TUSSIN SUGAR FREE COUGH - dextromethorphan hydrobromide, guaifenes in liquid Atlantic Biologicals Corps

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

Dextromethorphan HBr, USP 10 mg Guaifenesin, USP 100 mg

Purpose

Dextromethorphan HBr......Cough suppressant Guaifenesin, USP.....Expectorant

Uses

• temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold • helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

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

• 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

• 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 this and all drugs out of the reach of children.

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Directions

• do not exceed 6 doses in a 24-hour period • this adult product is not intended for use in children under 12 years of age

adults and children 12 years and over 2 teaspoonfuls (tsps) every 4 hours children under 12 years do not use <u>AgeDose</u>

Other Information

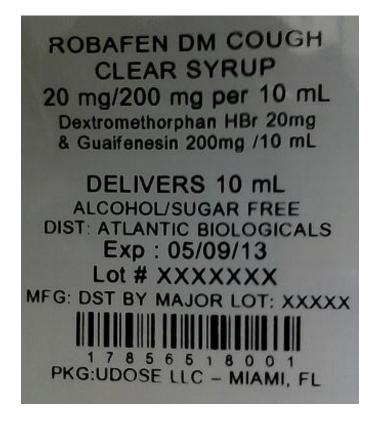
sugar-free dosage cup provided

• store at controlled room temperature alcohol-free

Inactive Ingredients

acesulfame potassium, citric acid, flavors, glycerin, methyl paraben, polyethylene glycol, povidone, propylene glycol, purified water, saccharin sodium, sodium benzoate

TUSSIN SUGAR FREE COUGH (DEXTROMETHORPHAN HYDROBROMIDE, GUAIFENESIN) LIQUID



TUSSIN SUGAR FREE COUGH

dextromethorphan hydrobromide, guaifenesin liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-5180(NDC:0904-5180)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	De xtro me tho rphan Hydro bro mide	10 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
acesulfame potassium (UNII: 23OV73Q5G9)		
citric acid monohydrate (UNII: 2968PHW8QP)		
glycerin (UNII: PDC6A3C0OX)		
methylparaben (UNII: A2I8C7HI9T)		
polyethylene glycol (UNII: 3WJQ0SDW1A)		
povidone (UNII: FZ989GH94E)		
propylene glycol (UNII: 6DC9Q167V3)		
saccharin sodium (UNII: SB8ZUX40TY)		
sodium benzoate (UNII: OJ245FE5EU)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY (Cherry)	Imprint Code	
Contains			

F	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-5180-1	10 mL in 1 CUP		
2	NDC:17856-5180-2	5 mL in 1 CUP		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/07/2009	

Labeler - Atlantic Biologicals Corps (047437707)

Registrant - Atlantic Biologicals Corps (047437707)

Establishment				
Name	Address	ID/FEI	Business Operations	
Atlantic Biologicals Corps		047437707	RELABEL, REPACK	

Revised: 11/2009 Atlantic Biologicals Corps