

CAREONE MUCUS RELIEF CHILDRENS- guaifenesin solution

American Sales Company

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.

American Sales Company Children's Mucus Relief Drug Facts

Active ingredient (in each 5 mL)

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 condition.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- mL = milliliter

Age	Dose
children 6 years to under 12 years	5 mL – 10 mL every 4 hours
children 4 years to under 6 years	2.5 mL – 5 mL every 4 hours
children under 4 years	do not use

Other information

- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

acesulfame potassium, anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, glycerin, maltitol solution, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredient in Children's Mucinex® Chest Congestion

For Ages 4 And Older

Children's

MUCUS RELIEF

CHEST CONGESTION

Expectorant - Guaifenesin 100mg

FOR RELIEF OF:

Chest Congestion

Breaks Up Mucus

Alcohol Free

Gluten Free

OUR PHARMACISTS RECOMMEND

Grape Flavor

4 FL OZ (118mL)



CAREONE MUCUS RELIEF CHILDRENS

guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-288
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	PURPLE (clear)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-288-26	1 in 1 CARTON	08/08/2007	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/08/2007	

Labeler - American Sales Company (809183973)

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American Sales Company