

**CHILDRENS TUSSNEX MULTI-SYMPTOM COLD- dextromethorphan hbr,  
guaifenesin, phenylephrine hcl liquid  
Guardian Drug Company**

*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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**Childrens Tussnex Multi-symptom cold**

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

### **PDP**

compare to active ingredients in Mucinex children's Multi-symptom cold

Children's Tussnex Multi-symptom cold

Dextromethorphan HBr

Cough suppressant

Guaifenesin

Expectorant

Phenylephrine HCl

Nasal decongestant

Relieves nasal and chest chest congestion

Thins and loosens mucus

Soothes cough

Alcohol free



## CHILDRENS TUSSNEX MULTI-SYMPOTOM COLD

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53041-615
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 405W7451VQ) (GUAIFENESIN - UNII:405W7451VQ)	GUAIFENESIN	100 mg

<b>GUAIFENESIN</b> (UNII: 493W7431VQ) (GUAIFENESIN - UNII:493W7431VQ)	GUAIFENESIN	in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>DEXTROSE</b> (UNII: IY9XDZ35W2)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53041-615-03	1 in 1 CARTON	12/01/2012	
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	12/01/2012	

