

**SOOTHE COMFORT II COUGH SYRUP HERBAL MINT- 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.*

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**RFXLMSootheComfortIICghSyrp**

***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***

coltsfoot flower bud extract, grosvenor momordica fruit extract, honey, peppermint extract, schisandra chinensis fruit extract, sichuan fritillary bulb extract, water, white mulberry root bark extract

### **Questions or comments?**

- 1-800-860-0888

### **Package Label**



# SOOTHE COMFORT II COUGH SYRUP HERBAL MINT

dextromethorphan liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76206-005
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN</b> (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)	
FRITILLARIA PRZEWALSKII BULB (UNII: 8B269H8XVH)	
SCHISANDRA CHINENSIS FRUIT OIL (UNII: 62023A4393)	
SIRAITIA GROSVENORII FRUIT (UNII: NOU2FB51TW)	
WATER (UNII: 059QF0KO0R)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

### 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:76206-005-01	1 in 1 BOX	04/23/2021	
1	NDC:76206-005-05	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)

Revised: 4/2021

RFX Pharmaceutical Co., Ltd.