

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.

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®
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)

SLEEP AID • SLEEP AID • SLEEP AID

Do not use if seal is broken

We hope F.A.S.T. relieved your sleeplessness.

For more info visit:
www.firstaidshottherapy.com

1018-009-000

FAST
—LIQUID—
RELIEF®



FIRST AID
SHOT THERAPY®

WARMING PEACH

FDA
OVER THE COUNTER

Diphenhydramine HCl
Nighttime sleep-aid
Alcohol 10%

1.35 FL OZ (40mL)

Single Dose Provides:

- Relief of occasional sleeplessness
- Reduces time to fall asleep
- Non-habit forming

		<p>Drug Facts (continued)</p> <p>Inactive ingredients alcohol, citric acid, flavors, glycerol, polyoxyl 40 stearate, purified water, sodium benzoate, sodium citrate, sucrose</p> <p>Questions or comments? 1-877-958-8331 (Monday-Friday 9AM-5PM PST). You may also report serious side effects to this number.</p> <p>Distributed by First Aid Shot Therapy® Burlingame, CA 94010 First Aid Shot Therapy® and cross symbol are registered trademarks of First Aid Shot Therapy®. www.firstaidshottherapy.com</p>	<p>Drug Facts</p> <p>Active ingredients Purpose (in each bottle) Diphenhydramine HCl 50 mg.,Nighttime sleep-aid</p> <p style="text-align: center;">1017-008-000</p>  <p style="text-align: center;">8 57596 00456 7</p> <p style="font-size: small;">LEFT PANEL FOR MORE DRUG FACTS INFORMATION, READ ALL WARNINGS UNDER LABEL BEFORE USE.</p>
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<p>Drug Facts (continued)</p> <p>Uses</p> <ul style="list-style-type: none"> • for the relief of occasional sleeplessness • reduces time to fall asleep if you have difficulty falling asleep <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> • 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 	<p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> • a breathing problem such as emphysema or chronic bronchitis • glaucoma • difficulty in urination due to enlargement of the prostate gland <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</p> <p>When using this product</p> <ul style="list-style-type: none"> • avoid alcoholic beverages <p>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.</p>	<p>Drug Facts (continued)</p> <p>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.</p> <p>Directions</p> <p>Adults and children 12 years and over: • One dose = one bottle (40 mL) at bedtime if needed or as directed by a doctor</p> <p>Children under 12 years: • Do not use</p> <p>Other information</p> <ul style="list-style-type: none"> • each 40mL contains: sodium 42 mg • store between 20-25°C (68-77°F)
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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

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 40 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
GLYCERIN (UNII: PDC6A3C0OX)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
ANHYDROUS 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)