CHILDRENS CHEST CONGESTION RELIEF - guaifenes in liquid Chain Drug Consortium, LLC

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.

Active ingredient

Drug Facts

Active ingredient (in each 5 mL teaspoonful)

Guaifenesin, USP 100 mg

Purpose

Expectorant

Keep out of reach of children

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control center right away.

Uses

• Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and makes 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.

Directions

• do not take more than 6 doses in any 24-hour period

age	dose
Children 6 years to under 12 years	1-2 teaspoonfuls every 4 hours.
Children 4 years to under 6 years	1/2-1 teaspoonful every 4 hours
Children under 4 years	do not use

Other information

- each 5 mL teaspoon contains: sodium 3 mg
- store between 20-25 ° C (68-77° F)
- do not refrigerate
- dosage cup provided
- Keep carton for full directions for use

Inactive ingredients

citric acid anhydrous, dextrose, FD and C Blue # 1, FD and C Red # 40, flavors, glycerin, maltitol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucralose, xanthan gum

Questions?

Call weekdays from 9:30 AM to 4:30 PM EST

1-877-798-5944

Product Label

NDC 68016-157-04 *COMPARE TO THE ACTIVE INGREDIENTS IN CHILDRENS MUCINEX® CHEST CONGESTION

Premier Value®

Childrens Chest Congestion Relief

Guaifenesin Oral Solution, USP

EXPECTORANT

Relieves Chest Congestion Thins and Loosens Mucus

Alcohol-Free For Ages 4 to 12

Grape Flavor

4 FL OZ (118mL)

INDEPENDENTLY TESTED SATISFACTION GUARANTEED PV **DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING**

*This product is not manufactured or distributed by Reckitt Benckiser Inc. distributor of Childrens Mucinex®

If for Any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

DISTRIBUTED BY CHAIN DRUG CONSORTIUM 3301 NW BOCA RATON BLVD SUITE 101, BOCA RATON, FL 33431

BX-011

DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

Drug Facts

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Guaifenesin, USP 100 mg..... 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
- 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

age	dose	
Children 6 years	1-2 teaspoonfuls	
to under 12 years	every 4 hours.	
Children 4 years	1/2-1 teaspoonful	
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Other information

- each 5 mL teaspoonful contains: sodium 3 mg
- store between 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided
- Keep carton for full directions for use

Drug Facts (continued)

Inactive ingredients

Anhydrous citric acid, dextrose, FD&C Blue # 1, FD&C Red # 40, flavor, glycerin, maltitol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucraiose, xanthan gum

Questions? Call weekdays from 9:30 am to 4:30 pm EST 1-877-798-5944

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Children's Chest Congestion Relief

Guaifenesin Oral Solution, USP EXPECTORANT

Relieves Chest Congestion Thins & Loosens Mucus



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BX-011

CHILDRENS CHEST CONGESTION RELIEF

guaifenesin liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68016-157 Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN 100 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		

DEXTROSE (UNII: IY9 XDZ35W2)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics		
Color		Score
Shape		Size
Flavor	GRAPE (Grape Flavor)	Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:68016-157-04	118 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/01/2012	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - AptaPharma Inc. (790523323)

Establishment			
Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(68016-157)

Revised: 4/2013 Chain Drug Consortium, LLC