

**CHILDRENS COLD, COUGH AND SORE THROAT - acetaminophen, guaifenesin, dextromethorphan hbr, phenylephrine hcl 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 10 mL or 2 teaspoons)**

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Guaifenesin 200 mg  
Phenylephrine HCL 5 mg

**Purpose**

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Pain reliever/fever reducer  
Cough suppressant  
Expectorant  
Nasal decongestant

**Keep out of reach of children**

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

**Uses**

- temporarily relieves these common cold and flu symptoms:
- nasal congestion
- minor aches and pains
- headache
- stuffy nose
- sore throat
- fever
- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

**Warnings**

**Liver warning:** This product contains acetaminophen. Sever liver damage may occur if your child if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

**Sore throat warning:** if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

**Do not use**

- with any other drugs containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 your child has**

- liver disease
- high blood pressure
- diabetes
- heart disease
- thyroid disease
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

**Ask a doctor or pharmacist before use if**

- your child is taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- redness or swelling is present
- nervousness, dizziness or sleeplessness occur
- new symptoms occur
- pain, nasal congestion or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- cough comes back, or occurs with rash or headache that lasts.

These could be signs of a serious condition.

**Directions**

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- **do not use more than directed (see Overdose warning)**

- **shake well before using**
- do not use more than 5 doses in any 24-hour period
- if needed, repeat dose every 4 hours while symptoms last
- do not use more than 5 days unless directed by a doctor
- use dose cup

Age	Dose
Children 6 to under 12 years of age	2 teaspoonfuls
Children under 6 years of age	do not use

### Other information

- each 10 mL (2 tsp) contains: **sodium 5 mg**
- store between 15-30 ° C (59-86° F)
- do not refrigerate
- dosing cup provided

### Overdose warning

#### When using this product

- **do not use more than directed (see Overdose warning)**
- Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

### Inactive ingredients

anhydrous citric acid, edetate disodium, FD and C Blue #1, FD and C Red # 40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

### Questions?

**1-877-798-5944**

### Product Label

NDC 68016-224-00

COMPARE TO THE ACTIVE INGREDIENTS IN CHILDREN'S MUCINEX® COLD, COUGH, and SORE THROAT LIQUID

### Premier Value®

#### Children's Cold, Cough, and Sore Throat

Acetaminophen / Guafenesin / Dextromethorphan HBr / Phenylephrine HCL

**PAIN RELIEVER / FEVER REDUCER**

**EXPECTORANT**

**COUGH SUPPRESSANT**

**NASAL DECONGESTANT**

Guaifenesin 100 mg  
Dextromethorphan HBr 5 mg  
Phenylephrine HCL 2.5 mg

- \* Cough
- \* Sore Throat
- \* Nasal Congestion
- \* Chest Congestion

For ages 6 to 12

Mixed Berry Flavor  
4 FL OZ (118mL)

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

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 Children's Mucinex® Cold, Cough and Sore Throat Liquid  
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  
BX028

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(in each 10 mL or 2 teaspoons)

Acetaminophen 325 mg.....Pain reliever/fever reducer  
Dextromethorphan HBr 10 mg.....Cough suppressant  
Guaifenesin 200 mg.....Expectorant  
Phenylephrine HCl 5 mg.....Nasal decongestant

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## Drug Facts (continued)

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BX028



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NDC 68016-224-00

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IN CHILDREN'S MUCINEX® COLD,  
COUGH, & SORE THROAT LIQUID



# Children's Cold, Cough & Sore Throat

Acetaminophen / Guaifenesin /  
Dextromethorphan HBr / Phenylephrine HCl

**PAIN RELIEVER/ FEVER REDUCER  
EXPECTORANT  
COUGH SUPPRESSANT  
NASAL DECONGESTANT**

- Cough
- Sore Throat
- Nasal Congestion
- Chest Congestion



For ages 6 to 12

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4 FL OZ (118 mL)



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acetaminophen, guaifenesin, dextromethorphan hbr, phenylephrine hcl liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-224
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

## Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY (MIXED BERRY)	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-224-00	118 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/01/2013	

**Labeler** - Chain Drug Consortium, LLC (101668460)

**Registrant** - Aptapharma Inc. (790523323)

## Establishment

Name	Address	ID/FEI	Business Operations
Aptapharma Inc.		790523323	manufacture(68016-224)