

SOOTHE COMFORT I COUGH SYRUP ORIGINAL- dextromethorphan liquid
RFX Pharmaceutical Co., Ltd.

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.

RFXLMSootheComfortICghSyrp

Active ingredient (in each 30 ml/2TBSP)

Dextromethorphan 30 mg

Purpose

Cough suppressant

Use

■ temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

Warnings

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

■ cough that occurs with too much phlegm (mucus)

■ cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask a doctor if

■ cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

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

- do not take more than 4 doses in any 24-hour period
- one dose is two tablespoons (TBSP)
- this adult product is not intended for use in children under 12 years of age

Age Dose

adults and children 12 years 30 mL (2TBSP)

and over every 6 hours

children 4 to under 12 years ask a doctor

children under 4 years do not use

Other Information

- store at 20-25°C (68-77°F). Do not refrigerate

Inactive ingredients

astragalus root extract, coltsfoot flower bud extract, epimedium leaf extract, honey, schisandra fruit extract, water, white mulberry root bark extract

Questions or comments?

- 1-800-860-0888

Package Label



SOOTHE COMFORT I COUGH SYRUP ORIGINAL

dextromethorphan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76206-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN (UNII: 7355X3ROTS) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
MORUS ALBA ROOT BARK (UNII: SV6B76DK9N)	
TUSSILAGO FARFARA FLOWER BUD (UNII: 6WBB6U5V2Q)	
HONEY (UNII: Y9H1V576FH)	
EPIMEDIUM SAGITTATUM LEAF (UNII: 8H775CGY31)	
SCHISANDRA CHINENSIS FRUIT OIL (UNII: 62023A4393)	
ASTRAGALUS CANADENSIS ROOT (UNII: 7JS169359F)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	brown (light brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76206-004-01	1 in 1 BOX	04/23/2021	
1	NDC:76206-004-05	155 mL in 1 BOTTLE, GLASS; 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	04/23/2021	

Labeler - RFX Pharmaceutical Co., Ltd. (530620871)

Establishment

Name	Address	ID/FEI	Business Operations
RFX Pharmaceutical Co., Ltd.		530620871	manufacture(76206-004)

Revised: 4/2021

RFX Pharmaceutical Co., Ltd.