ALTITUSS- dextromethorphan hbr, guaifenes in liquid Alternative Pharmacal 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.

Active Ingredients (in each 7.5 mL) Purpose

Dextromethorphan HBr...... 15 mg Cough suppressant

Glyceryl Guaiacolate 150 mg Expectorant

Purpose

Cough suppressant

Expectorant

Uses

Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes. 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 you are taking a prescription drug that contains MAOI; ask your 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

When using this product do not use more than directed.

Stop use and ask a doctor before use if: I 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.

IIf pregnant or breast-feeding, <code>Bask</code> a health profession before use.

IKeep 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.

Adults and children 12 years of age and over	10 ml (2tsp) every 4 hours
Children 6 years to under 12 years of age	5 ml (1tsp) every 4 hours
Children 2 years to under 6 years of age	2.5 ml (1/2 tsp) every 4 hours
Children under 2 years	Consult a doctor

□Inactiveingredients □□

Citric acid, flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose



Active Ingredients (in each 7.5mL) Purpose
Dextromethorphan HBr, USP....15 mgCough suppressant
Glyceryl Guaiacolate, USP.....150 mgExpectorant

Uses - Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.

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 you are taking a prescription drug that contains an MAOI; ask your 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.

When using this product do not use more than directed.

†Sorbutuss® is a registered trademark of Teral, Inc. This product is not manufactured, distributed or marketed by Teral, Inc.

Code #: L-52

Lot #:

Exp. Date:

NDC 53163-113-16

Altituss

Cough SuppressantExpectorant

Contains the same active ingredients as Sorbutuss® NR†



Sugar FREE Alcohol FREE Dye FREE

16 fl. oz. (473 mL)

Grape Flavor

Rev. 12/17

Drugs Facts (Continued)

Stop use and ask a doctor before use 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 6 doses in any 24-hour period

Adults and children 12 years of 10 ml (2tsp) every 4 hours.

Adults and children 12 years of age and over	10 ml (2tsp) every 4 hours.
Children 6 years to under 12 years of age	5 ml (1tsp) every 4 hours
, ,	2.5 ml (1/2tsp) every 4 hours
Children under 2 years	Consult a doctor

Other Information - Store at room temperature 15°-30°C (59°-86°F).

Tamper Evident Feature: Do not use if seal under cap is torn, broken or missing.

Pharmacist-Preserve and dispense in tight, light-resistant container with a child resistant cap as defined in the USP.

Inactive ingredients • Citric acid, flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose.

Questions or comments? 1-786-507-1566

Manufactured For: Alternative Pharmacal Corporation, Miami, FL 33147 www.alternativepharmacal.com

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING



ALTITUSS

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53163-113

Route of Administration ORAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 7.5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	150 mg in 7.5 mL

Inactive Ingredients

macuve ingredients	
Ingredient Name	Strength
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
METHYLPARABEN (UNII: A218 C7H19 T)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:53163-113-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 3/0 1/20 15			
Marketing Inf	ormation				
Marketing Inf		Marketing Start Date	Marketing End Date		
		Marketing Start Date 03/01/2015	Marketing End Date		

Labeler - Alternative Pharmacal Corporation (078528214)

Revised: 12/2020 Alternative Pharmacal Corporation