

CHEST CONGESTION- guaifenesin solution
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.

Chest Congestion

Drug Facts

Active ingredient (in each 5 mL = 1 teaspoon)

Guaifenesin, USP 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.

Ask a doctor before use if the child has a cough that occurs with too much phlegm (mucus) or persistent or chronic cough such as occurs with asthma.

Directions

- may be given every 4 hours
- do not use more than 6 times in 24 hours
- use only enclosed dosing cup to dose this product. Do not use any other dosing device.

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.

Consult your pharmacist or health care provider for any appropriate, additional dosage delivery device necessary for use when a physician recommends a dose that is different than the doses that appear on the dosage delivery device that accompanies this product.

Age (yr)	Dose (TSP)
under 4 yrs.	ask a doctor
4 to under 6	½ TSP to 1 TSP
6 to under 12	1 TSP to 2 TSP
or as directed by a doctor	

TSP = teaspoon

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In the case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222). Prompt medical attention is critical, even if you do not notice any signs or symptoms.

Other information

- **each teaspoon contains: sodium 3 mg**
- store between 20°-25°C (68°-77°F)
- **tamper evident:** do not use if foil seal over the mouth of the bottle is torn, broken, or missing.

Inactive ingredients

artificial flavor, citric acid, corn syrup FD&C blue #1, D&C red #33, glycerin, purified water sodium benzoate, sodium saccharin, sucralose, xanthan gum.

Questions?

877-434-2036

Distributed by: AccuDial® Pharmaceutical, Inc.
Palm Beach Gardens, FL 33408

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

ACCUDIAL®

Children's

Chest

Congestion

Guaifenesin

Oral Solution Expectorant

**Relieves Chest Congestion
Thins & Loosens Mucus**

***Earth-Friendly
Package!***

For Ages 4 yrs to under 12 yrs

Tamper Evident

Compares to
Mucinex® For Kids

**GRAPE
FLAVOR**

NDC 45014-163-04
4 FL. OZ. (118 mL)

5334-0712 224

▶▶▶TURN LABEL FOR DRUG FACTS▶▶▶TURN LABEL FOR DRUG FACTS▶▶▶TURN LABEL FOR DRUG FACTS▶▶▶

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 Guaifenesin Oral Solution Expectorant
 Relieves Chest Congestion Thins & Loosens Mucus

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U.S. Patent Nos. 6,276,533 and 7,172,668.

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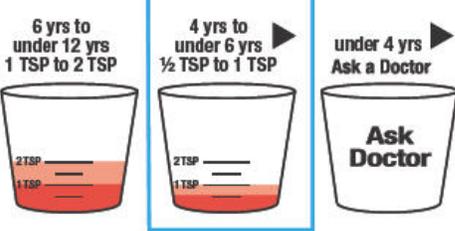
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Drug Facts (continued)
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6 yrs to under 12 yrs
1 TSP to 2 TSP

4 yrs to under 6 yrs
½ TSP to 1 TSP

under 4 yrs
Ask a Doctor

Ask Doctor

5343-0712 224
 Go Green Chest Congestion

CHEST CONGESTION

guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45014-163
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Corn Syrup (UNII: 9G5L16BK6N)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
D&C Red No. 33 (UNII: 9DBA0SBB0L)	

Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sucralose (UNII: 96K6UQ3ZD4)	
Xanthan Gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45014-163-04	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	02/01/2013	

Labeler - Accudial Pharmaceutical, Inc. (831999201)

Revised: 2/2013

Accudial Pharmaceutical, Inc.