# FIRST AID SHOT THERAPY SLEEP AID- diphenhydramine hydrochloride solution First Aid Beverages, 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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### First Aid Shot Therapy® Sleep Aid

**Drug Facts** 

### **Active ingredients**

Diphenhydramine HCl 50 mg

### Purpose (in each bottle)

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
- with other Nighttime 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 a serious underlying medical illness.

**If pregnant or breast-feeding,** ask a health care professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

### Directions

Adults and children 12 years and over:

• One dose = one bottle (40 mL) at bedtime if needed or as directed by a doctor

### Children under 12 years:

• Do not use

### Other information

- each 40mL contains: sodium 42 mg
- store between 20-25C°(68-77°F)

### **Inactive ingredients**

alcohol, citric acid, flavors, glycerol, polyoxyl 40 stearate, purified water, sodium benzoate, sodium citrate, sucrose

### Questions or comments?

**1-877-958-8331** (Monday-Friday 9AM-5PM PST). You may also report serious side effects to this number.

Distributed by First Aid Shot Therapy<sup>®</sup> Burlingame, CA 94010

### PRINCIPAL DISPLAY PANEL - 40 mL Bottle Label

SLEEP

**AID** 

**FAST** 

-LIQUID-

**RELIEF**®

**FIRST AID** 

**SHOT THERAPY**®

WARMING PEACH

**FDA** 

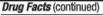
**COMPLIANT** 

Diphenhydramine HCl Nighttime sleep-aid Alcohol 10%

1.35 FL OZ (40mL)







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- such as antihistamines and nighttime cold/flu products
- with other Nighttime products

### Drug Facts (continued)

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### FIRST AID SHOT THERAPY SLEEP AID

diphenhydramine hydrochloride solution

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:57815-091

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
I	Diphenhydramine Hydrochloride	50 mg in 40 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)		
GLYCERIN (UNII: PDC6A3C0OX)		
TRISO DIUM CITRATE DIHYDRATE (UNII: B22547B95K)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SUCROSE (UNII: C151H8M554)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	PEACH	Imprint Code	
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:57815-091- 01	1 in 1 CARTON	07/01/2016		
1	40 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	07/01/2016	

## Labeler - First Aid Beverages, Inc. (078618157)

Revised: 6/2016 First Aid Beverages, Inc.