COUGH BE GONE- dextromethorphan hydrobromide guaifenesin 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.

Drug Facts

Active ingredient (in 10 ml)

Dextromethorphan Hydrobromide 20 mg

Guaifenesin USP 200 mg

Purpose

Cough suppressant

Expectorant

Use

■ Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold ■ Helps loosen phlegm (mucus) and thin bronchial secretions make coughs more productive

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

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

Keep out of reach of children

Directions

■ do not take more than 6 doses in any 24-hour period

■ one dose is one bottle

■ this adult product is not intended for use in children under 12 years of age

Age Dose

Adults and Children one bottle (10 ml)

12 years and over every 4 hours

Children under 12 years do not use

Inactive ingredients

Almond oil, Citrus peel, Ginger, Honey, Loquat leaf extract, Licorice, Menthol, Purified water

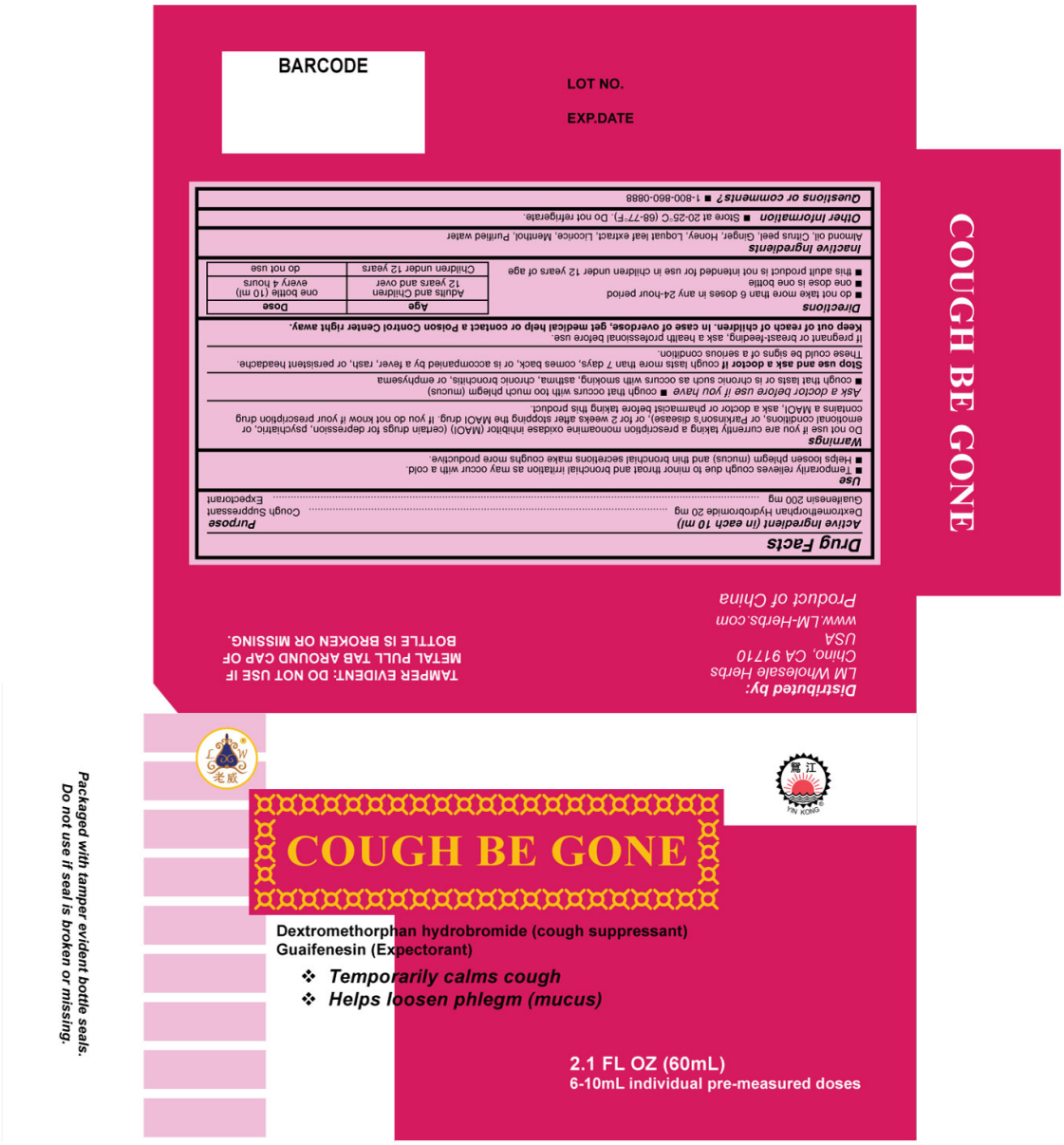
Other Information

■ Store at 20-25ºC (68-77ºF). Do not refrigerate

Questions or comments ?

■ 1-800-860-0888

Package Label



COUGH BE GONE

dextromethorphan hydrobromide guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76206-001
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 10 mL

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALMOND OIL (UNII: 66YXD4DKO9)	
GINGER (UNII: C5529G5JPQ)	
HONEY (UNII: Y9H1V576FH)	
ERIOBOTRYA JAPONICA LEAF (UNII: Z02066SV11)	
LICORICE (UNII: 61ZBX54883)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
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:76206-001-01	6 in 1 BOX	01/30/2014	
1	NDC:76206-001-10	10 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	01/30/2014	

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

Establishment

Name	Address	ID/FEI	Business Operations
RFX Pharmaceutical Co., Ltd.		530620871	manufacture(76206-001)

Revised: 5/2020 RFX Pharmaceutical Co., Ltd.