

COUGH FORMULA COUGH AND COLD- dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Rij Pharmaceutical Corporation

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 each 5 mLtsp)

Dextromethorphan HBr, USP 10 mg

Guaifenesin, USP 100 mg

Phenylephrine HCl, USP 5 mg

Purpose

Cough suppressant

Expectorant

Nasal decongestant

Uses

helps loosen phlegm (mucus) and thin bronchial secretions to to drain bronchial tubes

temporarily relieves these symptoms occurring with a cold

nasal congestion

cough due to minor throat and bronchial irritation

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

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

When using this product do not use more than directed.

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or are accompanied by fever
- cough that 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 6 doses in any 24-hour period

age	dose
adults and children 12 years and over	2 teaspoonfuls every 4 hours
children 6 years to under 12 years	1 teaspoonful every 4 hours
children 2 years to under 6 years	1/2 teaspoonful every 4 hours
children under 2 years	ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING**
- store at room temperature 15° - 30°C (59° - 86°F)
- alcohol free
- not a USP elixir
- each teaspoon (5 mL) contains: sodium 2 mg.

Inactive ingredients

citric acid, FD&C red no. 40, , flavors, glycerin, menthol, propylene glycol, sodium benzoate, sodium saccharin, water

PRINCIPAL DISPLAY PANEL

NDC 63807-531-04
 Preferred Plus Pharmacy
 Compare to the Active Ingredient in Robitussin® CF (new formulation)*
Cough Formula
 PSEUDOEPHEDRINE FREE
CF
 Cough & Cold
 ✓ Nasal Decongestant
 Cough Suppressant
 Expectorant
 ✓ Children & Adults
 Cough Formula
ALCOHOL FREE

4 FL. OZ. (118 mL)

Drug Facts

Active Ingredients (In each 5 mL tsp)
 Dextromethorphan HBr, USP 10 mgCough suppressant
 Guaifenesin, USP 100 mgExpectorant
 Phenylephrine HCl, USP 5 mgNasal Decongestant

Uses ■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes ■ temporarily relieves these symptoms occurring with a cold: ■ nasal congestion ■ cough due to minor throat and bronchial irritation

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
 ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ■ cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

When using this product do not use more than directed.
 ■ Stop use and ask a doctor if ■ you get nervous, dizzy, or sleepless ■ symptoms do not get better within 7 days or are accompanied by fever ■ 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 6 doses in any 24 hour period.

age	dose
adults and children 12 years and over	2 teaspoonsful every 4 hours
children 6 years to under 12 years	1 teaspoonful every 4 hours
children 2 years to under 6 years	1/2 teaspoonful every 4 hours
under 2 years	ask a doctor


Other Information ■ TAMPER EVIDENT: Do not use if breakaway band on cap is broken or missing. ■ Store at room temperature 15° - 30° C (59° - 86° F)
 ■ alcohol free ■ not a USP elixir
 ■ each teaspoon (5mL) contains: sodium 2 mg

Inactive Ingredients: citric acid, FD&C red no. 40, flavor, glycerin, menthol, propylene glycol, sodium benzoate, sodium saccharin, sorbitol, water

This product is not manufactured or distributed by the owner of the registered trademark Robitussin CF®. All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.
 Rev. 08/12

Manufactured By:
 RL PHARMACEUTICAL CORP.
 40 Commercial Avenue
 Middletown, NY 10941

Distributed By:
 Amray, Inc.
 Whitesboro, NY 11357



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COUGH FORMULA COUGH AND COLD

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-531
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MENTHOL (UNII: L7T10EIP3A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	RED	Score	
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Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-531-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
2	NDC:53807-531-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-531)

Revised: 4/2018

Rij Pharmaceutical Corporation