

CHILDRENS MUCUS RELIEF CHEST CONGESTION PLUS COUGH- dextromethorphan hbr, guaifenesin liquid

AptaPharma 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 Mucus Relief Chest Congestion Plus Cough

Drug Facts

Active ingredients (in each 5 mL)

Dextromethorphan HBr 5mg
Guaifenesin 100 mg

Purpose

Dextromethorphan HBr Cough suppressant
Guaifenesin..... Expectorant

Warnings

Do not use in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

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

When using this product • do not use more than directed

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.

Directions

- do not take more than 6 doses in any 24-hour period
- mL = milliliter

Age	Dose
Children 6 years to under 12 years	5 mL - 10 mL every 4 hours
Children under 6 years	Do not use

Other information

- **each 5mL contains:** sodium 3mg
- store between 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

Anhydrous citric acid, flavors, purified water, sodium benzoate, sucrose

Questions? Call weekdays from 9:30 AM to 4:30 PM EST at **1-877-798-5944**

Principal Display Panel

**CVS
Health_{TM}**

**Compare to the
active ingredients in
Children's Mucinex[®] Cough***

**Children's
Mucus Relief
Chest Congestion
Plus Cough**

**Free of alcohol, dyes &
artificial sweeteners**

**DEXTROMETHORPHAN HBr
Cough suppressant**

**GUAIFENESIN
Expectorant**

**Relieves:
Chest congestion & cough
Thins & loosens mucus**

Cherry Flavor

**For Ages
6 to 12 Years**

8 FL OZ (237 mL)

**DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN
Failure to follow these warnings could result in serious consequences**

DO NOT REFRIGERATE. STORE AT ROOM TEMPERATURE.

*This product is not manufactured or distributed by Reckitt
Benckiser, distributor of Children's Mucinex[®] Cough.

**Lot:
Exp:**

LR-113 REV 01 #338883

0 50428 61752 6

**DRUG FACTS →
CONTINUED
ON BACK**

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
© 2018 CVS/pharmacy
CVS.com[®] 1-800-SHOP CVS
V-34690

✓CVS Quality
Money Back Guarantee

↓Product Package↓

CVS Health. Compare to the active ingredients in Children's Mucinex® Cough*

Children's Mucus Relief
Chest Congestion Plus Cough

Free of alcohol, dyes & artificial sweeteners

DEXTROMETHORPHAN HBR
Cough suppressant
GUAIFENESIN
Expectorant

Relieves:
• Chest congestion & cough
• Thins & loosens mucus



For Ages 6 to 12 Years
8 FL OZ (237 mL)

Cherry Flavor

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN
Failure to follow these warnings could result in serious consequences

Drug Facts

Active ingredients (in each 5 mL)	Purpose
Dextromethorphan HBr, 5 mg.....	Cough suppressant
Guaifenesin, 100 mg.....	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 drain the bronchial tubes

Warnings
Do not use in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

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

When using this product • do not use more than directed

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.

Directions
• do not take more than 6 doses in any 24-hour period
• mL = milliliter

Drug Facts (continued)

Age	Dose
Children 6 years to under 12 years	5 mL - 10 mL every 4 hours
Children 4 years to under 6 years	Do not use

Other information
• each 5mL contains: sodium 2 mg
• store between 20-25°C (68-77°F)
• do not refrigerate
• dosing cup provided

DO NOT REFRIGERATE. STORE AT ROOM TEMPERATURE.

*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Children's Mucinex® Cough.

Lot:
Exp:
LR-113 REV 01 #338883



0 50428 61752 6

DRUG FACTS CONTINUED ON BACK

Peel Here

Drug Facts (continued)

Inactive ingredients
Anhydrous citric acid, flavor, purified water, sodium benzoate, sucrose

Questions? Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-798-5944

Distributed by: **CVS Pharmacy, Inc.**
One CVS Drive, Woonsocket, RI 02895
© 2019 CVS/pharmacy
CVS.com® 1-800-SHOP CVS
V-34690



Children's Mucus Relief Chest Congestion Plus Cough by CVS Pharmacy, Inc.

res

CHILDRENS MUCUS RELIEF CHEST CONGESTION PLUS COUGH			
dextromethorphan hbr, guaifenesin liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-314
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL	

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-314-26	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2018	

Labeler - Aptapharma Inc. (790523323)

Registrant - Aptapharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
Aptapharma Inc.		790523323	manufacture(76281-314)

Revised: 12/2019

Aptapharma Inc.