CHERATUSSIN AC- codeine phosphate and guaifenesin liquid Rebel Distributors Corp

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.

Cheratussin AC

CV

Active ingredients (in each 5 mL = 1 tsp)

Codeine phosphate, USP 10 mg Guaifenesin, USP 100 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 make coughs more productive
- calms the cough control center and relieves coughing

Warnings

Do not use

- in a child under 2 years of age
- if you or your child has a chronic pulmonary disease or shortness of breath
- if your child is taking other drugs, unless directed by a doctor

Ask a doctor before use if you have

- cough that occurs with excessive phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

When using this product constipation may occur or be aggravated

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

Directions

- take every 4 hours
- do not take more than 6 doses in any 24-hour period

adults and children 12 years and over
children 6 years to under 12 yearstake 10 mL (2 tsp)children 2 years to under 6 yearstake 5 mL (1 tsp)children under 2 yearsconsult a doctorchildren under 2 yearsdo not use

Attention: A special measuring device should be used to give an accurate dose of this product to children under 6 years of age. Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

Other information

store at 15° to 30°C (59° to 86°F)

You may report serious side effects to: 130 Vintage Drive, Huntsville, AL 35811.

Inactive ingredients

alcohol, caramel, citric acid, FD&C red #40, flavor, glycerin, menthol racemic, purified water, saccharin sodium, sodium benzoate, sorbitol solution

Made in the USA for Qualitest Pharmaceuticals Huntsville, AL 35811

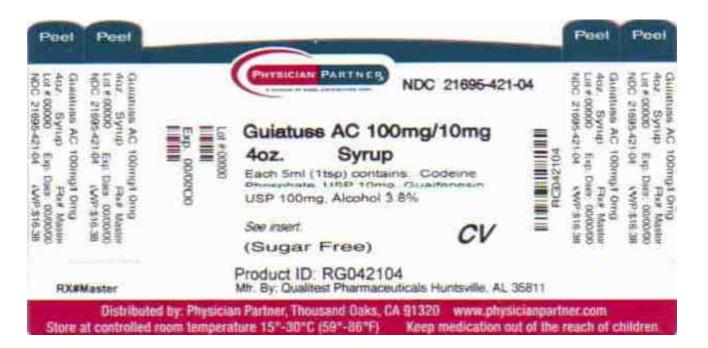
Rev. 11/09 R6 8081202 1075

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL



CHERATUSSIN AC

codeine phosphate and guaifenesin liquid

Product Information	1						
Product T ype		HUMAN OTC DRUG	Item Code (Sou	Code (Source) NDC 1075		C:21695-421(NDC:0603- 5)	
Route of Administration	ı	ORAL	DEA Schedule	Schedule CV			
Active Ingredient/Ac	ctive Moi	ety					
Ingredient Name Basis of Stre					fStrength	Strength	
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE - UNII:Q830PW7520) CODEINE PHOS				PHOSPHATE	10 mg in 5 mL		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN						100 mg in 5 mL	
<u>1</u>							
Inactive Ingredients		Ingredient N	ame			Strength	
ALCOHOL (UNII: 3K9958V90M)						ottength	
CARAMEL (UNII: T9D99G							
CITRIC ACID (UNII: 2968F							
FD&C RED NO. 40 (UNII: V		A)					
GLYCERIN (UNII: PDC6A3	COOX)						
MENTHOL (UNII: L7T10EI	P3A)						
WATER (UNII: 059QF0KO	0 R)						
SACCHARIN SODIUM (UN	NII: SB8ZUX4	40 TY)					
SODIUM BENZOATE (UN	II: OJ245FE5	EU)					
SORBITOL (UNII: 506T60	A25R)						
Product Characteris	tics						
Color	RI	ED	Score				
Shape			Size	Size			
Flavor	CI	HERRY	Imprint	Imprint Code			
Contains							
Packaging							
# Item Code	Pac	kage Descriptio	on Mark	Marketing Start Date		Marketing End Date	
1 NDC:21695-421-04	118 mL in 1	BOTTLE, PLASTIC	C				
Marketing Inform	mation						
Marketing Infori Marketing Category		on Number or Mo	nograph Citation	Marketing Start	Date Mar	·keting End Dat	

Establishment								
Name	Address	ID/FEI	Business Operations					
Rebel Distributors Corp		118802834	RELABEL, REPACK					

Revised: 2/2011

Rebel Distributors Corp