

CHILDRENS MULTI-SYMPTOM COLD - guaifenesin, dextromethorphan hydrobromide, phenylephrine hydrochloride 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 ingredients

Drug Facts

Active ingredients

(in each 5 mL teaspoon)

Guaifenesin 100 mg
Dextromethorphan HBr 5 mg
Phenylephrine HCL 2.5 mg

Purpose

Purpose

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

Uses

- helps to loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passage ways of bothersome mucus and make coughs more productive
- temporarily relieves these symptoms occurring with a cold:
- cough due to minor throat and bronchial irritation
- nasal congestion
- stuffy nose

Warnings

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**Ask a doctor before use if the child has**

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

When using this product**When using this product**

- do not use more than directed

Stop use and ask a doctor**Stop use and ask a doctor if**

- your child gets nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or occur with fever
- 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**Directions**

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

Age

Children 6 years to under 12 years

Children 4 years to under 6 years

Children under 4 years

Dose

2 teaspoons every 4 hours

1 teaspoon every 4 hours

Do not use

Other information**Other information**

- each 5 mL teaspoon contains: sodium 3 mg
- store between 15-30 ° C (59-86° F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

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citric acid anhydrous, D and C red #33, 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?

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

1-877-798-5944

Product Label

NDC 68016-134-00

*COMPARE TO THE ACTIVE INGREDIENTS IN CHILDREN'S MUCINEX® Multisymptom Cold

Premier Value®

CHILDREN'S MULTI- SYMPTOM COLD

EXPECTORANT

COUGH SUPPRESSANT

NASAL DECONGESTANT

Guaifenesin 100 mg

Dextromethorphan HBr 5 mg

Phenylephrine HCL 2.5 mg

* Stuffy Nose

* Cough

* Chest Congestion

* Breaks up Mucus

Alcohol free

For ages 4 to 12

Very Berry 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 Children's Mucinex® Multisymptom Cold

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-010

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

Drug Facts

Active ingredients Purpose (in each 5 mL teaspoonful)

Dextromethorphan HBr, USP 5 mg.....Cough suppressant
Guaifenesin, USP 100 mg.....Expectorant
Phenylephrine HCl, USP 2.5 mg.....Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
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Drug Facts (continued)

Directions

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

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

Other information

- each 5 mL teaspoonful contains: sodium 3 mg
- store between 15-30°C (59-86°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

anhydrous citric acid, D&C red #33, dextrose, FD&C blue #1, FD&C red #40, flavors, glycerin, maltitol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucralose, xanthan gum

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IN CHILDREN'S MUCINEX® Multisymptom Cold



CHILDREN'S MULTI- SYMPTOM COLD

EXPECTORANT COUGH SUPPRESSANT NASAL DECONGESTANT

Guaifenesin 100 mg
Dextromethorphan HBr 5 mg
Phenylephrine HCl 2.5 mg

- Stuffy Nose
- Cough
- Chest Congestion
- Breaks up Mucus

Alcohol free
For ages 4 to 12

Very Berry Flavor

4 FL OZ (118 mL)




CHILDRENS MULTI-SYMPOM COLD

guaifenesin, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-134
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
DEXTROSE (UNII: IY9XDZ35W2)	
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: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-134-00	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/27/2012	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(68016-134)