BIOSPEC DMX- dextromethorphan, guaifenes in liquid Advanced Generic 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 each 5 mL tsp.) Purpose

Dextromethorphan Hydrobromide 15 mg...... Cough Suppressant

Guaifenesin 25 mg Expectorant

Uses

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

Warnings

- Do not exceed recommended dosage.
- 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 such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms do not get better within 7 days or accompanied by fever
- 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.

Directions Do not take more than 6 doses in any 24-hour period, unless directed by a physician adults and children 12 years and over, 1 teaspoonfuls (5 ml) every 4 hours children 6 years to under 12 years, 1/2 teaspoonful (2.5 ml) every 4 hours children 4 to 6 years, 1/4 teaspoonful (1.25 ml) every 4 hours children under 4 years of age, 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 (or cello-band over cap) is torn, broken or missing.

Inactive ingredients Cherry Flavor, Glycerin, Menthol, Potassium Guaiacol Sulfonate, Sodium Benzoate, Sodium Citrate, Sodium Saccharin, Water.

Questions or comments? 1-305-403-3788

Manufactured For: Advanced Generic Corporation, Miami, FL 33166.

www.advancedgeneric.com

D	ru	a	F	a	CI	S

Active ingredients (in each 5 mL tsp.) Purpose Dextromethorphan HBr.....15 mg... Guaifenesin... . 25 mg. ... Expectorant

In a base containing Potassium Guaiacol Sulfonate and Sodium Citrate. Uses - temporarily relieves cough due to minor throat and bronchial

irritation as may occur with cold • helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive.

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> +Trispec® DMX is a trademark of Deliz Pharmaceutical Corp.

NDC 45737-211-16

- Cough Suppressant
- Expectorant

Alcohol FREE

Cherry Flavor

Drug Facts (continued)

Stop use and ask a doctor if - you get nervous, dizzy or sleeples symptoms do not get better within 7 days or accompanied by fever - 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 exceed more than 6 doses in 24 hours.

adults and children	take 1 teaspoonful (5 mL)
12 years of age and over	every 4 hours
children 6 to under	take 1/2 teaspoonful (2.5 mL)
12 years of age	every 4 hours
children 4 to under	take 1/4 teaspoonful (1.25 mL)
6 years of age	every 4 hours
children under 4 years of age	consult a doctor

Other information

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Lot #: SMP 1839 3/24/09

Exp. Date:

Drug Facts

Active ingredients (in each 5 mL tsp.) Purpose15 mg...Cough Suppressant Dextromethorphan HBr....25 mg.....

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NDC 45737-211-16

- Cough Suppressant Expectorant
 - Alcohol FREE

Cherry Flavor

Drug Facts (continued)

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Lot #:

SMP 1839 3/24/09

Exp. Date:

BIOSPEC DMX

dextromethorphan, guaifenesin liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-211	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	De xtro metho rphan Hydro bro mide	15 mg in 5 mL	
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	25 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
Menthol (UNII: L7T10EIP3A)			
Water (UNII: 059QF0KO0R)			
POTASSIUM GUAIACOLSULFONATE (UNII: TTK33Z47F1)			
Glycerin (UNII: PDC6 A3C0 OX)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
Sodium Citrate (UNII: 1Q73Q2JULR)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			

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

ı	Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 N	DC:45737-211-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2009		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	10/01/2009		

Labeler - Advanced Generic Corporation (831762971)