G-ZYNCOF - dextromethorphan hydrobromide and guaifenesin syrup
Kramer Novis

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.

G-ZYNCOF

Active ingredients (in each 5 mL tsp)

Dextromethorphan HBr, USP 20 mg

Guaifenesin, USP 400 mg

Purpose

Cough Suppressant

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 drain bronchial tubes

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 out of reach of children.

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

Directions

- do not take more than 6 doses in any 24-hour period
- EVERY 4 HOURS
- Adults and Children 12 years of age and over 5 mL (1 tsp)
- Children under 12 years of age consult physician

Other information

- Tamper evident feature: Do not use if inner seal is torn, broken or missing.
- Store at controlled room temperature 15°-30°C (59° to 86°F).
- Avoid excessive heat or humidity.

Inactive ingredients

Citric acid, eucalyptus oil, flavors, menthol, methyl paraben, polyethylene glycol, propylene glycol, propyl paraben, purified water, sodium citrate and sucralose.

Made in the USA for Kramer Novis.

San Juan, PR 00917

(787) 767-2072 / www.kramernovis.com

PRINCIPAL DISPLAY PANEL

G-ZYNCOF

dextromethorphan hbr and guaifenesin syrup

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:52083-600
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	
POLYETHYLENE GLYCOL 1450	
PROPYLENE GLYCOL	
PROPYLPARABEN	
WATER	
SODIUM CITRATE	
SUCRALOSE	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-600-16	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/03/2012	

Labeler - Kramer Novis (090158395)

Revised: 12/2012 Kramer Novis