# RESFRIDOL ANTITUSSIVE- guaifenesin, dextromethorphan hbr suspension Laboratorios Alfa

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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#### **Resfridol Antitussive**

### **Drug Facts**

## **Active ingredients and Purposes**

Active ingredients (in each 10 mL)	Purposes	
Guaifenesin 200 mg	Expectorant	
Dextromethorphan HBr 30 mg	Cough suppressant	

#### Uses

Temporarily relieves common cold symptoms:

- cough due to minor throat & bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to:
- drain bronchial tubes
- make coughs more productive

### Warnings

# Ask a doctor or pharmacist before 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.
- have a persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus)

# Stop use and ask a doctor if

a cough persists for more than 7 days, tends to recur, 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 accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

- do not exceed recommended dosage
- do not exceed 4 doses in a 24-hour period
- adults & children 12 year of age & over: 1 teaspoonful (10 mL), every 6 hours
- children 6 to under 12 years of age: 1/2 teaspoonful (5 mL), every 6 hours
- children under 6 years of age: do not use

#### Other information

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• store at room temperature between 77-86°F (25-30°C) **TAMPER EVIDENT:** Do not use if safety seal over cap is broken, torn, or missing.

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### **Inactive ingredients**

artificial flavors, citric acid, FD&C red no.40, sodium benzoate, sorbitol, sucralose, water

# **Questions?**

+1-809-544-0222 (M-F) 9 AM to 5 PM Eastern or www.laboratoriosalfa.com

# **Principal Display Panel**

Resfridol

**Antitussive** 

### Syrup

- Cough Suppressant
- Expectorant

Dextromethorphan Hbr and Guaifenesin

4 fl oz (120mL)



### **RESFRIDOL ANTITUSSIVE**

guaifenesin, dextromethorphan hbr suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72483-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 10 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72483-100- 04	1 in 1 BOX	08/01/2019	
1		120 mL in 1 BOTTLE; 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	08/01/2019	

# Labeler - Laboratorios Alfa (815941244)

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