

SAINT- cough spray liquid
Saint Medicine, 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.

Saint Cough Spray

Active ingredient

Menthol 3.2%

Purpose

Cough Suppressant

Use

To relieve cough, eliminate phlegm, anti-inflammatory, and relieve headache, sore throat, red eyes, throat and lung discomfort symptoms

Suitable for cough caused by the following diseases:

Cold, trachea and bronchitis, pulmonary fibrosis, pulmonary sarcoidosis

Warnings

For external use only

For nebulization inhalation only, do not take orally.

Please keep this product out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Please keep this product out of the reach of children.

Directions

- **see important warnings under "When using this product"**
- adults & children 2 years & over:
- use 1 tablespoon of solution for each quart of water or 1½ teaspoonful of solution for each pint of water
- add solution directly to cold water only in a hot steam vaporizer (follow manufacturer's directions for using vaporizer)
- breathe in the medicated vapors
- use up to three times daily or as directed by a doctor
- children under 2 years: ask a doctor

When using this product

- Use as instructed.
- The persons with a history of allergies should try and observe.

Consult a doctor when using:

- COPD, or a persistent chronic cough
- Asthma and emphysema patients
- Long-term smoking and coughing or cancer patients
- Patients with severe pulmonary heart disease
- Pregnant women, lactating women and children under the age of 12.

Usage

This product has been diluted and accurately dosed in accordance with FDA medication recommendations, 5 ml per vial, and it can be used by inhalation in an atomizer, each vial can be used once, 2-3 times a day.

Choose an atomizer and use it according to the manufacturer's instructions.

It is recommended to use mesh-sieve atomizer, medical-grade products should be selected, and that is product with medical device approval numbers.

Other information:

The product should be stored strictly away from light and should be kept at low temperature.

The total amount is 15.22 ounces (150 ml), including 90 vials, 0.1691 ounces (5ml) per vial.

Inactive ingredient

EGCG, Ginsenosides, N-Acetyl Cysteine, Nattokinase, Medical Purified Water

PRINCIPAL DISPLAY PANEL

72784-101-01

SAINT[®]

COUGH SPRAY

Purpose: To relieve cough, eliminate phlegm, anti-inflammatory, and relieve headache, sore throat, red eyes, throat and lung discomfort symptoms.

The Total Amount Is 15.22 Ounces (450 ML), Including 90 Vials, 0.1691 Ounces (5 ML) Per Vial.

FOR NEBULIZED INHALATION USE ONLY.

COUGH SPRAY

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Drug Facts	
Active Ingredient Menthol 3.2%	Purpose Cough suppressant
Purpose: To relieve cough, eliminate phlegm, anti-inflammatory, and relieve headache, sore throat, red eyes, throat and lung discomfort symptoms.	
Suitable for cough caused by the following diseases: Cold, trachea and bronchitis, pulmonary fibrosis, pulmonary sarcoidosis.	
Warning: For external use only. For nebulization inhalation only, do not take orally. Please keep this product out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
When using this product: <ul style="list-style-type: none"> • Use as instructed. • The persons with a history of allergies should try and observe. 	
Consult a doctor when using: <ul style="list-style-type: none"> • COPD or a persistent chronic cough • Asthma and emphysema patients • Long-term smoking and coughing or cancer patients • Patients with severe pulmonary heart disease • Pregnant women, lactating women and children under the age of 12. 	

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Other information: The product should be stored strictly away from light and should be kept at low temperature. Inactive ingredients: EGCG, Ginsenosides, N-Acetyl Cysteine, Nattokinase, Medical Purified Water.
Specification: The total amount is 15.22 ounces (450 ml), including 90 vials, 0.1691 ounces (5 ml) per vial.
Distributor: Saint Medicine Inc. 199 W Garvey Ave. Monterey Park, CA 91754 www.saint-st.com
Lot on: Expiration: NDC:

SAINT			
cough spray liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72784-101
Route of Administration	RESPIRATORY (INHALATION)		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.2 g in 100 mL
Inactive Ingredients			
	Ingredient Name		Strength
	EPIGALLOCATECHIN GALLATE (UNII: BQM438CTEL)		

GINSENOSESIDES (UNII: 3K198YD54P)	
ACETYLCYSTEINE (UNII: WYQ7N0BPYC)	
NATTOKINASE (UNII: H81695M5OP)	
WATER (UNII: 059QF0KOOR)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72784-101-01	90 in 1 BOX	07/20/2023	
1		5 mL in 1 VIAL; 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	07/20/2023	

Labeler - Saint Medicine, Inc. (081508032)

Establishment			
Name	Address	ID/FEI	Business Operations
Almil Nutritional Products, Inc.		153736301	manufacture(72784-101)

Revised: 7/2023

Saint Medicine, Inc.