# 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.

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# First Aid Shot Therapy® Pain Relief

# **Drug Facts**

Active ingredients	Purposes
Choline salicylate 650 mg (NSAID)*	Pain
Chothle safrcyfate 050 filg (NSAID)	reliever
Caffeine 65 mg	Pain
Carrettie 05 mg	reliever aid

<sup>\*</sup> 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<sup>®</sup> Burlingame, CA 94010

# PRINCIPAL DISPLAY PANEL - 40 mL Bottle Label

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**PAIN** 

FAST - LIQUID -RELIEF®

FIRST AID
SHOT THERAPY®

**BERRY** 

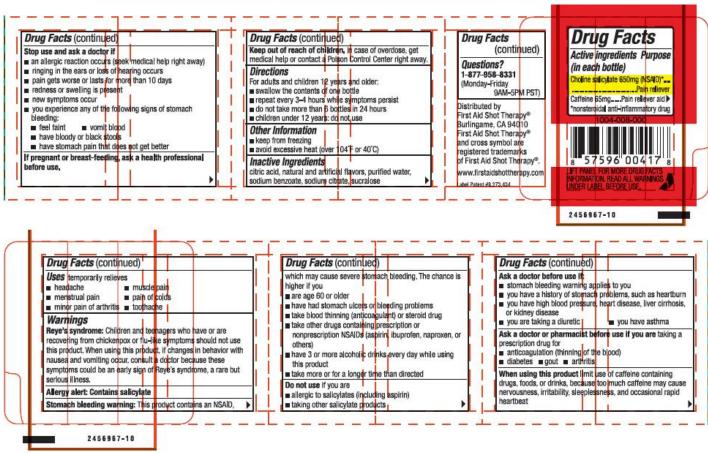
**FDA** 

**COMPLIANT** 

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

1.35 FL OZ (40mL)





#### 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: 3G6 A5W338E) (Caffeine - UNII:3G6 A5W338E)	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: 059QF0KO0R)				

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

ı	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	0 2/0 1/20 15	

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

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