CHEST CONGESTION- guaifenes in liquid Accudial Pharmaceutical, 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.

CHILDREN'S ACCUDIAL

CHEST CONGESTION

Drug Facts

Active ingredient (in each 5 mL tsp)

Guaifenesin 100 mg

Purpose

Expectorant

Uses

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Ask a doctor before use if the child has

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

Stop use and ask a doctor if cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

Keep out of reach of children. In case of 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
- to find right dose, use rotating bottle label to dose by weight; otherwise, use chart at right to dose by age
- specifically designed for use with enclosed dosing spoon. Use only enclosed dosing spoon to dose this product.

Do not use any other device

Age	Dose			
children 6 years to under 12	5 mL to 10 mL or 1-2			
years	teaspoonfuls every 4 hours			
childen 4 years to under 6	2.5 mL to 5 mL or 1/2-1			
years	teaspoonful every 4 hours			

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children under 4 years	do not use

Other information

- tamper evident: do not use if foil seal under bottle cap is broken or missing.
- store between 20°-25°C (68°-77°F)

Inactive ingredients

caramel powder, citric acid, corn syrup, FD&C red no. 40, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sodium saccharin.

Questions?

877-434-2036

PRINCIPAL DISPLAY PANEL - 118 mL Carton

CHILDREN'S ACCUDIAL

ROTATING DOSING LABEL

ACCURATE DOSING BY WEIGHT

Guaifenes in Oral Solution

Expectorant

RELIEVES Chest Congestion Thins & Loosens Mucus

For Ages 4 to under 12

Alcohol Free

Compares to Mucinex[®] For Kids!

MENTHOL FLAVOR

4 FL. OZ. (118 mL)

NDC 45014-150-04

Chest Congestion



CHEST CONGESTION guaifenesin liquid				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45014-150
Route of Administration	ORAL			
Active Ingredient/Active Moi	ety			
Ingre	dient Name		Basis of Strengt	th Strength

Guaifenesin

		Ingredient Name					Strength	
Caramel (U	NII: T9D99G2B	1R)						
Citric Acid	Monohydrate	(UNII: 2968PHW8QP)						
Corn Syrup	(UNII: 9G5L161	3K6N)						
FD&C RED	NO.40 (UNII: V	VZB9127XOA)						
Glycerin (U	NII: PDC6A3C0	OX)						
Menthol (U	NII: L7T10EIP3A	A)						
Propylene (Glycol (UNII: 61	DC9Q167V3)						
Water (UNI	I: 059QF0KO0R	2)						
Sodium Ber	nzoate (UNII: O	J245FE5EU)						
Saccharin S	Sodium (UNII: S	SB8ZUX40TY)						
Product	Characteris	tics						
Color	R	ED (Reddish-Pink) , PINK		:	Score			
Shape				:	Size			
Flavor	M	IINT		1	Imprint Co	de		
Contains								
Packagin	ıø							
	em Code	Package Description	Marketing	Start	Date	Ma	rketing End Dat	te
1 NDC:450		118 mL in 1 BOTTLE					8	
Mankat	ing Inform	nation						
	ing Inform					D .		-
	ng Category	Application Number or Monog			eting Start	Date	Marketing End	Dat
	GRAPH FINAL	part341		10/26/2	2000			

Labeler - Accudial Pharmaceutical, Inc. (831999201)

Revised: 10/2009

Accudial Pharmaceutical, Inc.