# CHILDRENS MUCUS RELIEF COUGH - dextromethorphan hydrobromide, 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.

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### **Active ingredients**

**Drug Facts** 

### Active ingredients (in each 5 mL teaspoonful)

Dextromethorphan HBr 5 mg Guaifenesin 100 mg

### **Purpose**

Cough suppressant 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

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps to 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 two weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or a pharmacist before taking 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

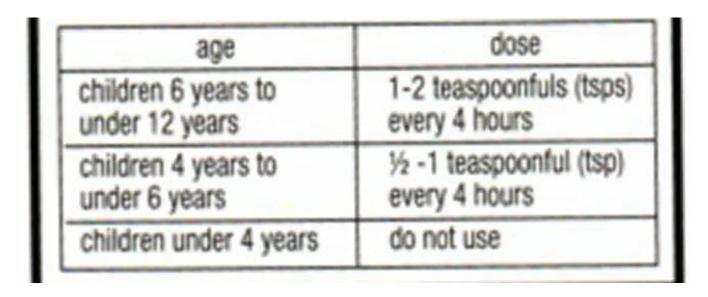
• do not use more than directed

### 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.

### Directions

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



### Other information

each 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, D and C Red # 33, 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 68016-158-04

\*COMPARE TO THE ACTIVE INGREDIENTS IN CHILDRENS MUCINEX $oldsymbol{\mathbb{R}}$  COUGH

**Premier Value®** 

Childrens Mucus Relief COUGH

Dextromethorphan HBr ..... Cough Suppressant

	Guaifenesin		Expectorar
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Relieves Chest Congestion Thins and Loosens Mucus

Alcohol Free For Ages 4 to 12 Cherry 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 Mucinex ${\mathbb R}$  Cough

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-015

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

### Drug Facts

Purpose Active Ingredients (in each 5 mL teaspoonful)

Dextromethorphan HBr, USP 5 mg... Cough suppressant Guaifenesin, USP 100 mg...

- 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

### 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

age	dose
children 6 years to	1-2 teaspoonfuls (tsps
under 12 years	every 4 hours
children 4 years to	1/2 -1 teaspoonful (tsp)
under 6 years	every 4 hours
children under 4 years	do not use

#### Other information

- each 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

### Drug Facts (continued)

### Inactive ingredients

Anhydrous citric acid, dextrose, D&C Red # 33, FD&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

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



## Children's Mucus Relief

### COUGH

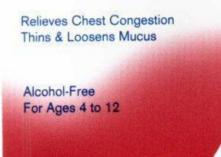
Dextromethorphan HBr.....Cough Suppressant Guaifenesin.....Expectorant



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-015



**Cherry Flavor** 

4 FL OZ (118 mL)

### CHILDRENS MUCUS RELIEF COUGH

dextromethorphan hydrobromide, guaifenesin liquid

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-158		
Route of Administration	ORAL				

Active Ingredient/Active Moiety				
Basis of Strength	Strength			
DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL			
GUAIFENESIN	100 mg in 5 mL			
	DEXTROMETHORPHAN HYDROBROMIDE			

Inactive Ingredients				
Ingredient Name	Strength			
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)				
DEXTROSE (UNII: IY9 XDZ35W2)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
MALTITOL (UNII: D65DG142WK)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
XANTHAN GUM (UNII: TTV12P4NEE)				

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY (Cherry Flavor)	Imprint Code		
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-158-04	118 mL in 1 BOTTLE		

<b>Marketing Info</b>	rmation		
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(68016-158)