

FIRST AID SHOT THERAPY PAIN RELIEF- choline salicylate and caffeine liquid
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® Pain Relief

Drug Facts

<i>Active ingredients</i>	<i>Purposes</i>
Choline salicylate 650 mg (NSAID)*	Pain reliever
Caffeine 65 mg	Pain reliever aid

* nonsteroidal anti-inflammatory drug

Uses

- headache
- muscle pain
- toothache
- menstrual pain
- pain of colds
- minor pain of arthritis

Warnings

Reye's syndrome

Children and teenagers who have or are recovering from chickenpox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: contains salicylate

Stomach bleeding warning

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use if you are

- allergic to salicylates (including aspirin)
- taking other salicylate products

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are taking a prescription drug for

- anticoagulation (thinning of the blood)
- diabetes
- gout
- arthritis

When using this product limit use of caffeine containing drugs, foods, or drinks, because too much caffeine may cause nervousness, irritability, sleeplessness, and occasional rapid heartbeat

Stop use and ask a doctor if

- an allergic reaction occurs (seek medical help right away)
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- redness or swelling is present
- new symptoms occur
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better

If pregnant or breast-feeding, ask a health 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:
 - swallow the contents of one bottle
 - repeat every 3-4 hours while symptoms persist
 - do not take more than 6 bottles in 24 hours
- Children under 12 years: Do not use

Other information

- keep from freezing
- avoid excessive heat (over 104°F or 40°C)

Inactive ingredients

Citric acid, natural and artificial flavors, purified water, sodium benzoate, sodium citrate, sucralose

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

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PAIN

FAST

– LIQUID –

RELIEF®

FIRST AID

SHOT THERAPY®

BERRY

FDA

COMPLIANT

choline salicylate & caffeine
pain reliever
(NSAID)/pain reliever aid

1.35 FL OZ (40mL)

• PAIN • PAIN • PAIN

Do not use if seal is broken

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

For more info visit:
www.firstaidshottherapy.com

FAST

— LIQUID —

RELIEF®



SINGLE DOSE TREATS:

- Headache
- Pain
- Muscle Ache



FIRST AID SHOT THERAPY®

BERRY

choline salicylate & caffeine pain reliever (NSAID)/pain reliever aid

1.35 FL OZ (40mL)

1003-008-000

<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ an allergic reaction occurs (seek medical help right away) ■ ringing in the ears or loss of hearing occurs ■ pain gets worse or lasts for more than 10 days ■ redness or swelling is present ■ new symptoms occur ■ you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better <p>If pregnant or breast-feeding, ask a health professional before use.</p>	<p>Drug Facts (continued)</p> <p>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>For adults and children 12 years and older:</p> <ul style="list-style-type: none"> ■ swallow the contents of one bottle ■ repeat every 3–4 hours while symptoms persist ■ do not take more than 6 bottles in 24 hours ■ children under 12 years: do not use <p>Other Information</p> <ul style="list-style-type: none"> ■ keep from freezing ■ avoid excessive heat (over 104°F or 40°C) <p>Inactive Ingredients</p> <p>citric acid, natural and artificial flavors, purified water, sodium benzoate, sodium citrate, sucralose</p>	<p>Drug Facts (continued)</p> <p>Questions? 1-877-958-8331 (Monday-Friday 9AM-5PM PST)</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 <small>Label Patent #8,273,634</small></p>	<p>Drug Facts</p> <p>Active ingredients Purpose (in each bottle)</p> <p>Choline salicylate 650mg (NSAID)*... Pain reliever</p> <p>Caffeine 65mg... Pain reliever aid</p> <p>*nonsteroidal anti-inflammatory drug</p> <p style="text-align: center;">1003-008-000</p>  <p style="text-align: center;">8 57596 00417 8</p> <p style="text-align: center;">LIFT PANEL FOR MORE DRUG FACTS INFORMATION. READ ALL WARNINGS UNDER LABEL BEFORE USE.</p> <p style="text-align: center;">2456967-10</p>
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<p>Drug Facts (continued)</p> <p>Uses temporarily relieves</p> <ul style="list-style-type: none"> ■ headache ■ muscle pain ■ menstrual pain ■ pain of colds ■ minor pain of arthritis ■ toothache <p>Warnings</p> <p>Reye's syndrome: Children and teenagers who have or are recovering from chickenpox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.</p> <p>Allergy alert: Contains salicylate</p> <p>Stomach bleeding warning: This product contains an NSAID.</p>	<p>Drug Facts (continued)</p> <p>which may cause severe stomach bleeding. The chance is higher if you</p> <ul style="list-style-type: none"> ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed <p>Do not use if you are</p> <ul style="list-style-type: none"> ■ allergic to salicylates (including aspirin) ■ taking other salicylate products 	<p>Drug Facts (continued)</p> <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> ■ stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you are taking a diuretic ■ you have asthma <p>Ask a doctor or pharmacist before use if you are taking a prescription drug for</p> <ul style="list-style-type: none"> ■ anticoagulation (thinning of the blood) ■ diabetes ■ gout ■ arthritis <p>When using this product limit use of caffeine containing drugs, foods, or drinks, because too much caffeine may cause nervousness, irritability, sleeplessness, and occasional rapid heartbeat</p>
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2456967-10

FIRST AID SHOT THERAPY PAIN RELIEF

choline salicylate and caffeine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57815-081
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Choline Salicylate (UNII: KD510K1IQW) (Salicylic Acid - UNII:O414PZ4LPZ)	Choline Salicylate	650 mg in 40 mL
Caffeine (UNII: 3G6A5W338E) (Caffeine - UNII:3G6A5W338E)	Caffeine	65 mg in 40 mL

Inactive Ingredients

Ingredient Name	Strength
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Sucralose (UNII: 96K6UQ3ZD4)	
Water (UNII: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57815-081-01	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 NOT FINAL	part343	02/01/2015	

Labeler - First Aid Beverages, Inc. (078618157)

Revised: 1/2015

First Aid Beverages, Inc.