GUAAP - guaifenesin liquid
A P J Laboratories Limited

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.

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purpose

Expectorant

keep out of reach of children

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

uses

helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

warning

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

Stop use and ask a doctor if
cough lasts for more than 7 days, comes back, or occurs with fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

direction

•do not take more than 6 doses in any 24-hour period

•this adult product is not intended for use in children under 12 years of age
age dose

adults and children 12 years and over: 2-4 teaspoons every 4 hours

children under 12 years: do not use

inactive ingredient

ASPARTAME

BRONOPOL

EDETIC ACID
MENTHOL

SUCROSE
SODIUM BENZOATE
SORBITOL
XANTHAN GUM
GUAIFENESIN

GUAAP

guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:46084-051
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (GUAIFENESIN)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
MENTHOL	10 ug in 5 mL
SUCROSE	200 mg in 5 mL
SORBITOL	50 mg in 5 mL
SODIUM BENZOATE	1 mg in 5 mL
BRONOPOL	0.5 mg in 5 mL
EDETIC ACID	0.5 mg in 5 mL
ASPARTAME	1 mg in 5 mL
XANTHAN GUM	0.5 mg in 5 mL

Product Characteristics

Color	yellow	**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46084-051-21	120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2013	

Labeler - A P J Laboratories Limited (677378339)

Registrant - A P J Laboratories Limited (677378339)

Establishment

Name	Address	ID/FEI	Business Operations
A P J Laboratories Limited		677378339	manufacture(46084-051)