

FIRST AID SHOT THERAPY COLD RELIEF- dextromethorphan hydrobromide, phenylephrine hydrochloride, and menthol 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® Cold Relief

Drug Facts

Active ingredients	Purposes
Dextromethorphan HBR 20 mg	Cough suppressant
Phenylephrine HCL 10 mg	Nasal decongestant
Menthol 8.5 mg	Oral anesthetic

Uses

temporarily relieves

- nasal and sinus congestion
- cough due to minor throat and bronchial irritation
- occasional minor irritation or sore throat

Warnings

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea or vomiting, consult a doctor promptly.

Do not use

- If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that lasts or is chronic such as occurs with smoking, asthma and emphysema
- cough accompanied by excessive phlegm (mucus)

When using this product

- **do not exceed recommended dosage**

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs

- cough gets worse or lasts more than 7 days
- cough comes back or occurs with a fever, rash or persistent headache
- symptoms do not improve within 7 days or occur with a fever
- sore mouth symptoms do not improve in 7 days.

These could be signs of a serious condition

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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs of symptoms.

Directions

For adults and children 12 years and over:

- Swallow the contents of one bottle every 4 hours

Children 4 to under 12 years:

- Ask a doctor

Children under 4 years:

- Do not use

Other information

- store at controlled room temperature 20-25°C (68-77°F)

Inactive ingredients

carboxymethylcellulose sodium, citric acid, natural flavors, pectin, purified water, sodium benzoate, 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

COLD

FAST

–LIQUID–

RELIEF®

FIRST AID

SHOT THERAPY®

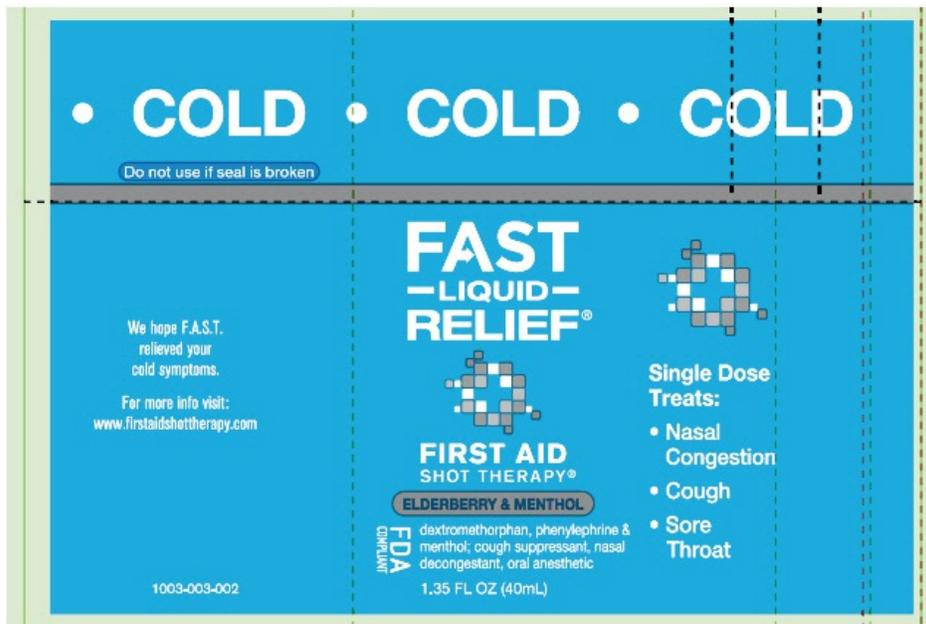
ELDERBERRY & MENTHOL

FDA

COMPLIANT

dextromethorphan, phenylephrine & menthol; cough suppressant, nasal decongestant, oral anesthetic

1.35 FL OZ (40mL)



<p>Drug Facts (continued)</p> <p>In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs of symptoms.</p> <p>Directions For adults and children 12 years and older: <ul style="list-style-type: none"> swallow the contents of one bottle every 4 hours Children 4 to under 12 years: <ul style="list-style-type: none"> Ask a doctor Children under 4 years: <ul style="list-style-type: none"> Do not use </p> <p>Other Information <ul style="list-style-type: none"> store at controlled room temperature 20-25°C (68-77°F) </p>	<p>Drug Facts (continued)</p> <p>Inactive Ingredients carboxymethylcellulose sodium, citric acid, natural flavors, pectin, purified water, sodium benzoate, sucralose</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) Dextromethorphan HBR 20 mg ----- Cough suppressant Phenylephrine HCL 10 mg ----- Nasal decongestant Menthol & 5 mg ----- Oral anesthetic</p> <p>1017-003-000</p> <p>8 57596 00403 1</p> <p>LIFT 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 temporarily relieves <ul style="list-style-type: none"> nasal and sinus congestion cough due to minor throat and bronchial irritation occasional minor irritation or sore throat </p> <p>Warnings Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea or vomiting, consult a doctor promptly.</p>	<p>Drug Facts (continued)</p> <p>Do not use <ul style="list-style-type: none"> If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. </p> <p>Ask a doctor before use if you have <ul style="list-style-type: none"> heart disease high blood pressure thyroid disease diabetes trouble urinating due to an enlarged prostate gland cough that lasts or is chronic such as occurs with smoking, asthma and emphysema cough accompanied by excessive phlegm (mucus) </p>	<p>Drug Facts (continued)</p> <p>When using this product <ul style="list-style-type: none"> do not exceed recommended dosage </p> <p>Stop use and ask a doctor if <ul style="list-style-type: none"> nervousness, dizziness, or sleeplessness occurs cough gets worse or lasts more than 7 days cough comes back or occurs with a fever, rash or persistent headache symptoms do not improve within 7 days or occur with a fever sore mouth symptoms do not improve in 7 days. These could be signs of a serious condition</p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p>
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dextromethorphan hydrobromide, phenylephrine hydrochloride, and menthol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57815-031
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	20 mg in 40 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	10 mg in 40 mL
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	8.5 mg in 40 mL

Inactive Ingredients

Ingredient Name	Strength
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Carboxymethylcellulose sodium, unspecified form (UNII: K679OBS311)	
Pectin (UNII: 89NA02M4RX)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sucralose (UNII: 96K6UQ3ZD4)	
Water (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MENTHOL	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57815-031-01	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 FINAL	part341	05/01/2015	

Labeler - First Aid Beverages, Inc. (078618157)