

CHILDRENS MULTI-SYMPTOM COLD- dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

WinCo Foods, 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.

Childrens Multi-symptom Cold Relief

Active ingredients (in each 5 mL)

Dextromethorphan HBr 5 mg

Guaifenesin 100 mg

Phenylephrine HCl 2.5 mg

Purpose

Cough suppressant

Expectorant

Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
- the intensity of coughing
- the impulse to cough to help your child get to sleep
- nasal congestion due to a cold
- stuffy nose

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 prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

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

When using this product

- **do not use more than directed**

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 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
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor

Age	Dose
children 6 years to under 12 years	10 mL every 4 hours
children 4 years to under 6 years	5 mL every 4 hours
children under 4 years	do not use

Other information

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

Inactive ingredients

citric acid anhydrous, D&C red 33, dextrose, edetate disodium, FD&C blue 1, FD&C red 40, flavor, glycerin, methylparaben, potassium sorbate, propyl gallate, propylene glycol, propylparaben, purified water, saccharin sodium, sodium hydroxide, sorbitol solution, sucralose, xanthan gum

Questions?

1-800-824-1706 Monday - Friday 9am-4pm MST.

You may also report side effects to this phone number

PDP

*Compare to the active ingredients in Children's MUCINEX[®] Multi-symptom cold

Children's Multi-symptom Cold Relief

Dextromethorphan HBr / Cough suppressant

Guaifenesin / Expectorant

Phenylephrine HCl / Nasal decongestant

Relieves: Stuffy Nose, Cough, Chest Congestion

Thins and Loosens Mucus

For Ages 4-12 Years

Very Berry Flavor

4 FL OZ (118 mL)



CHILDRENS MULTI-SYMP TOM COLD			
dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-220
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
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)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-220-18	1 in 1 CARTON	12/12/2014	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/12/2014	

Labeler - WinCo Foods, LLC (056098817)

Revised: 12/2019

WinCo Foods, LLC