

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

Active ingredients (in each bottle)	Purpose
Choline salicylate 500mg (NSAID)*	Pain reliever/fever reducer
Caffeine 65mg	Pain reliever aid

* nonsteroidal anti-inflammatory drug

Uses

temporarily relieves

- headache
- muscle pain
- toothache
- menstrual pain
- pain and fever of colds
- minor pain of arthritis
- temporarily reduces fever

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
- fever lasts more than 3 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

For adults and children 12 years and older:

- swallow the contents of one bottle
- repeat every 3-4 hours while symptoms persist
- do not take more than 8 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?

1-877-958-8331 (Monday-Friday 9AM-5PM PST)

Distributed by
First Aid Shot Therapy®
Burlingame, CA 94010

PRINCIPAL DISPLAY PANEL - 40mL Bottle Label**F.A.S.T.**

RELIEF

FIRST AID

SHOT THERAPY®

PAIN relief

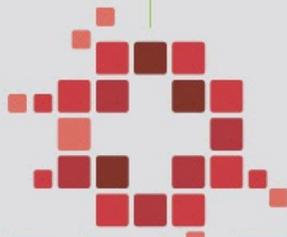
choline salicylate & caffeine
pain reliever/fever reducer
(NSAID)/pain reliever aid

FDA

COMPLIANT

Berry Flavor

1.35 FL OZ (40mL)



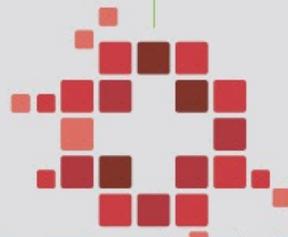
F.A.S.T.
RELIEF

Do not use if seal under shrink is broken

Single Dose

FIRST AID
SHOT THERAPY®

1003-001-001



F.A.S.T.
RELIEF

FIRST AID
SHOT THERAPY®

PAIN relief

choline salicylate & caffeine
pain reliever/fever reducer
(NSAID)/pain reliever aid
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LIFT PANEL FOR MORE DRUG FACTS
INFORMATION. READ ALL WARNINGS
UNDER LABEL BEFORE USE.

1004-001-001



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Drug Facts (continued)

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■ headache ■ muscle pain ■ toothache

■ menstrual pain ■ pain and fever of

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www.firstaidshottherapy.com

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choline salicylate and caffeine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:578 15-011
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Choline Salicylate (UNII: KD510K1IQW) (SALICYLIC ACID - UNII:O414PZ4LPZ)	Choline Salicylate	500 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: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:578 15-011-01	40 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	09/05/2013	

Labeler - First Aid Beverages, Inc. (078618157)