

**Fred Tested for Satisfaction**

**Compare To  
Vicks ZzzQuil®\***

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4300 NEW GETWELL RD, MEMPHIS, TN 38118  
www.fredsinc.com

**fred's** Promise  
Not Happy With This Product?  
Just Bring It Back For a Refund!

0 84579 12659 0

Lot:   
Exp:

**fred's**  
NDC 55315-003-12

**fred's**  
Warming  
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Failure to follow these warnings could result  
in serious consequences.

<b>Drug Facts</b>	
Active ingredient	Purpose
(in each 30 mL or 2 tablespoons) Diphenhydramine HCl 50 mg ...	Nighttime sleep-aid
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• for the relief of occasional sleeplessness</li> <li>• reduces time to fall asleep if you have difficulty falling asleep</li> </ul>	
<b>Warnings</b>	
<p>Do not use</p> <ul style="list-style-type: none"> <li>• for children under 12 years of age</li> <li>• with any other product containing Diphenhydramine, even one used on skin</li> <li>• with other drugs that cause drowsiness</li> </ul>	

**TAMPER EVIDENT: Do not use if printed shrinkband is missing or broken.**

**fred's**

\*This product is not manufactured by or distributed by Proctor & Gamble owner of the registered trademark ZzzQuil®

<b>Drug Facts</b> (continued)
such as antihistamines and nighttime cold/flu products
<b>Ask a doctor before use if you have</b>
<ul style="list-style-type: none"> <li>• a breathing problem such as asthma, emphysema, or chronic bronchitis</li> <li>• glaucoma</li> <li>• difficulty in urination due to enlargement of the prostate gland</li> <li>• heart disease</li> </ul>
<b>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep aid</b>
<b>When using this product</b>
<ul style="list-style-type: none"> <li>• avoid alcoholic beverages and other drugs that cause drowsiness</li> <li>• drowsiness will occur</li> <li>• be careful when driving a motor vehicle or operating machinery</li> </ul>
<b>Stop use and ask a doctor if</b>
sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

<p><b>Drug Facts</b> (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p><b>Keep out of reach of children.</b></p> <p><b>Overdose warning:</b> 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)</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• take only one dose per day (24 hours) – see Overdose warning</li> <li>• use dose cup or tablespoon</li> </ul> <table border="1"> <tr> <td>adults &amp; children 12 yrs &amp; over</td> <td>One Dose = 30 mL (2 tablespoons) at bed time if needed or as directed by a doctor</td> </tr> </table>	adults & children 12 yrs & over	One Dose = 30 mL (2 tablespoons) at bed time if needed or as directed by a doctor	<p><b>Drug Facts</b> (continued)</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• each 30 mL dose (2 tablespoons) contains: sodium 21 mg</li> <li>• store at room temperature</li> <li>• protect from light. Does not meet USP &lt;671&gt;.</li> </ul> <p><b>Inactive ingredients</b> citric acid, ethyl alcohol, FD&amp;C blue #1, FD&amp;C red #40, flavors, glycerin, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol</p> <p><b>Questions? 1-732-249-6363</b></p>
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**NIGHTTIME SLEEP AID**  
diphenhydramine hydrochloride liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55315-003
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>Sodium Benzoate</b> (UNII: OJ245FE5EU)	
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Saccharin Sodium</b> (UNII: SB8ZUX40TY)	
<b>Alcohol</b> (UNII: 3K9958V90M)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>Sodium Citrate</b> (UNII: 1Q73Q2JULR)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>FD&amp;C Blue NO. 1</b> (UNII: H3R47K3TBD)	
<b>Water</b> (UNII: 059QF0K00R)	

**Product Characteristics**

<b>Color</b>	PURPLE (Dark)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY, BERRY, STRAWBERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-003-12	177 mL in 1 BOTTLE, PLASTIC		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	10/23/2013	

**Labeler** - fred's, Inc. (005866116)**Registrant** - davAgen Pharmaceutical, LLC (967545935)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
davAgen Pharmaceutical, LLC		967545935	MANUFACTURE(55315-003) , PACK(55315-003) , LABEL(55315-003) , ANALYSIS(55315-003)

Revised: 12/2013

fred's, Inc.