

COUGH SYRUP DM - guaifenesin, dextromethorphan hbr syrup
Zee Medical Inc

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 ml) Guaifenesin 100 mg, Dextromethorphan HBr 10 mg

Purpose-Cough Suppressant, Expectorant

Uses ■ temporarily relieves cough due to minor throat and bronchial irritation that occur with a cold or inhaled irritants
■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Directions

- shake well before using
- adults and children over 12 years: take 2 teaspoons (one packet) every 4 hours
- do not exceed 12 teaspoons (6 packets) in 24 hours
- children under 12 years: do not use

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.

Stop use and ask a doctor 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.□

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

If pregnant or breast-feeding baby, 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.

Inactive ingredients

citric acid, FDC red 40, flavor, glycerin, methyl paraben, propylene glycol, propyl paraben, purified water, sodium citrate, sucralose

MM1



BEYER GRAPHICS	
send user :	ULTRA SEAL
item :	:6 COUNT COUGH RELIEF
code # :	
size :	:4 X 145/8 X 3+11/16
ref # :	:1EBG247B2
material :	:015 SBS
view :	:PRINT SIDE
date :	:06/16/2009

4 TEETH/INCH (.211X.039)

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COUGH SYRUP DM

guaifenesin, dextromethorphan hbr syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35418-119
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

Inactive Ingredients

Ingredient Name	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0K0OR)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	red (cherry red)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35418-119-37	6 in 1 CARTON		
1	NDC:35418-119-42	10 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/12/2012	

Labeler - Zee Medical Inc (009645623)

Registrant - Ultra Seal Corporation (085752004)

Establishment

Name	Address	ID/FEI	Business Operations
Ultratab Laboratories, Inc.		151051757	manufacture(35418-119)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	repack(35418-119)

Revised: 11/2012

Zee Medical Inc