

CHERATUSSIN AC - codeine phosphate and guaifenesin liquid
Dispensing Solutions, Inc.

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	take 10 mL (2 tsp)
children 6 years to under 12 years	take 5 mL (1 tsp)
children 2 years to under 6 years	consult a doctor
children under 2 years	do 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

PRINCIPAL DISPLAY PANEL

<p>BULK SOURCE DATA MFD. FOR: QUALITEST PHARMACEUTICALS HUNTSVILLE, AL 35811</p> <p>PRODUCT ID: AMBER ROUND BOTTLE WHITE / BLACK / TAN / BROWN LABEL PRINTED NDC 0603-1075-54</p> <p>BULK SOURCE NDC: 00603-1075-54 MFR. LOT: XXXXXX PEDIGREE #: 867043 DISPENSE IN THIS TIGHT/LIGHT RESISTANT CONTAINER</p> 	 <p>GUAIFEN/COD 100 mg/10 mg per 5 mL</p> <p>4 FL OZ SYRUP</p> <p>NDC 55045-1495-09</p> <p>PRODUCT # 8G0404</p> <p>RX ONLY*</p> <p><small>*UNDER FEDERAL LAW, THIS IS AVAILABLE WITHOUT A PRESCRIPTION. CERTAIN STATE LAWS MAY DIFFER.</small></p> <p>LOT# SAMPLE EXP: 00-00 Rx# 20998702</p>	<p>WARNING: KEEP OUT OF CHILDREN'S REACH STORE AT 68°- 77° F. SEE USP.</p> <p>8G0404 NDC 55045-1495-09 GUAIFEN/COD 100 mg/10 mg per 5 mL 4 FL OZ C-5 SYRUP LOT # SAMPLE EXP: 00-00 MN 00603-1075-54 RX# 20998702</p> <p>8G0404 NDC 55045-1495-09 GUAIFEN/COD 100 mg/10 mg per 5 mL 4 FL OZ C-5 SYRUP LOT # SAMPLE EXP: 00-00 MN 00603-1075-54 RX# 20998702</p> <p>8G0404 NDC 55045-1495-09 GUAIFEN/COD 100 mg/10 mg per 5 mL 4 FL OZ C-5 SYRUP LOT # SAMPLE EXP: 00-00 MN 00603-1075-54 RX# 20998702</p> 
<p>Rev. Date: 01/10</p> <p>Rev. Date: 01/10</p> <p>Rev. Date: 01/10</p>		
<p>TAKE _____ TEASPOONFUL(S) EVERY _____ HOURS AS NEEDED FOR COUGH. MAY CAUSE DROWSINESS. AVOID ALCOHOLIC BEVERAGES.</p>		<p>Packaged Exclusively By: DISPENSING SOLUTIONS^{INC} Santa Ana, CA 92704</p>

NDC 55045-1495-09

CHERATUSSIN AC

codeine phosphate and guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55045-1495(NDC:0603-1075)
Route of Administration	ORAL	DEA Schedule	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE - UNII:Q830PW7520)	CODEINE PHOSPHATE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CAMEL (UNII: T9D99G2B1R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55045-1495-9	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/01/1996	

Labeler - Dispensing Solutions, Inc. (066070785)

Registrant - PSS World Medical, Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel, repack

Revised: 2/2012

Dispensing Solutions, Inc.