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 HBr 10 mg..... Cough Suppressant

Guaifenesin 187 mg Expectorant

Purpose

Cough suppressant

expectorant

Uses

Itemporarily 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

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

• 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. IIn case of overdose, get medical help or contact a Poison Control Center right away.

Directions Do not take more than 8 teaspoonfuls in any 24-hour period

adults and children 12 years of age and over	take 2 teaspoonfuls (10 mL) every 4 hours
children 6 years to under 12 years of age	take 1 teaspoonful every 4 hours
children 2 years to under 6 years of age	take 1/2 teaspoonful every 4 hours
children under 2 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 Icitric acid, glycerin, methylparaben, natural and artificial flavors, potassium sorbate, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

Questions or comments? 1-305-403-3788



BIOSPEC DMX

dextromethorphan, guaifenesin l	iquid					
Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:45737-264		
Route of Administration	ORAL					
Active Ingredient/Active M	niety					
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		187 mg in 5 mL		
Inactive Ingredients						
Ingredient Name					Strength	
ANHYDRO US CITRIC ACID (UNII: 3	KF417D3PSL)					
GLYCERIN (UNII: PDC6A3C0OX)						

Μ	ETHYLPARABEN (U						
P							
Pl	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)						
P	ROPYLPARABEN (U						
W	ATER (UNII: 059QF						
s	O DIUM CITRATE (U						
SUCRALOSE (UNII: 96K6UQ3ZD4)							
	Dackaging						
Р	ackaging						
P #	ackaging Item Code	Package Description	Marketing Start Date	Marketing End Date			
#	Item Code	Package Description 473 mL in 1 BOTTLE; Type 0: Not a Combination Product	Marketing Start Date 03/01/2015	Marketing End Date			
#	Item Code NDC:45737-264-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	U	Marketing End Date			
#	Item Code	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	U	Marketing End Date			
# 1	Item Code NDC:45737-264-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product ormation	U	Marketing End Date Marketing End Date			
# 1 N	Item Code NDC:45737-264-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product ormation	0 3/0 1/20 15				

Labeler - Advanced Generic Corporation (831762971)

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Advanced Generic Corporation