

BIO-Z-COUGH- dextromethorphan hydrobromide, 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 fahrenheit)
- 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

<p>Drug Facts</p> <p>Active ingredients (in each 5 mL tsp.) Purpose Dextromethorphan HBr..... 20 mg.....Cough suppressant Guaifenesin..... 400 mg.....Expectorant</p> <p>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.</p> <p>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 you are taking a prescription drug that contains an MAOI, ask your doctor or pharmacist before taking this product.</p> <p>Ask a doctor before use if you have • Cough that occurs with too much phlegm (mucus) • A cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema.</p> <p>When using this product do not use more than directed. →</p> <p>†Zyncof® is a registered Trademark of Kramer Novis. This product is not manufactured, distributed or marketed by Kramer Novis.</p>	<p>NDC 45737-251-16</p> <p>BIO-Z-COUGH</p> <p>● Cough Suppressant ● Expectorant</p> <p>Decongestant FREE • Sugar FREE Alcohol FREE • Dye FREE</p>	<p>Drug Facts (continued)</p> <p>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.</p> <p>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.</p> <p>Directions Do not exceed more than 6 doses in any 24-hour period.</p> <table border="1"> <tr> <td>adults and children 12 years of age and over</td> <td>take 1 teaspoonful (5 mL) every 4 hours</td> </tr> <tr> <td>children under 12 years of age</td> <td>consult a physician</td> </tr> </table> <p>Other information • store at controlled room temperature 15°-30°C (59° - 86°F). Tamper Evident Feature Do not use if seal under cap is torn, broken or missing. Avoid excessive heat or humidity.</p> <p>Inactive ingredients Citric acid, eucalyptus oil, menthol, methylparaben, propylparaben, propylene glycol, polyethylene glycol, grape flavor, sodium citrate, sucralose, and purified water.</p> <p>Questions or comments? 1-305-403-3788</p> <p>Manufactured For: Advanced Generic Corporation, Miami, FL 33166. www.advancedgeneric.com</p>	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
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<p>Lot #: Rev. 07/12</p> <p>Exp. Date:</p>	<p>Manufactured For:</p>  <p>advanced generic corporation Miami, FL 33166 www.advancedgeneric.com</p> <p>16 fl. oz. (473 mL)</p>	 <p>3 45737 25116 6</p>				

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NDC 45737-251-16

BIO-Z-COUGH

- Cough Suppressant
- Expectorant

Decongestant FREE • Sugar FREE
Alcohol FREE • Dye FREE

Grape Flavor

Contains the Same Active Ingredients as Zyncof®†

Manufactured For:



advanced generic corporation
 Miami, FL 33166
 www.advancedgeneric.com

16 fl. oz. (473 mL)

Lot #:

Rev. 07/12

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Drug Facts (continued)

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BIO-Z-COUGH

dextromethorphan hydrobromide, guaifenesin liquid

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

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; Type 0: Not a Combination Product	07/01/2012	

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: 12/2020

Advanced Generic Corporation