BIO-Z-COUGH - dextromethorphan hydrobromide and guaifenesin 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 tps.)	**Purpose**
Dextromethorphan Hydrobromide.... 20 mg	Cough suppressant
Guaifenesin.... 400 mg	Expectorant

Uses:

- Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.
- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold.

Warnings:

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 before use 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.

Do not use:

If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs of 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 MAOI; ask your doctor or pharmacist before taking this product.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding, ask a health professional before use.

Direction: do not exceed more than 6 doses in any 24 hours period.

Adults and children 12 years of age and over.	Take 1 teaspoonful (5 mL) every 4 hours
Children under 12 years of age.	Consult a physician

Other Information:

- Store at room temperature 15 - 30 degrees celsius (59 - 86 degrees farenheit)
- Tamper evident feature Do not use if seal under cap is torn, broken or missing.
- Avoid excessive heat or humidity.

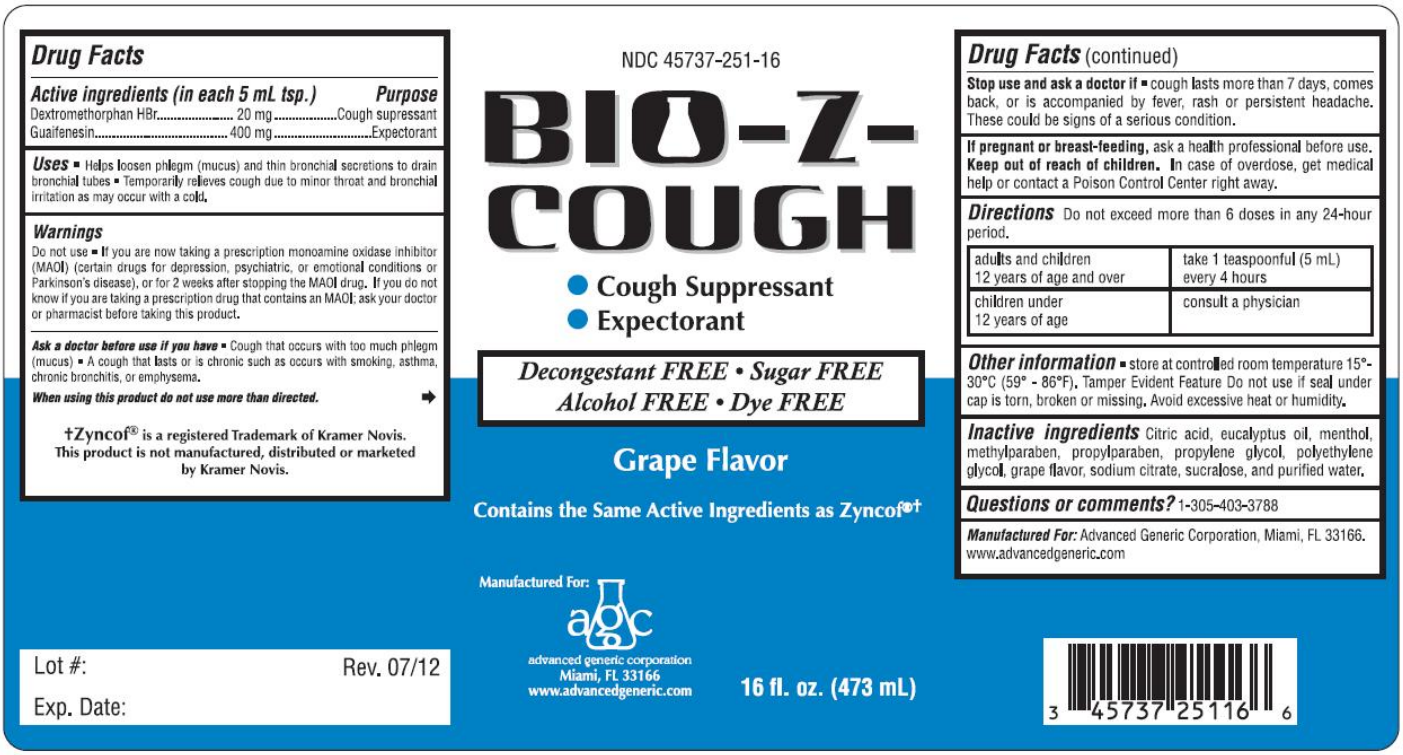
Inactive Ingredients:

Citric Acid, eucalyptus oil, menthol, methylparaben, propylparaben, propylene glycol, sodium citrate, polyethylene glycol, grape flavor, sucralose, and purified water.

Questions or comments? 1-305-403-3788

Manufactured for: Advanced Generic Corporation
Miami, FL 33166

www.advancedgeneric.com



BIO-Z-COUGH

dextromethorphan hydrobromide, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:45737-251
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (DEXTROMETHORPHAN)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
GUAIFENESIN (GUAIFENESIN)	GUAIFENESIN	400 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE	
EUCALYPTUS OIL	
MENTHOL	
METHYLPARABEN	
PROPYLPARABEN	
POLYETHYLENE GLYCOLS	
SUCRALOSE	
WATER	
PROPYLENE GLYCOL	
SODIUM CITRATE	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE (grape flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-251-16	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2012	

Labeler - Advanced Generic Corporation (831762971)

Revised: 10/2012 Advanced Generic Corporation