

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

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 congestion
 Thins and loosens mucus
 Soothes cough
 Alcohol free

COATING FREE AREA

COATING FREE AREA

Drug Facts	
Active Ingredients (in each 5 mL) Purpose	
Dextromethorphan HBr 5 mg.....	Cough suppressant
Guaifenesin 100 mg.....	Expectorant
Phenylephrine HCl 2.5 mg.....	Nasal decongestant
Uses	
<ul style="list-style-type: none"> ■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive ■ temporarily relieves: <ul style="list-style-type: none"> ■ 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	
<p>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.</p> <p>Ask a doctor before use if the child has</p> <ul style="list-style-type: none"> ■ 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) <p>When using this product</p> <ul style="list-style-type: none"> ■ do not use more than directed <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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. <p>These could be signs of a serious illness.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
Directions	
<ul style="list-style-type: none"> ■ 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 	

COATING FREE AREA

Drug Facts (continued)	
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	
<ul style="list-style-type: none"> ■ 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	

KEEP BOX FOR COMPLETE INFORMATION

DO NOT USE IF SEAL UNDER CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

*This product is not manufactured or distributed by Reckitt Benckiser, the distributor of Children's Mucinex® Multi-Symptom Cold.

Guardian Drug Company
 2 Charles Court
 Dayton, NJ 08810

CHILDRENS TUSSNEX MULTI-SYMPOTOM COLD

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (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: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYL GALLATE (UNII: 8D45NN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
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: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 Drug	M012		12/01/2012	

Labeler - Guardian Drug Company (119210276)

Registrant - Guardian Drug Company (119210276)

Establishment			
Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	manufacture(53041-615)

Revised: 12/2024

Guardian Drug Company