

ULTRA TUSS SAFE- guaifenesin dextromethorphan hbr syrup
Ultra Seal 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 Ingredients (In 5 ml)

Guaifenesin 100 mg

Dextromethorphan HBr 10 mg

Purpose: Expectorant, Antitussive (Anti Cough)

Uses: temporarily:

- helps loosen phlegm (mucus)
- thin bronchial secretions to drain bronchial tubes, and make coughs more productive.
- restores free breathing
- suppresses cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants

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 MAOI drug. If you do not know if your prescription drug contains an MAOI, consult a doctor or pharmacist before taking this product.
- more than the recommended dose.

Stop use and ask a doctor if:

- symptoms do not improve within 7 days or are accompanied by fever
- cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. These could be signs of a serious condition.

Ask a doctor before use if you have:

- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema or where cough is accompanied by excessive phlegm (mucus)

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. 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 6 doses in any 24 hour period.

Adults and children 12 years of age and older: Take 2 teaspoons (10 ml) every 4 hours as needed, or as directed by a doctor.

Children 6-12 years: Take 1 teaspoon (5 ml) every 4 hours as needed, or as directed by a doctor.

Not to be used for children under 6 years of age.

Inactive Ingredients: Citric Acid, Flavor, Glycerin, Methyl Paraben, Potassium Sorbate, Propyl Paraben, Propylene Glycol, Purified Water, Sodium Citrate, Sucralose

ULTRATUSS SAFE
COUGH SUPPRESSANT
EXPECTORANT

NDC# 42213-162-86

ULTRATUSS SAFE

Dextromethorphan HBr
COUGH SUPPRESSANT
Guafenesin
EXPECTORANT

~ Sugar Free
~ Alcohol Free
~ Saccharin Free
~ Dye Free

 **CHERRY FLAVOR**

4 Fl. oz. (118.5 mL)

ULTRA SEAL
Manufactured in the U.S.A. for:
Ultra Seal Corp., New Paltz, NY 12561

0 01500 16286 1

Drug Facts (continued)
Ask a doctor before use if you have:
■ a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema or where cough is accompanied by excessive phlegm (mucus)

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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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Other information:
■ Avoid excessive heat and humidity.
■ Tamper Evident. Do not use if inner seal is torn, cut or opened.
■ Store at controlled room temperature 15° to 30° C (59° to 86° F).

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Guafenesin 100 mg Expectorant
Dextromethorphan HBr 10 mg ...Antitussive (Anti Cough)

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1/2
PRINT SIDE GLUE



ULTRA TUSS SAFE

guaifenesin dextromethorphan hbr syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42213-162
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)
(DEXTROMETHORPHAN - UNII:7355X3ROTS)

DEXTROMETHORPHAN
HYDROBROMIDE

10 mg
in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (sweet cherry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42213-162-83	1 in 1 CARTON	06/19/2012	
1	NDC:42213-162-86	119 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	06/19/2012	

Labeler - Ultra Seal Corporation (085752004)

Registrant - Ultra Seal Corporation (085752004)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(42213-162)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	pack(42213-162)